International Compilation of Human Research Standards
2024 Edition

Compiled By:

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

OASH | Office for Human Research Protections

PURPOSE

The International Compilation of Human Research Standards enumerates over 1,000 laws, regulations, and guidelines (collectively referred to as "standards") that govern the protection of research participants in more than 130 countries, as well as standards from various international and regional organizations. First published in 2005, the Compilation is intended for use by researchers, IRBs/Research Ethics Committees, sponsors, and others who are involved in the conduct or oversight of research involving human participants around the world.

ORGANIZATION

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

This document is organized by world region in alphabetical order: Africa, Asia/Pacific, Europe, Latin America and the Caribbean, Middle East/North Africa, and North America. Before the world regions, there is a section for standards provided by several international organizations. Under each section, you will find the countries or international organizations organized also in alphabetical order. For each country or international organization, the information is then categorized as it relates to:

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

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

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

TOPICS NOT COVERED

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

1. Standards from the state, provincial, or local levels
2. Enabling legislation, i.e., laws that only authorize an agency to promulgate standards, but that themselves do not include substantive standards
3. Laws, regulations, or guidelines that are disease-specific or focus on research integrity, clinical ethics, products liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, informed consent in clinical practice, radiation or environmental safety, etc.

4. Ethics codes of academic, medical, or other professional organizations
5. Working papers, drafts, commentaries, or discussion papers

GENERAL REQUEST FOR PUBLIC INPUT AND COMMENTS

To request that we include a new standard or a new country in the International Compilation, or to let us know of changes to these standards or broken links, please email us at: OHRP-Edu@hhs.gov.

DISCLAIMER

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinion. In addition, because the standards contained in this Compilation may be created, changed, or revoked on a continuing basis, this Compilation is not an exhaustive source of all current standards, and the information provided may be incomplete or outdated. Users of this compilation must not rely only on the information it provides and should check with local authorities, legal counsel, and/or research ethics committees before commencing research activities.

TABLE OF CONTENTS

International Compilation of Human Research Standards
2024 Edition

International Organizations

INTERNATIONAL ORGANIZATIONS

General

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

- 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): http://www.icrc.org

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

The TRUST Code: http://www.globalcodeofconduct.org

- Global Code of Conduct for Research in Resource-Poor Settings (2018): http://www.globalcodeofconduct.org/2018/05/Global-Code-of-Conduct

UNAIDS: http://www.unaids.org/

- Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials (2011): http://www.unaids.org/JC1853_GPP_Guidelines/2011
- Ethical Considerations in Biomedical HIV Prevention Trials (2012): https://www.unaids.org/2012/jc1399_ethical_considerations

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/declataion/bioethicsandhumanrights/2005

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

- Research Ethics Review Committee (ERC): https://www.who.int/groups/research-ethics-review-committee
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011): https://www.who.int/guidance/ethicsreviewhealthresearchhumanparticipants/2011
- Ethical Issues in Patient Safety Research: Interpreting Existing Guidance (2013): https://www.who.int/ethicalissuespatientsafetyresearch/interpretingguidance/2013
- 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
- WHO Expert Group on Ethics and Governance of Artificial Intelligence for Health: https://www.who.int/groups/who-expert-group-on-ethics-and-governance-of-artificial-intelligence-for-health

- Various: https://www.who.int/healthtopics

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

- 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): https://iris.who.int/GDP/guidanceforimplementation/2005
- Operational Guidance: Information Needed to Support Clinical Trials of Herbal Products (2005): https://iris.who.int/guidance/informationneedclinicaltrialsherbalproducts/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/clinicalinvestigationmedicaldevices/humansubjects/GCP/2015/statement
- 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: https://www.iso.org/standard/83968.html

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/

- Resolution WHA 58.34 (2005): https://who.int/resolution58.34/2005

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

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

- European Medicines Agency, Clinical Trials Information System (CTIS): https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/clinical-trials-human-medicines/clinical-trials-information-system

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: https://unesdoc.unesco.org/codeofconduct/ethicalguidelines/socialscienceresearch

Privacy/Data Protection

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

- 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/
- Global Repository on National Digital Health Strategies: https://www.who.int/teams/digital-health-and-innovation/global-repository-on-national-digital-health-strategies

Human Biological Materials

International Air Transport Association: http://www.iata.org/

- Infectious Substances Shipping Regulations (ISSR) (2005): https://www.iata.org/en/publications/store/infectious-substances-shipping-regulations/

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): https://iris.who.int/guidelines/safetransportinfectioussubstances/diagnosticspecimens/1997

Genetic Research

World Medical Association

- Human Genome Editing, Recommendations: https://www.who.int/publications/i/item/9789240030381
- Human Genome Editing (HGE) Registry: https://www.who.int/groups/expert-advisory-committee-on-developing-global-standards-for-governance-and-oversight-of-human-genome-editing/registry

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/instree/dnastatement.html
- Statement on Gene Therapy Research (2001): https://www.eubios.info/GENTHER.htm
- Statement on Human Genomic Databases (2002): https://www.cairn.info/revue-journal-international-de-bioethique-2003-3-page-207.htm

UNESCO Bioethics Program: https://www.unesco.org/en/ethics-science-technology?hub=387

- Universal Declaration on the Human Genome and Human Rights Section 16 of III Programme for 1998-1999 (1997): http://unesdoc.unesco.org/section16/1997
- International Declaration on Human Genetic Data: Section 22 of Major Programme III – Social and Human Sciences (2003): http://unesdoc.unesco.org/section22/2003

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 (2021): https://www.isscr.org/guidelines

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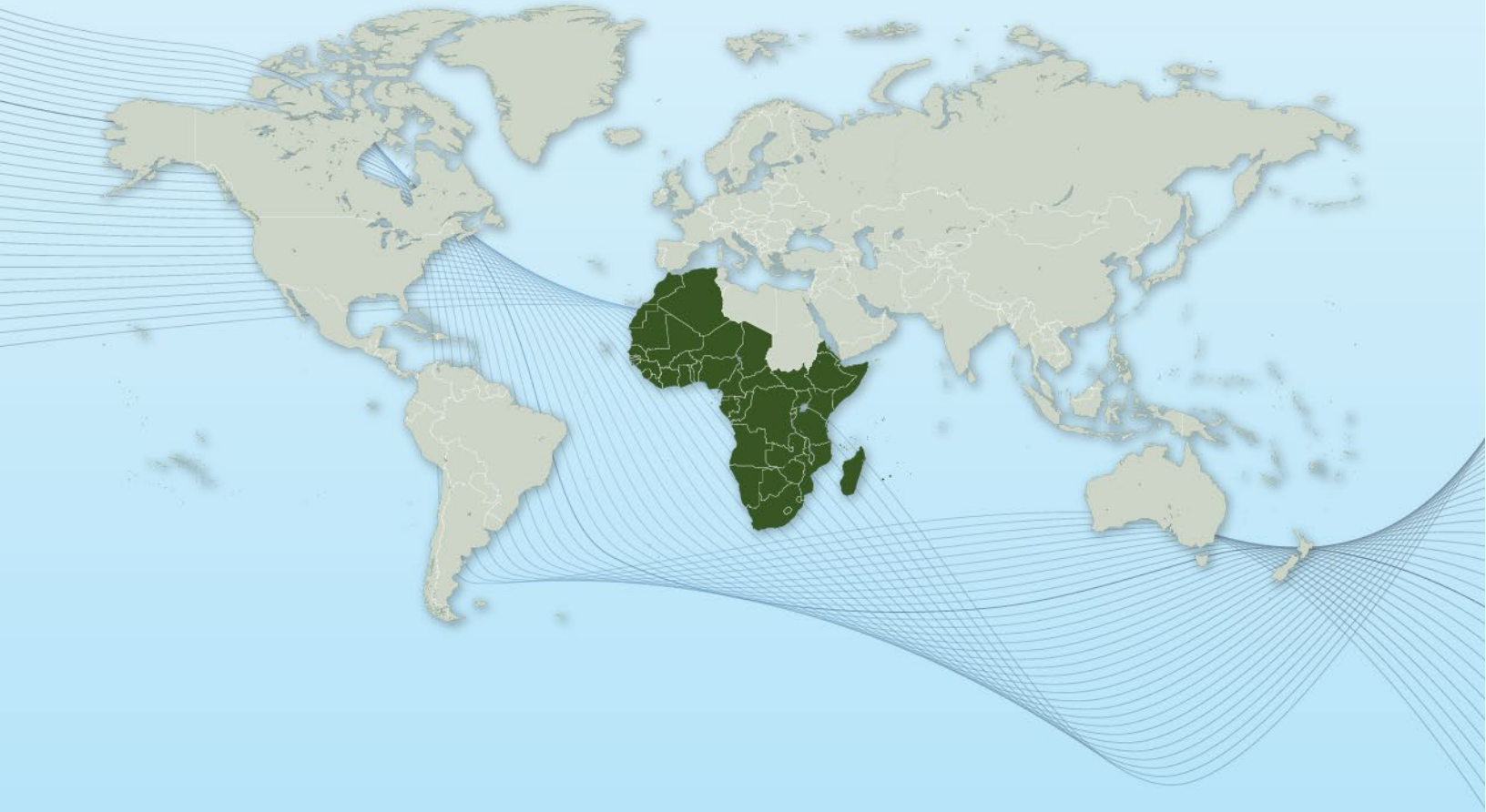
Africa



AFRICA – Regionwide

Clinical Trial Registries

Pan African Clinical Trials Registry: https://pactr.samrc.ac.za/

- PACTR, Terms and Conditions: https://pactr.samrc.ac.za/TermsAndConditions.aspx
- PACTR, FAQs: https://pactr.samrc.ac.za/FAQ.aspx
- African Clinical Trials Community: https://ctc.africa/

AFRICA – Angola

General

Key Organizations

- National Institute for Health Research (INIS): https://inis.gov.ao/
- INIS Ethics Committee (CEINIS): https://inis.gov.ao/comite-de-etica/

Relevant Standards

- INIS/CEINIS, Documents and Forms Required for Submitting Protocols: https://inis.gov.ao/comite-de-etica/

AFRICA – Benin

General

Key Organizations

- Ministry of Health: http://www.sante.gouv.bj/

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: https://www.moh.gov.bw/

Relevant Standards

- Anthropological Research Act 45 (1967): https://botswanalaws.com/consolidated-statutes/principle-legislation/anthropological-research
- Botswana National Drug (Medicine) Policy, Section 15 (2002, First Edition published 2005): www.moh.gov.bw/nationalmedicinepolicy/2002/2005
- Guidelines for Application for Research Permit: https://www.gov.bw/learning-and-teaching/application-research-permit
- National Health Quality Standards (2013): https://www.moh.gov.bw/Publications/standards/Volume_1_ED.pdf

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health and Wellness: https://www.moh.gov.bw/

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)

AFRICA – Burkina Faso

General

Key Organizations

- Ministry of Health and Public Hygiene: https://www.sante.gov.bf/accueil
- Technical Directorate of the National Institute of Public Health (INSP), The MURAZ Center: https://www.centre-muraz.bf/le-centre-muraz/
- Ministry of Health and Public Hygiene, Fundamental Texts: https://www.sante.gov.bf/ressources/textes-fondamentaux

AFRICA – Cameroon

General

Key Organizations

- Cameroon Bioethics Initiative: www.cambin.org
- Republic of Cameroon, Presidency of the Republic: https://www.prc.cm/en/

Relevant Standards

- Ministerial Order No. 079/A/MSP/DS of MINSANTE (1987): https://www.prc.cm/79/A/MSP/DS/1987
- Law on Medical Research Involving Humans (2022): https://perma.cc/DV9U-JZZQ

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

Key Organizations

- Ministry of Health: https://sante.gouv.cd/

Relevant Standards

- Order No. 1250 on the Organization of the National System of Pharmacovigilance in the Democratic Republic of Congo (2015): https://www.leganet.cd/1250/2015/
- 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

General

Key Organizations

- Ministry of Health, Public Hygiene and Universal Health Coverage: https://guce.gouv.ci/health

Drugs, Biologics, and Devices

Key Organizations

- Ivorian Authority for Pharmaceutical Regulation (AIRP): https://www.airp.ci/

Relevant Standards

- Decree No. 2020-407 of April 22, 2020, Regulating Clinical Trials
- Order Relating to the Organization and Operation of the National Committee for Ethics in Life Sciences and Health (2018): https://api.airpdigital.com/nationalcommitteeethicslifesciencesandhealth/order/2018/
- Decision No. 03, Regulation of Medical Devices (2022): https://api.airpdigital.com/regulationofmedicaldevices/03/2022

AFRICA – Ethiopia

General

Key Organizations

- Ministry of Health: https://www.moh.gov.et/
- Ethiopian Science and Technology Commission, Health Department

Relevant Standards

- Proclamation 60/1999, Section 21
- National Health Research Ethics Review Guideline (2020): https://learning.ahri.gov.et/nationalhealthresearchethicsreview/guideline/2020

Drugs, Biologics, and Devices

Key Organizations

- Ethiopian Food and Drug Authority (EFDA): http://www.efda.gov.et/

Relevant Standards

- Drug Administration and Control Proclamation No. 176/1999, Article 21

- Pharmacovigilance and Clinical Trial Lead Executive Office Guideline for Clinical Trial Authorization: http://www.efda.gov.et/wp-content/uploads/2023/10/Clinical-Trial-Authorization-Guideline-4th-edition.pdf
- 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/

AFRICA – Gambia

General

Key Organizations

- MRC: The Gambia Unit (London School of Hygiene & Tropical Medicine): http://www.mrc.gm/
- Gambia Research Ethics and Methodology Training Initiative (GamREMTI): https://gamremti.gm/

Relevant Standards

- MRC, Research Governance & Integrity: https://www.lshtm.ac.uk/research/research-governance-integrity
- 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/

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/publichealthact/851/2012
- 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/applicationsforclinicaltrials/publichealthact/851/2012
- 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/country/guinea

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.verti.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/CNERS/D/218/1998
- 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/publichealthcode/301-302/1997

AFRICA – Kenya

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

General

Key Organizations

- National Council for Science and Technology (NCST): http://www.nacosti.go.ke/
- Ministry of Health (MOH): 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/nationalguidelinesethicalconductofresearchhumansubjects/2008

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- MOH, Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005)
- Guidelines for the Conduct of Clinical Trials in Kenya (2022): https://pharmacyboardkenya.org/guidelines-for-the-conduct-of-clinical-trials-in-kenya/
- Guidelines for the conduct of clinical trials during public health emergencies and pandemics in Kenya (2022): https://pharmacyboardkenya.org/guidelines-for-the-conduct-of-clinical-trials-during-public-health-emergencies-and-pandemics-in-kenya/

Human Biological Materials

Key Organizations

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

Relevant Standards

- Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, page 44 (2005): https://www.globalgiving.org/pfil/1108/projdoc.pdf

AFRICA – Liberia

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

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/IRBpoliciesprocedures/2020
- Ethics Committee Guidelines: Procedures for Researchers, Section 1 (2011): http://clinregs.niaid.nih.gov/ethicscommitteeguidelines/researchers/2011
- Operational Guidelines of the National Research Ethics Board (2019): https://clinregs.niaid.nih.gov/operationalguidelines/nationalresearchethicsboard/2019
- Guideline for Application to Conduct Clinical Trials in Liberia (2014): https://clinregs.niaid.nih.gov/documents/liberia/G-LibClinTrial.pdf

AFRICA – Madagascar

General

Key Organizations

- Ministry of Public Health (MSANP): http://www.sante.gov.mg/ministere-sante-publique/

Relevant Standards

- National Health Policy (2016): http://www.sante.gov.mg/nationalhealthpolicy/2016
- National Health Research Policy (2016)

AFRICA – Malawi

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

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: https://www.health.gov.mw/

Relevant Standards

- Constitution of Malawi, Article 19(5) (1994): https://www.constituteproject.org/constitution/Malawi_2017
- NCST, Research Policies and Guidelines: https://www.ncst.mw/policies-and-guidelines/
- NCST, National Committee on Research In The Social Sciences And Humanities: https://www.ncst.mw/national-committee-on-research-in-the-social-sciences-and-humanities/
- 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 (2014): https://malawilii.org/pharmacymedicinesandpoisonsact/2014

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/framework/guidelines/researchinssh/2011

Human Biological Materials

Key Organizations

- National Commission for Science and Technology: 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/circular/humanbiologicalsamples/participantsrecompense/researchhumansubjects/2019

Genetic Research

Key Organizations

- National Research Council of Malawi (NRCM): www.sdnp.org.mw/nrcm/

Relevant Standards

- Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2003): https://www.future-agricultures.org/procedures/guidelines/geneticresources/2003

AFRICA – Mali

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

Relevant Standards

- Law No. 09-059 of 28 December 2009 Governing Biomedical Research on Humans: https://clinregs.niaid.nih.gov/documents/LawNo09-059.pdf

AFRICA – Namibia

General

Key Organizations

- Ministry of Health and Social Services: https://mhss.gov.na/

Drugs, Biologics, and Devices

Key Organizations

- Namibia Medicines Regulatory Council (NMRC): https://nmrc.gov.na/

Relevant Standards

- Namibia Medicines and Related Substances Control Act 2003 Act No 13 of 2003Namibia Medicines Regulatory Council Guideline for Section 27 Applications: https://nmrc.gov.na/downloads/-/document_library/fWrwrqO3yOpJ/view_file/81842

- NMRC, National Guidelines for Medicine Safety Surveillance (2011): https://nmrc.gov.na/downloads/-/document_library/fWrwrqO3yOpJ/view_file/410136

AFRICA – Nigeria

General

Key Organizations

- National Health Research Ethics Committee: https://nhrec.net/
- Ministry of Health: http://site.health.gov.ng/

Relevant Standards

- National Health Act (2014): https://nigeriahealthwatch.com/nationalhealthact/2014
- Nigerian Code of Health Research Ethics (2007): http://www.nhrec.net/codeofhealthresearchethics/2007
- Policy Statement Regarding Enrollment of Children in Research in Nigeria (2016): http://nhrec.net/childreninresearch/2016
- Guides and Forms, various: https://nhrec.net/download-guides-and-forms/

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Decree No. 15 of 1993: https://faolex.fao.org/docs/pdf/nig48230.pdf
- Good Clinical Practice Guidelines (2020): https://www.nafdac.gov.ng/NAFDAC-Good-Clinical-Practices-Guidelines-2020
- NAFDAC, Various Guidelines (filter by product type): https://nafdac.gov.ng/regulatory-resources/guidelines/
- NAFDAC, Various Gazette Regulations (filter by product type): https://nafdac.gov.ng/regulatory-resources/nafdac-regulations/

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

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

AFRICA – Rwanda

General

Key Organizations

- Ministry of Health: https://www.moh.gov.rw/
- National Ethics Committee: http://www.rnecrwanda.org/
- National Council for Science and Technology: https://www.ncst.gov.rw/

Relevant Standards

- Laws, various: https://www.moh.gov.rw/laws

AFRICA – Senegal

General

Key Organizations

- National Committee on Health Research Ethics (CNERS): https://www.cners.sn/

Relevant Standards

- For a comprehensive listing of research ethics standards in Senegal, visit https://www.cners.sn/, click on "About," then click on "Resources."

AFRICA – Sierra Leone

NOTE: For an overview of the clinical research regulations in Sierra Leone, see the ClinRegs report: https://clinregs.niaid.nih.gov/country/sierra-leone

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

- Clinical Trials, Various: http://www.pharmacyboard.gov.sl/ClinicalTrials.php
- Good Clinical Practice Guidelines (2021): https://pharmacyboard.gov.sl/gcpguidelines/2021
- Guidelines for the Application and Authorization of Clinical Trials of Medicines, Vaccines, and Medical Devices (2021): https://pharmacyboard.gov.sl/guidelines/clinicaltrials/2021
- Guidelines for the Inspection of Clinical Trials (2021): https://pharmacyboard.gov.sl/guidelines/inspectionofclinicaltrials/2021
- 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/guidelines/conductingclinicaltrials/2014
- Guideline for Good Clinical Practice (GCP) in Sierra Leone, Sections 3.2 and 3.3 (2018): https://clinregs.niaid.nih.gov/guideline/GCP/2018

AFRICA – South Africa

NOTE: For an overview of the clinical research regulations in South Africa, see the ClinRegs report: https://clinregs.niaid.nih.gov/country/south-africa

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://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): https://www.gov.za/nationalhealthact/2003
- Regulations Relating to Research with Human Participants No. R719 (2014): https://www.gov.za/regulations/researchhumanparticipants/2014
- DH, Ethics in Health Research: Principles, Structures, and Processes (2015): https://www.sun.ac.za/ethicsinhealthresearch/2015
- 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

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/ethicsinhealthresearch/2015

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.gov.za/nationalhealthact/2003
- Regulations Relating to the Use of Human Biological Material, 2 March 2012: https://www.gov.za/sites/default/files/gcis_document/201409/35099rg9699gon177.pdf
- Regulations Relating to Blood and Blood Products, 2 March 2012: 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

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)
- Regulations relating to Stem Cell Banks, 2 March 2012: 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: https://clinregs.niaid.nih.gov/country/tanzania

General

Key Organizations

- Ministry of Health (MOH): https://www.moh.go.tz/
- National Institute for Medical Research (NIMR): http://www.nimr.or.tz/
- National Health Research Ethics Committee (NHREC): https://www.health.gov.ng/Source/74/National-Health-Research-Ethics-Committee
- 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://nimr.or.tz/wp-content/uploads/2022/01/NIMR_Act.pdf
- Tanzania Commission for Science and Technology, Act No. 7 of 1986: http://www.parliament.go.tz/commissionforscienceandtechnology/1986
- NIMR, Research Policies, Guidelines, and Regulations (1979): https://nimr.or.tz/wp-content/uploads/2022/03/NIMR-Research-Policy.pdf
- Guidelines on Ethics for Health Research in Tanzania (2009): https://clinregs.niaid.nih.gov/documents/tanzania/G-EthicsHR.pdf
- The Personal Data Protection (Personal Data Collection and Processing) Regulations, 2023: https://oagmis.agctz.go.tz/portal/legislation/1350

Drugs, Biologics, and Devices

Key Organizations

- Tanzania Medicines and Medical Devises 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/fooddrugscosmeticsact/2003
- Medical devices, various: https://www.tmda.go.tz/publications/39
- Tanzania Commission for Science and Technology (COSTECH): https://www.costech.or.tz/

AFRICA – Uganda

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

General

Key Organizations

- Ministry of Health: https://www.health.go.ug/
- Uganda National Council for Science and Technology (UNCST): https://www.uncst.go.ug/

Relevant Standards

- Uganda National Council for Science and Technology Act of 1990 (CAP 209): https://faolex.fao.org/docs/pdf/uga96724.pdf
- 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 (2020): https://www.uncst.go.ug/manage/files/downloads/National%20Guidelines(1).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/

- National Research Biobanking Guidelines (2021): https://www.uncst.go.ug/manage/files/downloads/National_Biobanking_Gudelines(2).pdf

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/nationalhealthresearchact/2013

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.parliament.gov.zm/medicinesalliedsubstancesact/2013
- Guidelines on Regulating the Conduct of Clinical Trials in Human Participants, First Edition: https://www.zamra.co.zm/wp-content/uploads/2023/05/Guidelines-on-Application-for-Clincal-Trial-Authorisation.pdf

Human Biological Materials

Relevant Standards

- National Health Research Act, Part VI (2013): http://www.parliament.gov.zm/nationalhealthresearchact/2013

AFRICA – Zimbabwe

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

General

Key Organizations

- Ministry of Health and Child Care: https://www.mohcc.gov.zw/
- Medical Research Council of Zimbabwe: http://www.mrcz.org.zw

Relevant Standards

- Research Act (1986): https://faolex.fao.org/docs/pdf/zim93551.pdf
- Medical Research Council of Zimbabwe, Various Protocol-related Forms: http://www.mrcz.org.zw/forms/

Drugs, Biologics, and 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.jsc.org.zw/upload/Acts/2016/1503updated.pdf
- Medicines and Allied Substances Control Act, General Regulations (1991): https://faolex.fao.org/docs/pdf/zim117614.pdf
- Statutory Instrument 150 of 1991: https://faolex.fao.org/docs/pdf/zim117614.pdf
- Pharmacovigilance and Clinical Trials, Various Guidelines: https://www.mcaz.co.zw/pharmacoviligance-and-clinical-trials/clinical-trials

Privacy/Data Protection

Key Organizations

- 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
- Access to Information and Protection of Privacy Act, Chapter 10:27: http://www.veritaszim.net/accessinformationandprotectionprivacyact/10/27

Human Biological Materials

Key Organizations

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

Relevant Standards

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

Genetic Research

Key Organizations

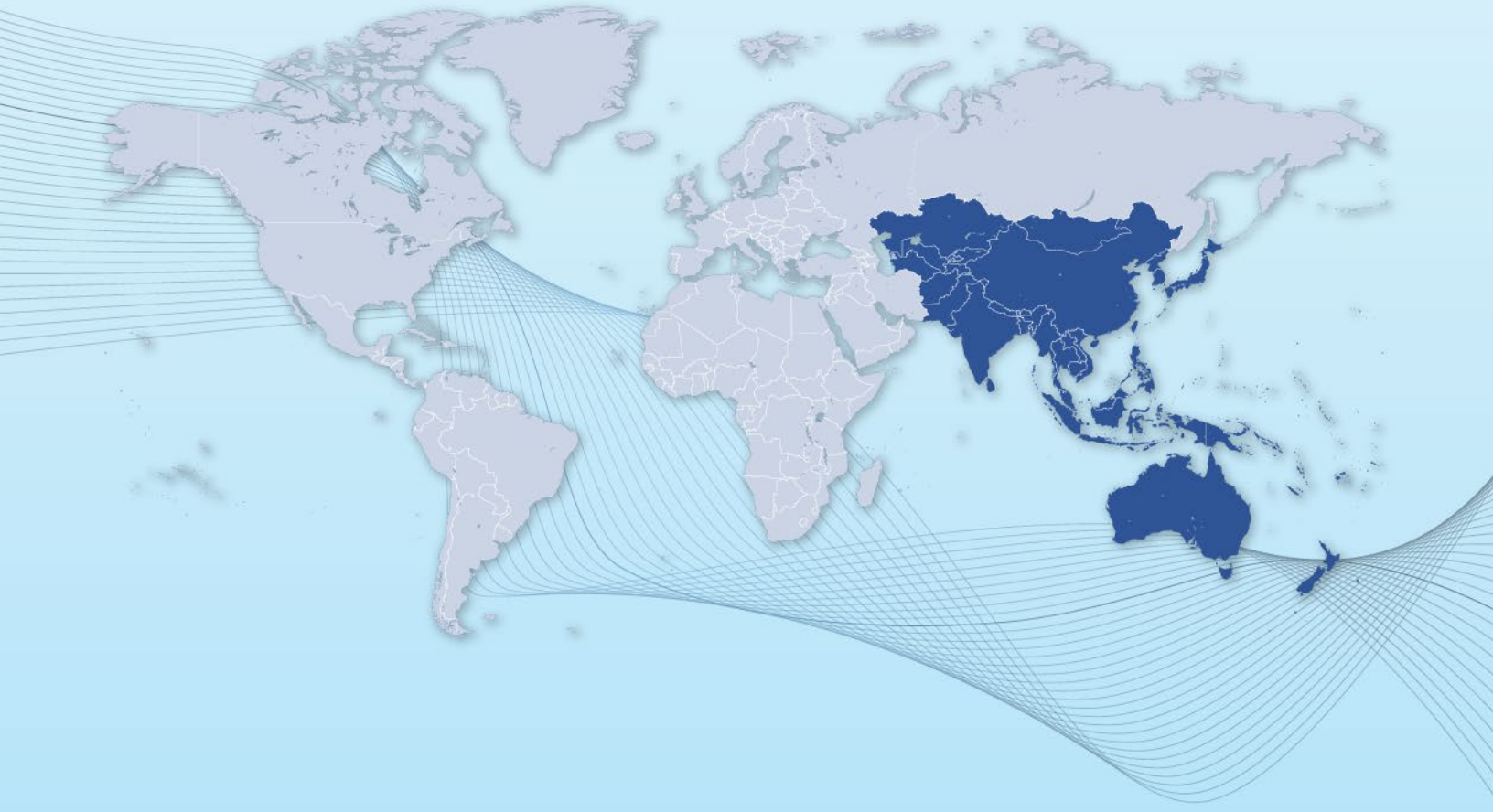
- National Biotechnology Authority of Zimbabwe: http://www.nba.ac.zw/

Relevant Standards

- National Biotechnology Authority Act, Chapter 14:31 (2006): https://www.jsc.org.zw/upload/Acts/2011/1431post.pdf

International Compilation of Human Research Standards
2024 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.safetyandquality.gov.au/our-work/health-and-human-research/national-mutual-acceptance-scheme-ethical-and-scientific-review-multi-centre-research
- AIATSIS, Code of Ethics for Aboriginal and Torres Strait Islander Research (The AIATSIS Code) and Associated Guidance for Applying It: AIATSIS Code of Ethics and Guidance

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

- 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

- Therapeutic Goods Regulations, Statutory Rules No. 394 (1990) (as amended and in force on March 1, 2024): https://www.legislation.gov.au/F1996B00406/latest/text
- Australian Regulatory Guidelines for Medical Devices (ARGMD) (2011): http://www.tga.gov.au/industry/devices-argmd.htm

Clinical Trials Registry

Key Organizations

- Australian Clinical Trials: https://www.australianclinicaltrials.gov.au/
- Australian New Zealand Clinical Trials Registry (ANZCTR): 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
- Australian Clinical Trials, Resources: https://www.australianclinicaltrials.gov.au/resources
- ANZCTR, 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, Indemnity & Compensation Guidelines: https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/
- 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
- 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 (2023): 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
- NHMRC, National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2023): 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 (2023): 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/EthicalGideline
- Standard Operating Procedures (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.dgdagov.info/index.php/information-center/good-clinical-practice-gcp

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
- People's Republic of China Human Genetic Resources Management Regulations (2019): 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
- 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

Key Organizations

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

Relevant Standards

- National Medical Products Administration, Laws and Regulations, Various: https://english.nmpa.gov.cn/lawsandregulations_3.html
- National Medical Products Administration, Regulatory Information, Various: https://english.nmpa.gov.cn/regulatoryinformation.html
- Provisions for Adverse Drug Reaction Reporting and Monitoring, Decree No. 81 (2011): 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
- Guidelines on Ethical Review of Drug Clinical Trials, No. 436 (2010): http://www.gov.cn/gzdt/2010-11/08/content_1740976.htm

Clinical Trial Registries

Key Organizations

- Chinese Clinical Trial Registry (ChiCtr): https://www.chictr.org.cn/aboutEN.html

Relevant Standards

- ChiCtr, FAQs: https://www.chictr.org.cn/questionEN.html

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
- 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
- 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
- Code of Practice on Human Resource Management (2016): https://main.icmr.nic.in/sites/default/files/guidelines/guidelines_GTP.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
- National Medical Products Administration, Laws and Regulations, Various: https://english.nmpa.gov.cn/lawsandregulations_3.html
- National Medical Products Administration, Regulatory Information, Various: https://english.nmpa.gov.cn/regulatoryinformation.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

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
- 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

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
- Ethical Guidelines for Research on Human Embryo Stem Cells (2003): 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: https://clinregs.niaid.nih.gov/country/india

General

Key Organizations

- Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/
- Department of Health Research (DHR): https://dhr.gov.in/

Relevant Standards

- ICMR, Guidelines, Various (scroll down to "Ethics"): https://main.icmr.nic.in/content/guidelines-0
- National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During Covid-19 Pandemic: https://ethics.ncdirindia.org/asset/pdf/EC_Guidance_COVID19.pdf
- DHR, National Ethics Committee Registry for Biomedical and Health Research: https://naitik.gov.in/DHR/Homepage#

Drugs, Biologics, and Devices

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

Drugs

- CDSCO, Drugs and Cosmetics Act (1940 amended up to 31st December, 2016): Drugs and Cosmetics Act (page 584)
- CDSCO, New Drugs and Clinical Trials Rules (2019): New Drugs and Clinical Trials Rules, 2019 (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 Guidelines for Good Clinical Laboratory Practices (GCLP) (2021): https://main.icmr.nic.in/sites/default/files/upload_documents/GCLP_Guidelines_2020_Final.pdf
- ICMR, Guidelines, Various (scroll down to "Ethics"): https://main.icmr.nic.in/content/guidelines-0

Devices

- CDSCO, Medical Devices Rules, 2017 General Statutory Rules 78(E) (English from page 143): Medical Devices Rules, 2017
- 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

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): New Drugs and Clinical Trials Rules, 2019 (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

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

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/
- Ministry of Electronics & Information Technology (MeiTY): https://www.meity.gov.in/home
- National Health Authority (NHA): https://nha.gov.in/

Relevant Standards

- ICMR, 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
- NACO, Data Protection Guidelines of the National AIDS Control Programme: Data Protection Guidelines
- Digital Personal Data Protection Act (2023): https://www.meity.gov.in/writereaddata/files/Digital%20Personal%20Data%20Protection%20Act%202023.pdf
- National Digital Health Mission, Health Data Management Policy: https://abdm.gov.in:8081/uploads/health_data_management_policy_455613409c.pdf
- Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare: https://main.icmr.nic.in/sites/default/files/upload_documents/Ethical_Guidelines_AI_Healthcare_2023.pdf

Human Biological Materials

Key Organizations

- Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/
- Central Drug Standards Control Organization (CDSCO): https://cdsco.gov.in/opencms/opencms/en/Home/

Relevant Standards

- Govt. of India Office Memorandum (O.M. No.19015/53/1997 - IH Pt.) 19th November, 1997 on Exchange of Human Biological Material for Biomedical Research Purposes

- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 11 (2017): https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

Genetic Research

Key Organizations

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

Relevant Standards

- DBT, Environmental Protection Act (1986)
- DBT, Recombinant DNA Safety Guidelines (1990)
- DBT, Regulations and Guidelines for Recombinant DNA Research and Biocontainment (2017): Regulations and Guidelines for Recombinant DNA
- 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
- National Guidelines for Gene Therapy Product Development and Clinical Trials (2019): https://main.icmr.nic.in/sites/default/files/guidelines/guidelines_GTP.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
- Department of Health Research (DHR): https://dhr.gov.in/

Relevant Standards

- ICMR and DBT Combined, National Guidelines for Stem Cell Research (2017): National Guidelines for Stem Cell Research
- 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/
- The Surrogacy (Regulation) Act (2021): https://dhr.gov.in/sites/default/files/Surrogacy%20Regulation%20ACT%202021.pdf

- The Surrogacy Regulation Rules (2022): https://dhr.gov.in/sites/default/files/Surrogacy%20Rules2022.pdf
- National Guidelines for Hematopoietic Cell Transplantation (2021): https://main.icmr.nic.in/sites/default/files/upload_documents/Nat_Guide_HCT.pdf
- The Assisted Reproductive Technology (Regulation) Act: https://dhr.gov.in/sites/default/files/The%20%20Gazette%20of%20India%2C%20ART.pdf
- The ART Regulations Rules (2022): https://dhr.gov.in/sites/default/files/ART%20Rules%202022%20notification%20dated%2007062022%20published%20on%2008%20june.pdf
- Guidelines for Umbilical Cord Blood Banking: https://main.icmr.nic.in/sites/default/files/upload_documents/GUCBB_F.pdf

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: 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
- Clinical Trials Act (2009): https://elaws.e-gov.go.jp/document?lawid=429AC0000000016

Drugs, Biologics, and 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 Drugs (2020): https://elaws.e-gov.go.jp/document?lawid=409M50000100028_20200901_502M60000100155

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/en/index/
- 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
- 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_shiryou3.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
- Enforcement Rules for the Act on the Protection of Personal Information (2016): https://www.ppc.go.jp/files/pdf/PPC_rules.pdf
- 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

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
- 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
- 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

- Ordinance for Enforcement of Act on Regulation of Human Cloning Techniques (2021): 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
- 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
- English version (2010): 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
- 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
- Guidelines for Research Using Gene-altering Technologies on Human Fertilized Embryos (2021): https://www.lifescience.mext.go.jp/files/pdf/n2282_01.pdf

ASIA/PACIFIC – Kazakhstan

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
- 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: https://www.gov.kg/en/post/s/21942-ministerstvo-zdravookhraneniya-soobshchaet-po-sostoyaniyu-na-utro-200922

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

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
- 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 04.08.1998г. (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, National Institutes of Health (NIH): http://www.nih.gov.my/
- Academy of Sciences Malaysia (ASM): https://www.akademisains.gov.my/

Relevant Standards

- Malaysian Guidelines of Good Clinical Practice (2020): Guidelines of Good Clinical Practice
- Ministry of Health Malaysia, National Institutes of Health, Medical Review and Ethics Committee (MREC): https://nih.gov.my/images/media/publication/guidelines/NIH_Guideline_2021.pdf
- ASM, The Malaysian Code of Responsible Conduct in Research (2020): The Malaysian Code of Responsible Conduct in Research
- Clinical Trials and Biomedical Research (2007): https://mmc.gov.my/wp-content/uploads/2019/11/Clinical-TrialsBiomedical-Research.pdf
- Malaysian Guideline for Application of Clinical Trial Import License and Clinical Trial Exemption, 7th Edition (2021): https://npra.gov.my/easyarticles/images/users/1140/Malaysian-Guideline-for-Application-of-CTIL-and-CTX-8th-Ed-Final.pdf

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health Malaysia, National Pharmaceutical Regulatory Agency (NPRA): https://npra.gov.my/index.php/en/
- National Committee for Clinical Research (NCCR): http://www.nccr.gov.my/
- Medical Device Authority (MDA), Ministry of Health Malaysia: https://portal.mda.gov.my/
- Clinical Research Malaysia (CRM), Ministry of Health: https://clinicalresearch.my/

Relevant Standards

- NPRA, Various Directives: https://npra.gov.my/index.php/en/informationen/general-information/circulars.html
- NPRA, Malaysian Guidelines of Good Clinical Practice, 4th Ed (2018): https://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Clinical_Trial/MalaysianGuidelineforGoodClinicalPractice.pdf
- NPRA, Malaysian Guidelines of Good Clinical Practice (GCP) Inspection, Edition 2.1 (2020): Malaysian Guidelines of Good Clinical Practice
- NPRA, Malaysian Guideline for Phase I Unit Inspection and Accreditation Program (2018): Malaysian Guideline for Phase I Unit Inspection
- NPRA, FAQ: Clinical Trials – Safety Reporting (Updated 18 April 2024): https://www.npra.gov.my/index.php/en/clinical-trials-safety-reporting.html
- NCCR, Various Guidelines: http://www.nccr.gov.my/index.cfm?menuid=17
- CRM, Guidelines & Circulars, Various: https://clinicalresearch.my/resources/
- MDA, Various Legislations: https://www.mda.gov.my/index.php/doc-list/legislation
- MDA, Circular Letters of The Medical Device Authority, Various: https://www.mda.gov.my/index.php/doc-list/circular-letter
- MDA, Guidance Documents under the Medical Device Act of 2012 (Act 737), Various: https://www.mda.gov.my/index.php/doc-list/guidance-document

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/
- Department of Occupational Safety and Health (DOSH), Ministry of Human Resources: https://www.dosh.gov.my/index.php/about-us/dosh-profile

Relevant Standards

- Occupational Safety and Health Act 1994: Section 32: Occupational Safety and Health Act 1994
- NPRA, Malaysian Guidelines of Good Clinical Practice, 4th Ed (2018): Guidelines_on_Clinical_Trial

Social-Behavioral Research

Key Organizations

- Academy of Sciences Malaysia (ASM): https://www.akademisains.gov.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): Malaysian Code of Responsible Conduct in Research

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): Personal Data Protection Act

Human Biological Materials

Key Organizations

- National Committee for Clinical Research (NCCR): http://www.nccr.gov.my/

Relevant Standards

- Act 130, Human Tissues Act (1974): Section 2 Removal of parts of bodies for therapeutic purpose: Human Tissues Act
- Act 699, DNA Identification Act 2009. Malaysian Government Gazette of 3 September 2009: DNA Identification Act
- Act 795 Access to Biological Resources and Benefit Sharing Act (2017): https://www.mybis.gov.my/pb/3567
- Ministry of Energy and Natural Resources, User's Guide to the Access to Biological Resources and Benefit Sharing Act 2017 (Act 795): https://www.mybis.gov.my/pb/4497

- 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

Genetic Research

Key Organizations

- 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
- University of Malaysia: https://mohre.um.edu.my/

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
- Guidelines for Institutional Biosafety Committees, Use of Living Modified Organisms and Related Materials (2010): https://mohre.um.edu.my/img/files/Guidelines%20For%20Institutional%20Biosafety%20Committees.pdf
- MOH, Guidelines on Ethical Issues in the provision of Medical Genetics Services in Malaysia (2019): Ethical Issues in the provision of Medical Genetics Services
- Act 795 Access to Biological Resources and Benefit Sharing Act (2017): https://www.mybis.gov.my/pb/3567
- Ministry of Energy and Natural Resources, 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 Malaysia, National Pharmaceutical Regulatory Agency (NPRA): https://npra.gov.my/index.php/en/
- Ministry of Health, National Institutes of Health (NIH): http://www.nih.gov.my/
- 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
- Malaysian Medical Council (MMC): http://mmc.gov.my/
- Malaysian Society of Transplantation (MST): http://www.mst.org.my/

Relevant Standards

- NIH, 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
- NPRA, 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
- MOH, 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
- MOH, National Standards for Cord Blood Banking and Transplantation: http://www.moh.gov.my/moh/resources/auto%20download%20images/589d78e8689af.pdf
- MOH, 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
- MOH, National Guidelines For Haemopoietic Stem Cell Therapy (2009): https://www.moh.gov.my/index.php/database_stores/store_view_page/70/47
- MMC, Stem Cell Research and Stem Cell Therapy, MMC Guideline 002/2009 (2009): Stem Cell Research and Stem Cell Therapy, MMC Guideline
- MST, National Organ, Tissue and Cell Transplantation Policy: http://www.mst.org.my/articles/MALAYSIA%20TRANSPLANT%20POLICY.pdf

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 (FDA): https://www.fda.gov.mm/

Relevant Standards

- National Drug Law (1992) (page 163): National Drug Law
- FDA, Various Drug Regulations: https://www.fda.gov.mm/?cat=16
- FDA, Various Drug Guidelines: https://www.fda.gov.mm/?cat=20
- FDA, Various Medical Device Regulations: https://www.fda.gov.mm/?cat=17

- FDA, Various Medical Device Guidelines: https://www.fda.gov.mm/?cat=21

Human Biological Materials

Relevant Standards

- Blood and Blood Products Law (2003): https://www.myanmar-law-library.org/IMG/pdf/myanmar_laws_2003.pdf (page 1)
- Body Organ Donation Law (2004): https://www.myanmar-law-library.org/spip.php?page=pdfjs&id_document=103#page=7 (page 1)
- Organ Donation Law (Law No. 58/2015) (Burmese): Organ Donation Law

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: https://www.hrc.govt.nz/resources/hrc-ethics-committee
- National Ethics Advisory Committee (NEAC): http://www.neac.health.govt.nz/
- Ministry of Health (MOH): https://www.health.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): Code of Health and Disability Services
- 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

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: https://www.hrc.govt.nz/resources/standing-committee-therapeutic-trials-scott#:~:text=The%20Health%20Research%20Council's%20Standing,not%20trials%20should%20be%20approved.

Relevant Standards

Drugs

- 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

- 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

- Australian New Zealand Clinical Trials Registry, 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: Health Information Privacy Code

Human Biological Materials

Key Organizations

- Ministry of Health (MOH): https://www.health.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)
- Human Tissue Act 2008
- MOH, Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (2007): Human Tissue for Future Unspecified Research

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/
- Ethics Committee on Assisted Reproductive Technology (ECART): http://ecart.health.govt.nz/
- Ministry of Health: https://www.health.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

- National Bioethics Committee, Various Guidelines: http://nbcpakistan.org.pk/guidelines.html

- National Bioethics Committee, Various Relevant Downloads: http://nbcpakistan.org.pk/downloads.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/assets/ppi_guidelines_may_2011-1--final-copy-on-pmrc-wbesite.pdf

Human Biological Materials

Key Organizations

- National Bioethics Committee: http://nbcpakistan.org.pk/

Relevant Standards

- National Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials (2020): Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials
- Ethical Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials (2016): http://nbcpakistan.org.pk/assets/hbm-guidelines-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/assets/guidelines_for_stem_cells.pdf

ASIA/PACIFIC – Philippines

General

Key Organizations

- Philippine Health Research Ethics Board (PHREB): 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

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

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

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
- 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): Data Privacy Act Rules and Regulations

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- National Ethical Guidelines for Health and Health-Related Research, Pages 91, 157 and 163 (2017): https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=98:neghhr-2017

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

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

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
- 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
- Health Products (Medical Device) Regulations 2010: http://sso.agc.gov.sg/SL/HPA2007-S436-2010
- 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
- HSA, Regulatory Overview of Clinical Trials: https://www.hsa.gov.sg/clinical-trials/overview

- HSA, Guidance Documents for Clinical Trials: https://www.hsa.gov.sg/clinical-trials/regulatory-guidances
- HSA, Clinical Trials of Medical Devices: https://www.hsa.gov.sg/medical-devices/clinical-trials

Research Injury

Key Organizations

- Ministry of Health (MOH): http://www.moh.gov.sg/
- Health Sciences Authority (HSA): 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 (page under construction as of June 2024)

Privacy/Data Protection

Key Organizations

- Ministry of Health (MOH): http://www.moh.gov.sg/
- 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/guidelines-and-consultation/2017/10/advisory-guidelines-for-the-healthcare-sector
- Personal Information in Biomedical Research (2007): Personal Information in Biomedical Research

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): Prohibition against Commercial Trading of Human Tissue
- 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
- Bioethics Advisory Committee, Human Tissue Research (2002): https://www.bioethics-singapore.gov.sg/files/publications/reports/human-tissue-research-full-report.pdf
- Directive on the Use of Cell, Tissue and Gene Therapy Products Manufactured In-House by Healthcare Institutions (2020): Directive on the Use of Cell, Tissue and Gene Therapy Products

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
- Directive on the Use of Cell, Tissue and Gene Therapy Products Manufactured In-House by Healthcare Institutions (2020): Directive on the Use of Cell, Tissue and Gene Therapy Products

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): Ethical, Legal and Social Issues in Stem Cell Research
- 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
- 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
- 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): Act No. 16250
- Medical Device Act No. 16402 (2019.04.23): 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): Act No. 16433
- 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
- Regulations for Clinical Trial Personnel Education and Certification for the Educational Institution Notice No.2019-3 (2019.01.17): Clinical Trial Personnel Education and Certification
- 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)
- Regulation on Approval for Investigational Device Exemption Application No. 2019-33 (2019.04.30): 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)
- Regulation on Medical Device Re-examination No. 2020-29 (2020.05.01): https://www.law.go.kr/행정규칙/의료기기재심사에관한규정/(2020-29,20200501)
- Guidelines on Human Research Protection Program 0053-01 (2014.3) 2017.5.31 고시: https://nedrug.mfds.go.kr/bbs/38/65
- Bioethics and Safety Act No. 16372 (2019.04.23): Act No. 16372
- Enforcement Decree of Pharmaceutical Affairs Act No. 30141 (2019.10.22): Enforcement Decree of Act No. 30141
- 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

- MFDS, Various Laws, Enforcement Decrees, and Enforcement Rules: https://www.mfds.go.kr/brd/m_203/list.do
- MFDS, Various Regulations: Various Regulations
- 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

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

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
- 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
- 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
- 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

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
- 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
- Bioethics and Safety Act No. 16372 (2019.04.23): 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): Use of Health and Medical data

- Standard Personal Information Protection Guidelines (2020.08.11): Personal Information Protection Guidelines
- 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): Biological Material Management in Clinical Trial

Genetic Research

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
- 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
- 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
- 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
- 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

ASIA/PACIFIC – Sri Lanka

Drugs, Biologics, and Devices

Key Organizations

- Cosmetics, Devices, and Drugs Regulatory Authority: Website under construction as of July 25th, 2024. In the meantime, this link provides access to important information.

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
- Informed Consent Exemptions for Human Research (2012): 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
- Regulations Governing the Organization and Operation of the Human Research Ethics Review Board (2018): https://law.moj.gov.tw/Eng/LawClass/LawAll.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

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): https://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=L0020162
- Administrative Regulations on the Establishment of Human Biobanks (2011): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020173

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.nstc.gov.tw/?l=en

Relevant Standards

- Human Biobank Management Act (2012): Human Biobank Management Act
- 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
- Guidance for Information Safety of Human Biobank (2010) (Chinese): 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

General

Key Organizations

- Ministry of Public Health: https://moh.tj/en/

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/country/thailand

General

Key Organizations

- National Research Council of Thailand (NCRT): http://deven.nrct.go.th/home
- Medical Council of Thailand (MCT): https://tmc.or.th/En /
- Forum for Ethical Review Committees in Thailand (FERCIT): http://www.fercit.org/

Relevant Standards

- NCRT, Initial Registration of an REC-EC-IRB (2022): http://deven.nrct.go.th/service//detail/194
- NCRT, National Policy and Guidelines for Human Research (2015): https://sp.mahidol.ac.th/pdf/ref/National_Policy_Guidelines_for_Human_Research2015.pdf
- MCT, Various Acts and Rules: https://tmc.or.th/En/act_rules_en.php
- NCRT, Regulation on the Permission of Foreign Researchers (1982): https://op.mahidol.ac.th/ra/contents/research_fund/MU-SURF/REGULATION-FOREIGN_2550_EN.pdf
- NCRT, Guidance for Foreign researcher Conducting Research in Thailand, various: https://foreignresearcher.nrct.go.th/index.php?lang=en&mod=forms&op=guidelines_en
- FERCIT, Ethical Guidelines for Research on Human Subject in Thailand (2007): http://www.fercit.org/file/Guideline_English_version.pdf

Drugs, Biologics, and Devices

Key Organizations

- Food and Drug Administration: https://en.fda.moph.go.th/
- Medical Council of Thailand (MCT): https://tmc.or.th/En/

Relevant Standards

- FDA, Various Laws and Regulations, Medicines: https://en.fda.moph.go.th/cat2-health-products/category/lr-medicines
- FDA, Various Laws and Regulations, Devices: https://en.fda.moph.go.th/cat2-health-products/category/health-products-medical-devices
- 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
- MCT, Thailand Good Clinical Practice Guidelines (2002)
- 1988 Medical Device Act

Clinical Trial Registries

Key Organizations

- Thai Clinical Trials Registry: http://www.clinicaltrials.in.th/

Relevant Standards

- FAQs: Clinical Trials Registry FAQs

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): Official Information Actwe
- Ministerial Regulations, various: https://sp.mahidol.ac.th/pdf/ref/National_Policy_Guidelines_for_Human_Research2015.pdf

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 Pharmaceutical Products Safety: https://www.uzpharm-control.uz/en/
- Scientific Boards of Medical Institutes

Relevant Standards

- Center for Pharmaceutical Products Safety, Various Laws, Decrees, Resolutions, State Standards, etc.: https://www.uzpharm-control.uz/en/documents
- 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)

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/country/vietnam

General

Key Organizations

- Ministry of Health (MOH): 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): Circular No. 45/2017/TT-BYT
- 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

Drugs, Biologics, and Devices

Key Organizations

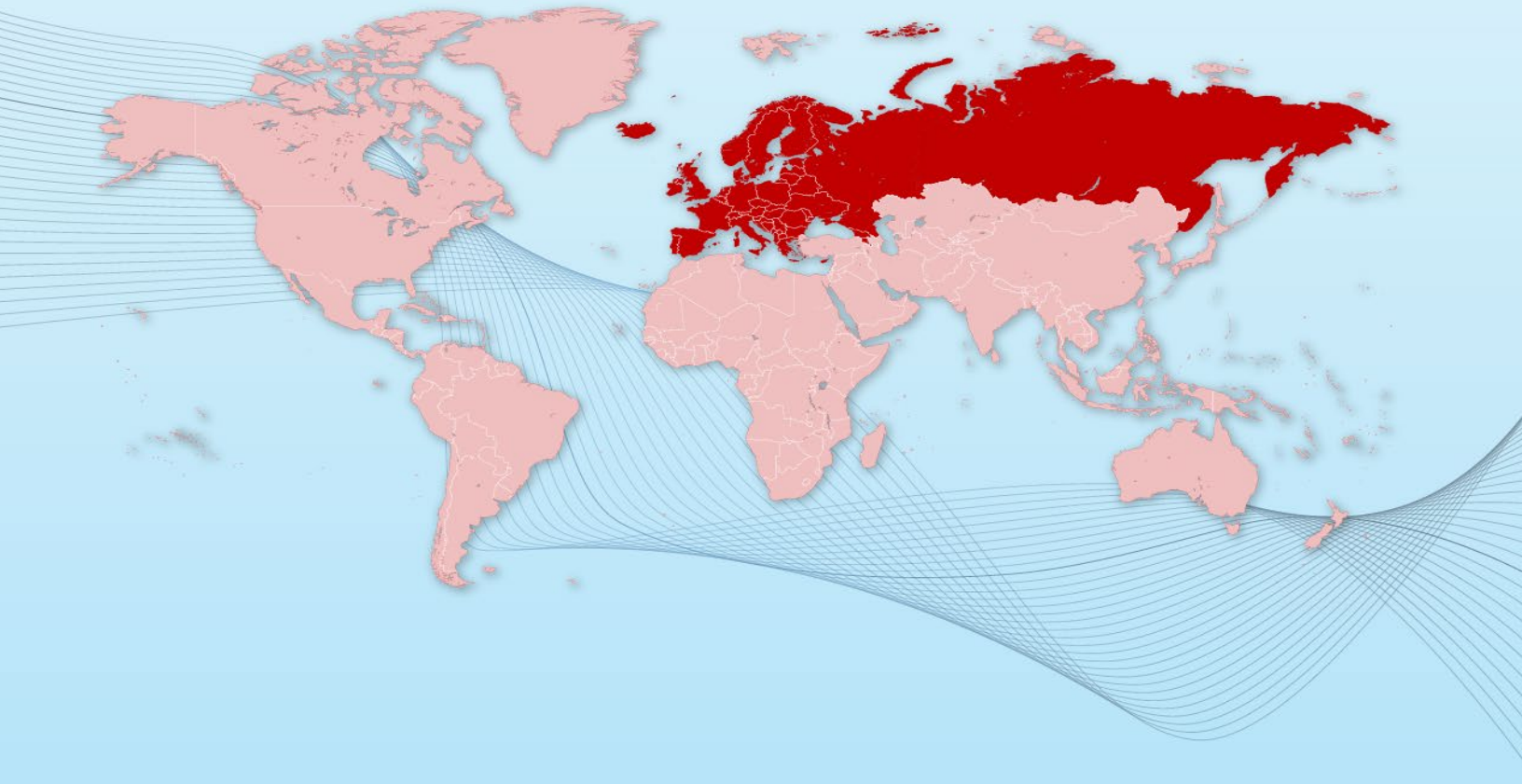
- Ministry of Health: https://www.moh.gov.vn/en_US/web/ministry-of-health

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
- 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
- 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
2024 Edition

Europe



EUROPE – Regionwide

General

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

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

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

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

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

Drugs, Biologics, and Devices

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

Drugs

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

Devices

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

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

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

Drugs

- Human Regulatory, Research and development, various: https://www.ema.europa.eu/en/human-regulatory-overview/research-development
- Human Regulatory, Clinical Trials in Human Medicines, various: https://www.ema.europa.eu/clinicaltrialshumanmedicines
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997): https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e6-r1-guideline-good-clinical-practice_en.pdf
- Reflection Paper on Ethical and GCP Aspects of Clinical Trials of Medicinal Products for Human Use Conducted Outside of the EU/EEA and Submitted in Marketing Authorization Applications to the EU Regulatory Authorities (2012): https://www.ema.europa.eu/system/files/documents/regulatory-procedural-guideline/reflection_paper_on_ethical_and_gcp_aspects_of_clinical_trials_en.pdf
- Guideline for Good Clinical Practice E6(R2) (2016): https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-good-clinical-practice
- Data Quality Framework for EU Medicines Regulation (2023): https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/data-quality-framework-eu-medicines-regulation_en.pdf

Devices

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

Clinical Trial Registries

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

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

Research Injury

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

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

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

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

Privacy/Data Protection

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

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

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

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation): http://eur-lex.europa.eu/2016/679/personaldataprocessingprotection
- Guidelines on consent under Regulation 2016/679, WP259 rev.01: http://ec.europa.eu/consentguidelines/679/2016
- Various Guidelines, Recommendations, Best Practices: https://www.edpb.europa.eu/our-work-tools/general-guidance/guidelines-recommendations-best-practices_en
- Various Opinions: https://www.edpb.europa.eu/our-work-tools/consistency-findings/opinions_en
- Transfers of Personal Data to Third Countries: Applying Articles 25 and 26 of the EU Data Protection Directive (1998): http://ec.europa.eu/justice/article-29/1998
- Working Document on Adequacy Referential (2018): https://ec.europa.eu/newsroom/article29
- Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (2019): https://edpb.europa.eu/our-work-tools/our-documents/opinion-art-70/opinion-32019-concerning-questions-and-answers_en
- Data Quality Framework for EU Medicines Regulation (2023): https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/data-quality-framework-eu-medicines-regulation_en.pdf
- Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European Data Governance and Amending Regulation (EU) 2018/1724 (Data Governance Act): https://eur-lex.europa.eu/datagovernanceact

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

- European Medicines Agency policy on publication of clinical data for medicinal products for human use: https://www.ema.europa.eu/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf
- Questions and Answers on the European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use (2015): https://www.ema.europa.eu/en/documents/report/questions-and-answers-european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf

- External Guidance on the Implementation of the European Medicines Agency Policy on the Publication of Clinical Data for Medicinal Products for Human Use (2016): https://www.ema.europa.eu/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data

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

- Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981): https://rm.coe.int/1680078b37
- Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (2018): https://rm.coe.int/16808ac918
- Recommendation No. R (97) 5 on the Protection of Medical Data (1997): https://rm.coe.int/cmrec-97-5-on-the-protection-of-medical-data
- Recommendation CM/Rec(2019)2 of the Committee of Ministers to member States on the protection of health-related data (2019): https://edoc.coe.int/en/international-law/7969-protection-of-health-related-date-recommendation-cmrec20192.html
- Article 29 Working Party Documentation: https://ec.europa.eu/justice/article-29/documentation/index_en.htm

Human Biological Materials

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

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

- Blood, Tissues, Cells and Organs: Key Documents: https://health.ec.europa.eu/blood-tissues-cells-and-organs/key-documents
- Directive 2004/23/EC on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage, and Distribution of Human Tissues and Cells: http://eur-lex.europa.eu/directive2004/23/EC
- Guidelines on Good Clinical Practice Specific to Advanced Therapy Medicinal Products: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/atmp_guidelines_en.pdf

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

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

Genetic Research

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

- Regulation (EC) No. 1394/2007 on Advanced Therapy Medicinal Products and Amending Directive 2001/83/EC and Regulation (EC) No. 726/2004: https://eur-lex.europa.eu/1394/2007

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

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

Embryos, Stem Cells, and Cloning

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

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

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

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

EUROPE – Armenia

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

Drugs, Biologics, and Devices

Key Organizations

- The Scientific Center of Drug and Medical Technologies Expertise (SCDMTW): http://www.pharm.am/
- Ethics Committee of the Ministry of Health
- Ethical Committee of the National Center for AIDS Prevention

Relevant Standards

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

EUROPE – Austria

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

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

Devices

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

Research Injury

Key Organizations

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

Relevant Standards

- Austrian Drug Law, Article 32 (2013): http://www.ris.bka.gv.at/austriandruglaw/32/2013

Privacy/Data Protection

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

Key Organizations

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

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Data Protection Act No. 165/1999: https://www.ris.bka.gv.at/dataprotectionact/165/1999
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj

Human Biological Materials

Key Organizations

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

Relevant Standards

- Law on Safety of Blood (2009): http://www.ris.bka.gv.at/safetyofblood/law/2009
- Law on Quality and Safety of Human Tissue and Cells (2013): http://www.ris.bka.gv.at/qualitysafetyhumantissueandcells/law/2013
- Regulation on Tissue Banks (2014): http://www.ris.bka.gv.at/tissuebanksregulation/2014
- Bioethics Commission, various publications: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html

Genetic Research

Key Organizations

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

Relevant Standards

- Gene Technology Act (2012): http://www.ris.bka.gv.at/genetechnologyact
- Bioethics Commission, various publications: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- Reproductive Medicine Act (2010): http://www.ris.bka.gv.at/reproductivemedicineact/2010
- Bioethics Commission, various publications: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html

EUROPE – Belarus

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

General

Key Organizations

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

Relevant Standards

- Constitution of the Republic of Belarus, Article 25 (2004): https://president.gov.by/article25/2004
- Law on Health Care System, Articles 40, 46 (2010): http://pravo.by/healthcaresystem/law
- Ordinance No. 274 on Establishing the National Bioethics Committee (2006)
- Decree No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/no55/2008
- Code of Medical Ethics (1999): http://www.levonevski.net/medicalethics/code/1999
- Guidelines for Ethics Committees on Standard Operational Proceedings (No. 55-0004, 2000): http://www.levonevski.net/no55-0004/2000
- Procedure for the Organization and work of the Ethics Committee of April 21, 2000 (amended 2009): http://www.levonevski.net/pravo/norm2009/num35/d35896/page2.html

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

- Law on Drugs, Articles 15,16 (2009)
- Law on Health Care System, Article 40 (2010): http://pravo.by/healthcaresystem/law
- Ordinance No. 254 on Clinical Drug Trials and Good Clinical Practice (1999): http://www.levonevski.net/no254/1999
- Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (1999): http://www.levonevski.net/no161/1999
- Decree No. 55 on Ethics Committees (2008): http://www.levonevski.net/no55/2008
- Decree No. 50 on Certain Aspects of Clinical Drug Trials (2009)
- Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004): http://www.levonevski.net/no55-0504/2004

Devices

- Law on Health Care System, Article 40 (2010): http://pravo.by/healthcaresystem/law
- Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (1999): http://www.levonevski.net/no161/1999
- Decree No. 216 on Certain Aspects of Clinical Trials of Medical Devices (2008) (Russian)
- Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004): http://www.levonevski.net/no55-0504/2004

Clinical Trial Registries

Key Organizations

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

Research Injury

Key Organizations

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- Constitution of the Republic of Belarus, Article 28 (2004): https://president.gov.by/en/gosudarstvo/constitution
- Law on Health Care System, Article 46 (2010): http://pravo.by/healthcaresystem/law

Human Biological Materials

Key Organizations

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

Relevant Standards

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

EUROPE – Belgium

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

General

Key Organizations

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

Relevant Standards

- Law Relating to Experimentation on Humans (2004): http://www.ejustice.just.fgov.be/cgi_loi/experimentationonhumans/law
- Royal Decree Dated 4 April 2014 Determining the Measures for Carrying Out the Law Dated 7 May 2004 Relating to Experiments on Humans Regarding the Ethics Committee: http://www.ejustice.just.fgov.be/experimentsonhumans/measures/decree
- Royal Decree Dated 30 June 2004 Determining the Measures for Carrying Out the Law Dated 7 May 2004 Relating to Experiments on Humans, Modified by the Royal Decree Dated 18 May 2006: http://www.ejustice.just.fgov.be/experimentsonhumans/measures/decree/modify
- FAMHP, Various Circulars: https://www.famhp.be/en/human_use/medicines/medicines/research_development/ethic_committee
- BACB, various: https://www.health.belgium.be/en/list-opinions

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Law Relating to Experimentation on Humans (2004): http://www.ejustice.just.fgov.be/humanexperimentation/law
- Royal Decrees to Experimentation on Humans: https://www.famhp.be/en/human_use/medicines/medicines/research_development/ethic_committee
- Royal Decrees on Clinical Trials: https://consultativebodies.health.belgium.be/en/advisory-and-consultative-bodies/ct-college-clinical-trial-college
- BACB, Opinion No. 58: Financing Expensive Medication: https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/opinion_58_web.pdf

Research Injury

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Act on the Protection of Natural Persons with Regard to the Processing of Personal Data (30 July 2018)
- Belgian Data Protection Authority, various publications: https://www.privacycommission.be/citoyen/publications/toutes-les-publications

Human Biological Materials

Key Organizations

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Key Organizations

- Federal Commission for Medical and Scientific Research on Embryos in Vitro: https://consultativebodies.health.belgium.be/en/advisory-and-consultative-bodies/federal-commission-medical-and-scientific-research-embryos-vitro
- Federal Agency for Medicines and Health Products (FAMHP): https://www.famhp.be/en/human_use/medicines/medicines
- Belgian Advisory Committee on Bioethics (BACB): https://www.health.belgium.be/en/belgian-advisory-committee-bioethics

Relevant Standards

- Act on Research on Embryos in Vitro (2003): https://organesdeconcertation.sante.belgique.be/fr/organe-d'avis-et-de-concertation/commission-federale-embryons
- Law on Medically Assisted Reproduction and the Destination of Supernumerary Embryos and Gametes (2007): https://www.afmps.be/fr/humain/produits_de_sante/materiel_corporel_humain/banques_de_materiel_corporel_humain/legislation/apres_le_01_12_2009
- Royal Decree Fixing the Criteria for the Program Applicable to the Care Programs 'Reproductive Medicine' (15 February 1999): http://www.ejustice.just.fgov.be/criteriaforreproductivemedicine/decree
- BACB, various: http://www.health.belgium.be/en/belgian-advisory-committee-bioethics

EUROPE – Bosnia and Herzegovina

General

Federation of Bosnia and Herzegovina

Key Organizations

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

Relevant Standards

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

Republic of Srpska

Key Organizations

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

Drugs, Biologics, and Devices

Federation of Bosnia and Herzegovina

Key Organizations

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

Relevant Standards

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

Republic of Srpska

Key Organizations

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

Relevant Standards

- Law on Drugs No. 58/08: https://almbih.gov.ba/wp-content/uploads/2023/10/medicinal_products_and_medical_devices_act.pdf
- Law on Changes and Amendments of Law on Drugs No. 34/08
- Ordinance on Clinical Trials on Medical Products and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf
- Regulation about Medical Devices (2010): https://almbih.gov.ba/wp-content/uploads/2023/10/ordinance_on_medical_devices.pdf

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

Research Injury

Federation of Bosnia and Herzegovina

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Medicinal Products and Medicinal Devices Act, Articles 52 and 116 (2008): http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf
- Law on Health Insurance of the Federation of Bosnia and Herzegovina, Official Gazette No. 46/10
- Regulation about Clinical Testing of IMP and Medical Devices, 4/10: https://almbih.gov.ba/ordinance_on_clinical_trials_on_medicinal_products_and_medical_devices.pdf
- Legislation at the state level: https://almbih.gov.ba/en/documents/

Republic of Srpska

Key Organizations

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

Relevant Standards

- Medicinal Products and Medicinal Devices Act, Article 52 and 116
- Law on Health Insurance of the Republic of Srpska, Official Gazette Republic of Srpska No. 106/09: http://www.farmaceutska-komora.org/healthinsurancelaw/106/09

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

Social-Behavioral Research

Federation of Bosnia and Herzegovina

Key Organizations

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

Republic of Srpska

Key Organizations

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- Law on the Protection of Personal Data in Bosnia and Herzegovina (2005): https://www.azlp.ba/lawonprotectionofpersonaldata
- Law on Amendments to the Law on the Protection of Personal Data in Bosnia and Herzegovina, Official Gazette of Bosnia and Herzegovina No. 76/11 (2011): https://www.azlp.ba/lawonamendmentstolawonprotectionofpersonaldata
- Regulation on the Manner of Keeping the Records of Personal Data Filing Systems and the Pertinent Records Form (2009)
- Compilation of Domestic and International Data Protection Regulations: http://www.azlp.ba/domesticandinternationaldataprotectionregs

Human Biological Materials

Federation of Bosnia and Herzegovina

Key Organizations

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Federation of Bosnia and Herzegovina

Key Organizations

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

Relevant Standards

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

Republic of Srpska

Key Organizations

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

Relevant Standards

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

EUROPE – Bulgaria

General

Key Organizations

- https://www.mh.government.bg/en/

Relevant Standards

- Constitution of the Republic of Bulgaria, Amendment SG. 18/25, Article 29 (2015): http://www.parliament.bg/bg/const
- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Law Ratifying the Additional Protocol on Biomedical Research (2006): https://www.mh.government.bg/lawadditionalprotocolbiomedicalresearch
- Medicinal Products in Human Medicine Act (2017): https://www.bda.bg/images/stories/documents/legal_acts/20210208_ZLPHM_English.pdf
- Healthcare Act, Articles 197-206 (2018)

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

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

Devices

- Medical Devices Act (2016): https://www.bda.bg/medicaldevicesact/2016
- Ordinance No. 10 (2008): http://www.bda.bg/Ordinance_Clinical_investigations
- Various: http://www.bda.bg/en/114-information-for-companies-section/medical-devices-category
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: https://eur-lex.europa.eu/regulation745/2017
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use: https://eur-lex.europa.eu/regulation536/2014

Clinical Trial Registries

Key Organizations

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

Relevant Standards

- Medical Products in Human Medicine Act: https://www.bda.bg/medicinalproducts/humanmedicineact
- Ordinance No. 31 for Determining the Principles of Good Clinical Practice: https://www.bda.bg/goodclinicalpractice/ordinance31

Research Injury

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Medicinal Products in Human Medicine Act, Chapter 4, Articles 91 and 92 (2016): http://www.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf
- Regulation 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice, Section 5.8 (2012) (Bulgarian): http://www.bda.bg/images/stories/documents/regulations/naredbi/20180320_Naredda_31.pdf

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Act on Transplantation of Organs, Tissues and Cells https://iamn.bg/en/legislation/
- Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006) Genetic Research

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

- Act on Transplantation of Organs, Tissues and Cells: https://iamn.bg/en/legislation/
- Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006)

EUROPE – Croatia

General

Key Organization

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

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

Devices

- Medical Devices Act (2013): http://narodne-novine.nn.hr/medicaldevicesact
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: https://eur-lex.europa.eu/745/2017
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (effective 31 January 2022): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536&qid=1722524150296

Clinical Trial Registries

Key Organizations

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

- Agency for Medicinal Products and Medical Devices: http://www.halmed.hr/

Relevant Standards

- Various: https://zdravlje.gov.hr/standards
- HALMED Front Page for Industry Representatives: https://www.halmed.hr/Predstavnici-industrije/

Research Injury

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Law on Mandatory Health Insurance (2013): http://www.hzzo.hr/mandatoryhealthinsurancelaw
- Medicinal Product Act (2013): http://narodne-novine.nn.hr/medicinalproductact
- Rule Book on Amendments to Medicinal Product Act (2014): http://narodne-novine.nn.hr/amendmentstomedicinalproductact
- Ordnance on Clinical Trials and Good Clinical Practice, Articles 11 and 16, Act 5.8., 6.8., and 8.2.5 (2015): http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html
- Various: https://zdravlje.gov.hr/various

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

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

- Law about Blood and Blood Products (2006): http://narodne-novine.nn.hr/clanci/sluzbeni/2006_07_79_1916.html
- Rule Book on Amendments to Law about Blood and Blood Products (2011): http://narodne-novine.nn.hr/bloodandbloodproductslawamendments
- Law on the Implementation of Human Tissues and Cells (2012): http://narodne-novine.nn.hr/implementationhumantissuesandcells/2012
- Law on Transplantation of Human Organs for the Purpose of Treatment (2012): http://narodne-novine.nn.hr/transplantationhumanorgansfortreatment/2012
- Various: https://zdravlje.gov.hr/arhiva-80/zakonodavstvo/zakoni-i-pravilnici/701

Genetic Research

Key Organizations

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

EUROPE – Cyprus

General

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Law for Good Clinical Practice (2004)

Research Injury

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Legislation Concerning Medicinal Products of Human Use (Good Clinical Practice) No. 452/2004 Article 11 (8)

Privacy/Data Protection

Key Organizations

- Commissioner's Office for the Protection of Personal Data: http://www.dataprotection.gov.cy/officeforprotectionpersonaldata

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Protection of Natural Persons Against the Processing of Personal Data and the Free Circulation of such Data Act of 2018 (Law 125 (I)): http://www.dataprotection.gov.cy/law125

Human Biological Materials

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Relevant Standards

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

EUROPE – Czech Republic

General

Key Organizations

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

Relevant Standards

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

- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Act No. 130/2002 Collection on Research and Development Support, as Amended (2018)
- Act No. 372/2011 on Healthcare Services, As Amended (2019)
- Act. No. 373/2011 on Specific Healthcare Services, As Amended (2018)

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

- Act No. 378/2007 Collection on Pharmaceuticals, As Amended (2019)
- Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use: https://ec.europa.eu/health/536/2014
- Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products: https://www.sukl.eu/uploads/Legislativa/226_2008_clinical_trials.pdf
- Various: http://www.sukl.cz/medicinal-products-clinical-trials-guidelines-1

Devices

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

Clinical Trial Registries

Key Organizations

- EU Clinical Trials Register

Relevant Standards

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

Research Injury

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Relevant Standards

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

Genetic Research

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

EUROPE – Denmark

General

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Act No. 1338 on Research Ethics Review of Health Research and Health Data Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/1338
- Executive Order No. 825 on Obligation to Notify Health Research and Health Data Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/825
- Guidelines about Notification (Checklist) (2019): http://www.nvk.dk/forsker/forskervejledning

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Regulation No. 745 on Medical Devices (2017): https://eur-lex.europa.eu/745/2017
- Regulation No. 536 on Clinical Trials on Medicinal Products for Human Use (2014):
- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536&qid=1722524150296
- Act No. 1252 on Clinical Trials on Medicinal Products (2018): https://www.retsinformation.dk/eli/lta/2018/1252
- Act. No. 1853 on Research Ethics Review of Clinical Trials on Medical Devices, etc. (2020): https://www.retsinformation.dk/eli/lta/2020/1853
- Executive Order No. 295 on Clinical Trials of Medicinal Products on Humans (2004): https://www.retsinformation.dk/eli/lta/2004/295
- Executive Order No. 965 on Reporting Significant Health Findings from Health Research and Health Data Research Projects, Clinical Trials on Medical Devices, etc. and Certain Register Studies (2021): https://www.retsinformation.dk/eli/lta/2021/965
- Guidelines for Applications for Authorisation of Clinical Trials of Medical Products in Humans (2021): https://laegemiddelstyrelsen.dk/en/licensing/clinical-trials/trials-in-humans/guideline-for-applications-for-authorisation-of-clinical-trials-of-medicinal-products-in-humans/
- Danish Research Ethics Committees, Various Guidance: https://researchethics.dk/information-for-researchers

Clinical Trial Registries

Key Organizations

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

Relevant Standards

- Act No. 1338 on Research Ethics Review of Health Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/1338
- Executive Order No. 825 on Obligation to Notify Health Research and Health Data Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/825

- Executive Order No. 965 on Reporting Significant Health Findings from Health Research and Health Data Research Projects, Clinical Trials on Medical Devices, etc. and Certain Register Studies (2021): https://www.retsinformation.dk/eli/lta/2021/965
- Danish Research Ethics Committees, Overview of Mandatory Reporting: https://researchethics.dk/information-for-researchers/overview-of-mandatory-reporting
- Danish Research Ethics Committees, EU Clinical Trials Regulation (CTR) and EU Clinical Trials Information System (CTIS) Q&A: https://researchethics.dk/information-for-researchers/clinical-trials-with-medicinal-products-under-the-ctr/ctr-and-ctis-qanda

Research Injury

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Act No. 995 on the Right to Complain and Receive Compensation within the Health Service (2018): https://www.retsinformation.dk/eli/lta/2018/995

Privacy/Data Protection

Key Organizations

- Danish Data Protection Agency (DPA): https://eng.patienterstatningen.dk/

Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Act No. 1338 on Research Ethics Review of Health Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/1338
- Health Act No. 903 (2019): https://www.retsinformation.dk/eli/lta/2019/903

- Guidelines on the Use of Biological Material in Health Research Projects (2017): http://www.nvk.dk/emner/biobanker/vejledning-om-bio-mat

Genetic Research

Key Organizations

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

Relevant Standards

- Act No. 1338 on Research Ethics Review of Health Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/1338
- Executive Order No. 825 on Obligation to Notify Health Research and Health Data Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/825
- Executive Order No. 965 on Reporting Significant Health Findings from Health Research and Health Data Research Projects, Clinical Trials on Medical Devices, etc. and Certain Register Studies (2021): https://www.retsinformation.dk/eli/lta/2021/965
- Guidance on Genomics and Research in Sensitive Bioinformatics Data (2020): https://researchethics.dk/guidelines/guidance-on-genomics-and-research-in-sensitive-bioinformatics-data

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- Act No. 440 on Danish Council of Ethics (2004): https://www.retsinformation.dk/act440/2004
- Executive Order No. 902 on Medically Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. (2019): https://www.retsinformation.dk/assistedreproductionresearchact

EUROPE – Estonia

General

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Constitution of the Republic of Estonia, Paragraph 18 (2016): https://www.riigiteataja.ee/en/eli/521052015001/consolide
- Code of Ethics of Estonian Scientists: https://www.akadeemia.ee/wp-content/uploads/2020/06/code_ethics2002-3.pdf

Drugs, Biologics, and Devices

Key Organizations

- State Agency of Medicines: https://ravimiamet.ee/en/agency-and-contact/about-state-agency-medicines
- Minister of Social Affairs (MSA): https://www.sm.ee/en
- Estonian Health Board: http://www.terviseamet.ee/en/medical-devices.html

Relevant Standards

- Medicinal Products Act, Chapter 5 (2015): https://www.riigiteataja.ee/medicinalproductsact
- MSA, Rules of Procedure of Medical Ethics Committee for Clinical Trials, a List of Data to be Submitted for Obtaining Approval, Procedure for Adoption of Resolutions and Format of Application for Obtaining Approval (2005): https://www.riigiteataja.ee/ethicscommitteeforclinicaltrialsprocedure
- MSA, Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 (2005): https://www.riigiteataja.ee/regulation23/2005
- Medical Devices Act (2004): https://www.riigiteataja.ee/medicaldevicesact
- Regulation No. 86: 2010 of the Minister of Social Affairs on the Conditions and Procedures for the Clinical Investigation of Medical Devices

Research Injury

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Medicinal Products Act, Section 90: https://www.riigiteataja.ee/medicinalproductsact
- Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 of the Minister of Social Affairs of (2005): https://www.riigiteataja.ee/regulation23/2005/

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Genetic Research

Relevant Standards

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

Human Biological Materials

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Relevant Standards

- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002) (Estonian): https://www.riigiteataja.ee/akt/78569
- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Artificial Insemination and Embryo Protection Act, RT I 1997, 51, 824 (2011): https://www.riigiteataja.ee/en/eli/ee/530102013057/consolide/current

EUROPE – Finland

General

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Decree of the National Research Ethics Council of Finland No. 1347/1991
- Decree on Medical Research Nos. 986/1999, 313/2004, and 65/2016
- Decrees on the National Committee on Medical Research Ethics No. 820/2010 and 788/2018

- Report on Children in Medical Research (2003): https://tukija.fi/childrenmedicalresearchreport
- TUKIJA, Legislation ,Various: https://tukija.fi/en/legislation
- Act on Data Protection (1050/2018): https://www.finlex.fi/fi/laki/kaannokset/2018/en20181050.pdf https://www.finlex.fi/en/laki/kaannokset/2018/en20181050.pdf
- Criminal Code of Finland (39/1889, numerous amendments; the link includes amendments up until 766/2015): https://www.finlex.fi/fi/laki/kaannokset/1889/en18890039_20150766.pdf https://www.finlex.fi/en/laki/kaannokset/1889/en18890039.pdf
- Act on the Secondary Use of Health and Social Data (552/2019): https://www.finlex.fi/fi/laki/alkup/2019/20190552#Lidp445824016 (https://stm.fi/documents/1271139/1365571/The+Act+on+the+Secondary+Use+of+Health+and+Social+Data/a2bca08c-d067-3e54-45d1-18096de0ed76/The+Act+on+the+Secondary+Use+of+Health+and+Social+Data.pdf; unofficial translation)
- Medical Research Act No. 488/1999 (Amended 295/2004, 794/2010, 143/2015 and one related to a Government Proposal to the Parliament HE 18/2020vp in relation to the application of EU Clinical Trials Regulation 536/2014) upcoming: https://www.finlex.fi/fi/laki/kaannokset/1999/en19990488.pdf
- Medical Research Act No. 488/1999 (Amended 794/2010): http://www.finlex.fi/en/laki/kaannokset/1999/
- Government Decree on the National Institute for Health and Welfare (668/2008), latest amendment 1122/2015: https://www.finlex.fi/en/laki/kaannokset/2008/
- Responsible Conduct of Research and Procedures for Handling Allegations of Misconduct in Finland (2012): https://tenk.fi/sites/tenk.fi/files/HTK_ohje_2012.pdf and https://tenk.fi/en/advice-and-materials/RCR-Guidelines-2012
- The Ethical Principles of Research with Human Participants and Ethical Review in the Human Sciences in Finland (2019): https://tenk.fi/en/advice-and-materials/RCR-Guidelines-2012
- Agreeing on Authorship. Recommendation for Research Publications: https://tenk.fi/sites/tenk.fi/files/TENK_suositus_tekijyys.pdf

Drugs, Biologics, and Devices

Key Organizations

- Finnish Medicines Agency (FIMEA): https://fimea.fi/en/frontpage
- Ministry of Social Affairs and Health (MSAH): http://stm.fi/en/frontpage
- National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en
- Various Authorities, Advisory Committees, and Regional Research Ethics Committees: https://tukija.fi/en/cooperation
- National Supervisory Authority for Welfare and Health (VALVIRA): https://valvira.fi/

Relevant Standards

Drugs

- TUKIJA, Legislation, Various: https://tukija.fi/en/legislation
- Medicines Act 395/1987 (list of amendments and regulations made under the Act): https://www.finlex.fi/medicinesact
- Decree of the National Research Ethics Council of Finland No. 1347/1991: https://www.finlex.fi/fi/laki/alkup/1991/
- Decree on Medical Research, Nos. 986/1999, 313/2004 and 65/2016: https://finlex.fi/fi/laki/alkup/1999/19990986, https://finlex.fi/fi/laki/alkup/2016/
- Decrees on the National Committee on Medical Research Ethics No. 820/2010 and 788/2018: https://finlex.fi/fi/laki/alkup/2010/ , https://www.finlex.fi/fi/laki/alkup/2018/
- Operating Procedures of the National Committee on Medical Research Ethics (2021): https://tukija.fi/operatingproceduresTUKIJA
- Decree of the Ministry of Social Affairs and Health 817/2023 on the Fees Charged for Opinions of the National Medical Research Ethics Committee (2023): https://www.finlex.fi/fi/laki/alkup/2023/
- Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2012
- Finnish Medicines Agency Administrative Regulation on Clinical Trials on Medicinal Products (8/2019): https://fimea.fi/regulationclinicaltrialsonmedicinalproducts
- Report on Children in Medical Research (2003): https://tukija.fi/childrenmedicalresearch

Devices

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

Clinical Trial Registries

Key Organizations

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

Research Injury

Key Organizations

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

Relevant Standards

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

- Pharmaceutical Injuries Insurance: General Terms and Conditions (2017): https://www.laakevahinko.fi/en/potilaille/vakuutusehdot/

Social-Behavioral Research

Key Organizations

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

Relevant Standards

- The Ethical Principles of Research with Human Participants and Ethical Review in the Human Sciences in Finland (2019): https://www.tenk.fi/en/ethical-review-in-finland
- Act on the Secondary Use of Health and Social Data (552/2019): https://www.finlex.fi/secondaryuseofhealthandsocialdataact

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Act on the Medical Use of Human Organs, Tissues, and Cells No. 101/2001 (Finnish and Swedish): http://www.finlex.fi/act101/2001
- TUKIJA, Legislation ,Various: https://tukija.fi/en/legislation
- Tukija's Operating Procedures (Regulation and Biobank): https://tukija.fi/regulationandbiobankprocedures
- Law on Biobanks, No. 688/2012 (Finnish and Swedish): http://www.finlex.fi/fi/laki/ajantasa/2012/20120688
- Decree on Consent for Biobank No. 643/2013: http://www.finlex.fi/fi/laki/alkup/2013/20130643

- Decree on information on Biobank No. 649/2013: http://www.finlex.fi/fi/laki/alkup/2013/20130649
- Government Decree on Medical Use of Human Organs, Tissues, and Cells No. 594/2007
- Ministry Decree on Medical Use of Human Organs, Tissues, and Cells No. 1302/2007
- Act on the Secondary Use of Health and Social Data (552/2019): https://www.finlex.fi/secondaryuseofhealthandsocialdataact

Genetic Research

Key Organizations

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

Relevant Standards

- Gene Technology Act (377/1995) (Amended multiple times, the last one 39/2023): https://www.finlex.fi/genetechnologyact

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

EUROPE – France

General

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Law No. 2012-300 of 5 March 2012 on Research Involving Human Persons: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025441587
- Law No. 2011-814 of 7 July 2011 on Bioethics
- Public Health Code Articles R1121-1 and subsequent sections: https://www.legifrance.gouv.fr/publichealthcodearticles
- CCNE, Various Legislations and Rights: https://www.ccne-ethique.fr/en/topics/research-legislation-ethics/legislation-rights
- CCNE, Various Bioethics Laws: https://www.ccne-ethique.fr/en/topics/research-legislation-ethics/bioethics-laws

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Medications for Human Use, Articles 5111-1 and Subsequent Sections for Drugs and Medical Devices: https://www.legifrance.gouv.fr/medicationshumanusedrugsdevices
- Decision on Good Clinical Practices: http://www.legifrance.gouv.fr/decisiononGCP

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Act No. 78-17 of 6 January 1978 on Information Technology, Data Files, and Civil Liberties (2018): https://www.cnil.fr/fr/la-loi-informatique-et-libertes
- Law No. 2016-1321 of 7 October 2016 for a Numeric Republic: https://www.legifrance.gouv.fr/law1321/2016
- Data Protection Act (2018): https://www.legifrance.gouv.fr/dataprotectionact
- CNIL, Decree NO. 2019-536 of 29 May 2019 Enacted for the Application of Act No. 78-17 of 6 January 1978 on Data Processing, Data Files, and Civil Liberties: https://www.legifrance.gouv.fr/decree536/2019

- CNIL, Health Research: CNIL Adopts New Simplification Measures (2018): https://www.cnil.fr/fr/recherches-dans-le-domaine-de-la-sante-la-cnil-adopte-de-nouvelles-mesures-de-simplification
- CNIL, Health Research with Consent (2018): https://www.cnil.fr/healthresearchwithconsent
- CNIL, Health Research without Consent (2018): https://www.cnil.fr/healthresearchwithoutconsent
- CNIL, Practical Guide on the Protection of Personal Data: What Framework Applies to Research? (2018): https://www.cnil.fr/guidepersonaldataprotection
- CCNE, Manifesto for Digital Ethics (2023): https://www.ccne-ethique.fr/manifestodigitalethics

Human Biological Materials

Key Organizations

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

Relevant Standards

- Donation and Use of the Components and Products of the Human Body, Articles L1211-1 to L1274-3 (2004): https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006686056
- Public Health Code Articles L1243-3 and following sections (2012): http://www.legifrance.gouv.fr/initRechCodeArticle.do
- Decree No. 2017-1549 of 8 November 2017 on the Conservation and Preparation for Scientific Purposes of Elements of the Human Body and Amending the Public Health Code

Genetic Research

Key Organizations

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

Relevant Standards

- Civil Code Articles 16-10 to 16-13: http://www.legifrance.gouv.fr/civilcodearticles
- Article R1131-1 and Subsequent Sections of the Public Health Code: https://www.legifrance.gouv.fr/articleR1131-1

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- Law No. 2013-715 of 6th August 2013: http://www.legifrance.gouv.fr/decree715/2013
- Decree No. 2015-155 of 11 February, 2015: Public Health Code on Research on Embryos Article R2151-1 and Following Sections: http://legifrance.gouv.fr/decree155/2015
- Ethical Reflection Concerning Research on Human Embryonic Cells and on Human Embryos in Vitro (2010) : https://www.ccne-ethique.fr/researchethicsembryos

EUROPE – Georgia

General

Key Organizations

- Bioethics and Health Law Studies Society

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Additional Protocol to the Convention's on Human Rights and Biomedicine, concerning Biomedical Research, ETS No. 195 (2010)
- Law on Health Care, Chapter XIX (2017): https://matsne.gov.ge/healthcarelaw
- Law on Medicines and Pharmaceutical Activities No. 659 and 1586 (2015): https://matsne.gov.ge/medicinesandpharmaceuticalactivitieslaw

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Clinical Trial Registries

Key Organizations

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

Relevant Standards

- No public registry

Research Injury

Key Organizations

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

Relevant Standards

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

Social-Behavioral Research

Key Organizations

- Social and Psychological Agency

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Law on Data Protection (2018): https://matsne.gov.ge/dataprotectionlaw
- Various: https://personaldata.ge/en

Human Biological Materials

Key Organizations

- Bioethics and Health Law Studies Society

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

EUROPE – Germany

General

Key Organizations

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

Relevant Standards

- BÄK, (Model) Professional Code for Physicians in Germany, Article 15 (2018): https://www.bundesaerztekammer.de/professionalcodephysicians
- DFG, Guidelines for Safeguarding Good Research Practice (2022): https://zenodo.org/records/6472827

Drugs, Biologics, and Devices

Key Organizations

- Federal Institute for Drugs and Medical Devices (BfArM): https://www.bfarm.de/EN/Home/_node.html
- Paul-Ehrlich-Institut (PEI): https://www.pei.de/EN/home/home-node.html
- Federal Ministry of Health (BMG): https://www.bundesgesundheitsministerium.de/en/index.html
- German Research Foundation (DFG), Permanent Senate Commission on Key Questions in Clinical Research (SCCR): https://www.dfg.de/

Relevant Standards

- 2021 German version: Medicinal Products Act, Division 6 (2021): http://www.gesetze-im-internet.de/amg_1976/
- 2020 English version: Medicinal Products Act, Division 6 (2020): https://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p1005
- Promulgation on the Principles of the Conduct of Clinical Trials of Drugs According to the Rules (1987)
- Second Promulgation on the Clinical Trial of Drugs in Human (1997)
- Medical Device Law Implementation Act, Division 4 (2021): https://www.gesetze-im-internet.de/mpdg/
- DFG, Various Recommendations and Statements of the Senate Commission on Key Questions in Clinical Research: https://www.dfg.de/en/dfg-profile/statutory-bodies/senate/clinical-research/statements

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

Research Injury

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Federal Data Protection Act (BDSG) (2019): https://www.gesetze-im-internet.de/englisch_bdsg/index.html
- Data Protection Laws in German States: http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html

- DSK, Short Paper No. 4: Data Transmission to Third Countries: https://www.datenschutzkonferenz-online.de/media/kp/dsk_kpnr_4.pdf
- Act on the Improved Use of Health Data (2024): https://www.bundesgesundheitsministerium.de/improveduseofhealthdataact

Human Biological Materials

Key Organizations

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

Relevant Standards

- German Ethics Council, Act of Quality and Security of Human Tissue and Cells (2019): https://www.buzer.de/actqualitysecurityhumantissueandcells
- German Ethics Council, Transfusion Law (2020): http://www.gesetze-im-internet.de/tfg/
- German Ethics Council, Transplantation Law (2021): http://www.gesetze-im-internet.de/tpg/
- German Ethics Council, Opinion on Human Biobanks for Research (2010): https://www.ethikrat.org/opinionhumanbiobanksresearch
- ZEKO, Opinion on the (Re)Use of Human Body Material for Medical Research Purposes (2003): https://www.zentrale-ethikkommission.de/stellungnahmen/die-weiter-verwendung-von-menschlichen-koerpermaterialien-fuer-zwecke-medizinischer-forschung
- DGCH, Guidelines on Good Professional Practice (GPP) for the Procurement of Human Tissue and Cells for Drug Production: http://www.dgch.de/GPP

Genetic Research

Key Organizations

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

Relevant Standards

- Embryo Protection Act (2011): http://www.gesetze-im-internet.de/eschg/
- Genetic Engineering Act (2021): http://www.gesetze-im-internet.de/gentg/
- DFG, Various Recommendations and Statements of the Senate Commission on Key Questions in Clinical Research: https://www.dfg.de/en/dfg-profile/statutory-bodies/senate/clinical-research/statements

Embryos, Stem Cells, and Cloning

Key Organizations

- Federal Ministry of Education and Research (BMBF): https://www.bmbf.de/
- German Ethics Council: https://www.ethikrat.org/en/

- Central Ethics Committee of the German Medical Association (ZEKO): http://www.zentrale-ethikkommission.de/
- German Research Foundation (DFG): http://www.dfg.de/en/
- Central Ethics Committee for Stem Cell Research (ZES): http://www.rki.de/Committees/StemCell

Relevant Standards

- BMBF, Embryo Protection Act (2011): http://www.gesetze-im-internet.de/eschg/
- BMBF, Stem Cell Act (2017): http://www.gesetze-im-internet.de/stzg/
- BMBF, Regulation on the Central Ethics Committee for Stem Cell Research and the Competent Authority Pursuant to the Stem Cell Act (2017): http://www.gesetze-im-internet.de/zesv/
- German Ethics Council, The Import of Human Embryonic Stem Cells (2001): https://www.ethikrat.org/Stellungnahme_Stammzellimport.pdf
- German Ethics Council, Cloning for Reproductive Purposes and Cloning for the Purposes of Biomedical Research (2004): https://www.ethikrat.org/Stellungnahme_Klonen.pdf
- German Ethics Council, Should the Stem Cell Law be Amended? (2007): https://www.ethikrat.org/Stn_Stammzellgesetz.pdf
- German Ethics Council, Human-Animal Mixtures in Research (2011): https://www.ethikrat.org/opinion-human-animal-mixtures-in-research.pdf
- German Ethics Council, Stem Cell Research - New Challenges for the Ban on Cloning and Treatment of Artificially Created Germ Cells? (2014): https://www.ethikrat.org/recommendation-stem-cell-research.pdf
- German Ethics Council, Germline Intervention in the Human Embryo (2017): https://www.ethikrat.org/recommendation-germline-intervention-in-the-human-embryo.pdf
- German Ethics Council, Intervening in the Human Germline (2019): https://www.ethikrat.org/opinion-intervening-in-the-human-germline-summary.pdf
- ZEKO, Opinion on Stem Cell Research (2002): https://www.zentrale-ethikkommission.de/stellungnahmen/stellungnahme-der-zentralen-ethikkommission-zur-stammzellforschung
- DFG, Various Recommendations and Statements of the Senate Commission on Key Questions in Clinical Research: https://www.dfg.de/en/dfg-profile/statutory-bodies/senate/clinical-research/statements

EUROPE – Greece

General

Key Organizations

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

Relevant Standards

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

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Act 3418/2005 Code on Medical Ethics
- Ministerial Decision ΔΥΓ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC
- Ministerial Decision ΔΥΓ 3 α/79602/2007 Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2005/28/EC

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Greek Constitution 1975/1986/2001 Article 9.1
- Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998)
- Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by Laws 2819/2000 and 2915/2000)
- Act 3418/2005 Code on Medical Ethics
- General Data Protection Regulation (2016): https://www.lawspot.gr/nomikes-plirofories/nomothesia/genikos-kanonismos-gia-tin-prostasia-dedomenon?lspt_context=gdpr

Human Biological Materials

Relevant Standards

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

Genetic Research

Key Organizations

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

Relevant Standards

- Greek Constitution 1975/1986/2001, Article 5.5
- Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998)
- Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by Laws 2819/2000 and 2915/2000)
- Act 3418/2005 Code on Medical Ethics
- Recommendation on Banks of Biological Material of Human Origin (Biobanks) in Biomedical Research: https://bioethics.gr/biobanks
- Opinion on Prenatal and Pre-Implantation Diagnosis and Embryo Treatment: https://bioethics.gr/prenatalandpreimplantationdiagnosisandembryotreatment
- Opinion on Direct-To-Consumer Genetic Testing (2012): https://archive.bioethics.gr/directtoconsumergenetictesting
- Opinion on Incidental Findings in Research and Clinical Practice (2015): https://archive.bioethics.gr/opinionincidentalfindingsinresearchandclinicalpractice
- Opinion on Advances in Human Genome Editing (2016): https://bioethics.gr/opinionadvancesinhumangenomeediting

Embryos, Stem Cells, and Cloning

Key Organizations

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

- National Authority for Medically Assisted Reproduction

Relevant Standards

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

EUROPE – Hungary

General

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Fundamental Law of Hungary, Updated with the Fifth Amendment (2016), Articles II-III: http://njt.hu/cgi_bin/njt_doc.cgi?docid=140968.322953
- Act CLIV of 1997 on Health Care, Chapters VIII and IX: http://njt.hu/cgi_bin/njt_doc.cgi?docid=30903.339193
- Act VI. of 2002 on the Promulgation of the Oviedo Convention on Human Rights and Biomedicine: http://njt.hu/cgi_bin/njt_doc.cgi?docid=64201.264663
- Act LXXXI of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research
- Act C of 2012 on the Criminal Code, Chapter XVI Medical Procedures and Criminal Offenses Against the Order of Research, Sections 168-175
- Decree 23/2002 (V. 9.) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/decree23/2002
- Decree 35/2005 (VIII.26.) of the Minister of Health on the Clinical Trials of Investigational Medicinal Products for Human Use and on the Application of Good Clinical Practice: http://net.jogtar.hu/decree35/2005
- Decree No. 235/2009 (X.20.) from the Hungarian Government on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products, and for the Clinical Studies of the Medical Devices: http://net.jogtar.hu/decree235/2009
- 1997 CLIV. Law, Healthcare, Chapters VIII and IX

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

Clinical Trials:

- Act XCV of 2005 on Medicinal Products for Human Use, Section 3: https://net.jogtar.hu/actXCV/2005
- Decree 35/2005 (VIII. 26) of the Minister of Health on the Clinical Trial and Application of Correct Clinical Practices of Investigational Medicinal Products Intended for Use in Humans: http://net.jogtar.hu/decree35/2005
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (it will come in application on 31 January 2022): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536&qid=1722524150296

Non-Interventional Trials:

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

Devices

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

Clinical Trials:

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

Non-Interventional Trials:

- Decree 23/2002. (V. 9.) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/decree23/2002
- Government Decree 235/2009. (X.20.) on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products and for the Clinical Studies of the Medical Devices: http://net.jogtar.hu/decree235/2009
- Government Decree 27/2015 (II.25.) About the National Health Care Service System: http://njt.hu/decree27/2015

Research Injury

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Act XLVII of 1997 on the Handling of Medical and Other Related Data: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700047.TV&celpara=#xcelparam
- Act CXII of 2011 on Right of Informational Self-Determination and Freedom of Information: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A1100112.TV&celpara=#xcelparam
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Various Publications: https://naih.hu/kiadvanyok-publikaciok

Genetic Research

Key Organizations

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Act LXXX of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Transplantation of Organs and Tissues of Human Origin: http://net.jogtar.hu/actlxxx/2006
- Decree 18/1998 (XII 27) EüM on Implementing Act CLIV of 1997 on Health Care as Regards Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations: http://net.jogtar.hu/decree18/1998

EUROPE – Iceland

General

Key Organizations

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

Relevant Standards

- Act on Scientific Research in the Health Sector No. 44/2014: https://www.government.is/scientificresearchact
- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Regulation on the Structure of Research Projects in the Health Sector, Including Research Protocol, Internal Monitoring, and the Responsibilities of the Principal Investigator No. 520/2018: https://www.reglugerd.is/regulation520
- NBC, Vulnerable Groups Including Children: https://vsn.is/vidmid/vidkvaemir-hopar/
- NBC, Various Laws and Conventions: https://vsn.is/vidmid/

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

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

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

Devices

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

Research Injury

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Act No. 90/2018 on Data Protection and the Processing of Personal Data: https://www.althingi.is/altext/148/s/1296.html

Human Biological Materials

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Biobanks Act No. 110/2000 (2015): https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Biobanks-Act-as-amended-2015.pdf
- Regulations on the Keeping and Utilization of Biological Samples in Biobanks No. 1146/2010: https://www.reglugerd.is/reglugerdir/eftir-raduneytum/heilbrigdisraduneyti/nr/16910

Embryos, Stem Cells, and Cloning

Relevant Standards

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

EUROPE – Ireland

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Data Protection Act 2018: https://www.oireachtas.ie/en/bills/bill/2018/10/
- Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018: http://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/health-research-regulations-2018/
- DPC, For Organizations: http://gdprandyou.ie/organisations/
- DPC, International Transfers: https://www.dataprotection.ie/en/organisations/international-transfers/one-stop-shop-oss
- HRB, Health Research Regulations 2018 FAQ: http://www.hrb.ie/funding/gdpr-guidance-for-researchers/general-gdpr-faq/

Human Biological Materials

Key Organizations

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

Relevant Standards

- Human Biological Material: Recommendations for Collection, Use, and Storage in Research (2005): https://www.lenus.ie/handle/10147/622868

Genetic Research

Key Organizations

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

Relevant Standards

- Irish Medicines Board, Guidelines for Pharmacogenetic Research (2006): https://www.lenus.ie/pharmacogeneticresearchguidelines

EUROPE – Italy

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

- AIFA, Various Legislations, Trials: https://www.aifa.gov.it/en/normativa-di-riferimento-sperimentazione
- AIFA, National Coordination Centre of Local Ethics Committees for Clinical Trials Concerning Medicinal Products for Human Use and Medical Devices (CCNCE), Various Forms, Circulars, Regulations, and Related Documents: https://www.aifa.gov.it/centro-coordinamento-comitati-etici
- AIFA, Ethics Committee for Clinical Trials in the Pediatric Field, Various Forms, Circulars, Regulations, and Related Documents: https://www.aifa.gov.it/en/comitato-etico-per-le-sperimentazioni-cliniche-in-ambito-pediatrico
- AIFA, National Ethics Committee for Clinical Trials Relating to Advanced Therapies ("ATMP"): https://www.aifa.gov.it/en/comitato-etico-per-le-sperimentazioni-cliniche-relative-alle-terapie-avanzate-atmp-
- AIFA, Register of Observational Studies: https://www.aifa.gov.it/registro-studi-osservazionali
- AIFA/OsSc, Various Tutorials, Guides, and Manuals: https://www.aifa.gov.it/en/osservatorio-nazionale-sperimentazione-clinica
- MOH, Various Regulations (filter by year and topic on left columns): https://www.salute.gov.it/regulations
- Legislative Decree No. 211: Transposition of Directive 2001/20/EC Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Clinical Use (2003)
- Legislative Decree No. 200: Transposition of Directive 2005/28 EC Laying down Principles and Detailed Guidelines as Regards Investigational Medical Products for Human Use, as Well as the Requirements for Authorizing of Manufacturing or Importing of such Products (2007)

- Ministerial Decree of 21 December 2007: Directions for Submitting the Request for Authorization of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authority, for Communicating Substantial Amendments, for Declaring the End of the Trial and for the Request of an Opinion to the Ethics Committee
- Ministerial Decree of 31 March 2008: Definition of the Minimum Requirements that Contract Research Organisations (CROs) Shall Satisfy in Order to Work within Clinical Trials on Medicinal ProductsDevices
- Ministerial Decree 2 of August 2005: Procedures for the Presentation of Documentation to Notify about Clinical Investigations with Medical Devices
- Administrative Procedures Concerning the Conduction of Clinical Investigations with CE-Marked Medical Devices (2007)

Research Injury

Key Organizations

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

Relevant Standards

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

Social-Behavioral Research

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Italian Personal Data Protection Code, Legislative Decree No. 196 of June 30, 2003: https://www.gestaltitaly.com/contents/privacy_note.pdf
- Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000)
- Regulation for the Implementation of Articles No. 20 and 21 of the Legislative Decree No. 196 of June 30, 2003

- Ministerial Decree No. 277 (2007)
- General Principles of Processing Personal Data (2018): https://www.garanteprivacy.it/
- CCNE, Ethical and Regulatory Issues in the Processing of Personal Health Data in Observational Research (2023): https://www.aifa.gov.it/personalhealthdataprocessingethics

Genetic Research

Key Organizations

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

Relevant Standards

- ISS, Guidelines for Phase I Clinical Trials with Investigational Medicinal Products Employed in Gene Somatic Therapy (2004)
- SIGU, Various Guidelines, Recommendations, and Documents of Interest: https://sigu.net/guidelines

Embryos, Stem Cells, and Cloning

Relevant Standards

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

EUROPE – Latvia

General

Key Organizations

- Central Medical Ethics Committee

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

- Law on Pharmacy, Section 26 (2013): https://likumi.lv/ta/en/en/id/43127-pharmaceutical-law
- Cabinet Regulation No. 289: Regulations Regarding the Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal Products, Labelling of Investigational Medicinal Products and the Procedures for Assessment of Conformity of Clinical Trial of Medicinal Products with the Requirements of Good Clinical Practice: https://likumi.lv/regulationno.289

Devices

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

Research Injury

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Drugs: Cabinet Regulation No. 289: Regulations Regarding the Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal Products, Labelling of Investigational Medicinal Products and the Procedures for Assessment of Conformity of Clinical Trial of Medicinal Products with the Requirements of Good Clinical Practice, Sections 22, 31.6, 54.10, 55.9, and 61.14 (2010): https://likumi.lv/regulationno.289
- Devices: Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for Human Use, Sections 42.7 and 62.5 (2010): https://likumi.lv/ta/en/en/id/218764-procedures-for-the-clinical-trial-of-medical-devices-intended-for-human-use

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Personal Data Processing Law (2014): https://likumi.lv/personal-data-processing-law
- Law on the Rights of Patients, Section 10 (2013): https://likumi.lv/law-on-the-rights-of-patients
- Cabinet Regulation No. 446: Procedures for Using Patient Data in a Specific Research Study (2015): https://likumi.lv/ta/en/en/id/275747-procedures-for-using-the-patient-data-in-a-specific-research

Human Biological Materials

Key Organizations

- Central Medical Ethics Committee

Relevant Standards

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

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

Genetic Research

Key Organizations

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

Relevant Standards

- Human Genome Research Law (2005): https://likumi.lv/humangenomeresearchlaw
- Law on the Development and Use of the National DNA Database (2006): https://likumi.lv/nationalDNAdatabaselaw
- Regulation of the Cabinet of Ministers: "Procedures for Genetic Research" (2004): http://likumi.lv/geneticresearchprocedures

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

EUROPE – Lithuania

General

Key Organizations

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

Relevant Standards

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

- Changes of Law on Ethics of Biomedical Research No. 536/2014 (2017): https://www.e-tar.lt/ethicsofbiomedicalresearch
- V-405, Decree on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage, and Providing Information on Biomedical Research (2010): https://e-seimas.lrs.lt/V-405
- Government of the Republic of Lithuania: Decree No. 1458 on State Fees (2017): https://www.e-tar.lt/no.1458
- V-15, Decree on the Procedure for Calculating and Paying Compensation for the Expenses Incurred Due to Participation in Biomedical Research and the Time Spent (2018): https://www.e-tar.lt/V-15
- V-28, Decree on the Detailed Requirements for the Content of a Person's Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent (2018): https://www.e-tar.lt/V-28
- V-1483, Decree on the List of Interventional Methods of Biomedical Research Causing a Slightly Detrimental and Temporary Impact on the Subject's Health (2018): https://e-seimas.lrs.lt/V-1483
- V-235/A1-83, Decree on the Procedure for a Minor's Participation in Biomedical Research (2018): https://www.e-tar.lt/V-235
- V-28, Decree on the Procedure to Conduct Biomedical Research on Medical Documents, No. V-28 (2011): https://www.e-tar.lt/V-28
- V-7, Decree on the Sample Form of the Biomedical Research Protocol, Summary of the Protocol and the CV of Investigator (2017): https://www.e-tar.lt/V-7
- V-24, Decree on the Procedure for Submission of the Documents to the Lithuanian Bioethics Committee to Issue Favorable Opinion to Conduct a Clinical Trial on Medicinal Products or Approval to Conduct Biomedical Research by the Sponsor of the Clinical Trial on Medicinal Product or Other Type of Biomedical Research (2016): https://www.e-tar.lt/V-24
- V-4, Decree on the Request to Issue Approval to Conduct Biomedical Research, the Application Form and the Biomedical Research Ethical Assessment Form (2016): https://www.e-tar.lt/V-4
- Updated Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical Research of the LBEC (2023): https://bioetika.lrv.lt/guidelinesinformedconsent

Drugs, Biologics, and Devices

Key Organizations

- State Medicines Control Agency (SMCA): https://www.vvkt.lt/SMCA
- Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/LBEC
- Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG
- State Health Care Accreditation Agency Under the Ministry of Health (SHCA): http://www.vaspvt.gov.lt/en

Relevant Standards

Drugs

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

- Decree No. 320 on the Rules of Good Clinical Practice (2006): https://www.e-tar.lt/decree320
- Corrections of GCP Terminology in Lithuanian (2006): https://www.e-tar.lt/GCPterminology
- Decree No. V-6 on the Sample Form of the Request to Issue Favorable Opinion to Conduct Clinical Trial on Medicinal Product Form and the Ethical Assessment Form (2016): https://www.e-tar.lt/decreeV-6
- Decree No. 435 on the Procedure for Issuing a Favorable Opinion to Conduct Clinical Trials on Medicinal Product, Approval for Clinical Trials on Medicinal Product, and Conducting and Controlling Clinical Trials (2017): https://e-seimas.lrs.lt/decree435

Devices

- Decree No. V-2 on the Procedure to Issue Approvals to Conduct Biomedical Research (2017): https://www.e-tar.lt/decreeV-2
- Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/biomedicalresearchethicslaw
- Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/ethicsofbiomedicalresearch
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: https://eur-lex.europa.eu/no.745
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials on Medicinal Products for Human Use (Effective 31 January 2022): https://eur-lex.europa.eu/no.536
- LBEC, Issuance of Permits for Clinical Trials with a Medical Device: https://bioetika.lrv.lt/permitsclinicaltrialsmedicaldevice

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

Research Injury

Relevant Standards

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

Social-Behavioral Research

Key Organizations

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

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Law of the Republic of Lithuania on the Legal Protection of Personal Data: https://www.e-tar.lt/personaldataprotection

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Relevant Standards

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

Genetic Research

Key Organizations

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

Relevant Standards

- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002): https://www.coe.int/humanrightsdignitybiologyandmedicine
- Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/ethicsbiomedicalresearchlaw
- Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/ethicsbiomedicalresearch
- Decree No. V-660 on the Procedure to Issue Authorization for the Transit of Tissues of Human Embryonic Tissue, Embryonic Stem Cells and their Lines, Fetal Tissue, and Fetal Stem Cells throughout the Territory of the Republic of Lithuania (2007): https://www.e-tar.lt/decreeV-660
- Decree No. V-659 on the Procedure for Importing of the Stem Cells Taken from the Umbilical Cord or Placenta after the Birth of a Child and the Samples Taken for Genetic Research into the Territory of the Republic of Lithuania and Exporting Therefrom (2017): https://www.e-tar.lt/decreeV-659

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Approval of Samples of Stem Cells Extracted from the Umbilical Cord or Placenta After the Birth of a Child for the Purpose of Biomedical Research: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.302907

EUROPE – Luxembourg

General

Key Organizations

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

Relevant Standards

- National Ethics Commission, Opinion, Various Notices, Reviews, and Opinions: http://www.cne.public.lu/fr/publications/avis.html
- Regulation of the Government in Council of November 28, 2014 establishing an independent National Consultative Ethics Commission […]: http://www.cne.public.lu/fr/commission/statut.html
- CNER, Various Statutes and Legislations, International Framework and Luxembourg Legal Framework: https://cner.gouvernement.lu/en/statuts-legislation.html
- CNER, Various Guidance and Activity Reports: https://cner.gouvernement.lu/en/publications.html

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Relevant Standards

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

Genetic Research

Key Organizations

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

Relevant Standards

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

EUROPE – Malta

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

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

Devices

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

EUROPE – Moldova, Republic of

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

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Law No. 1409 Dated 17.12.1997 on Medicines, Articles 11 and 12: http://lex.justice.md/no.1409
- Law No. 263 Dated 27.10.2005 on Patients' Rights and Responsibilities. Articles 9, 10, 11, 12, 13, and 14: https://cis-legislation.com/document.fwx?rgn=11939
- Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Examination of Clinical Trial: https://cis-legislation.com/document.fwx?rgn=89422

Research Injury

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- Convention No. 108 for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981): https://www.coe.int/en/web/data-protection/moldova
- Decision of Parliament No. 483-XIV Dated 02.07.1999 on Ratification of Convention No. 108
- Law No. 982 Dated 11.05.2000 on Access to Information: http://lex.justice.md/no.982
- Law No.133 Dated 08.07.2011 on the Protection of Personal Data: https://cis-legislation.com/document.fwx?rgn=51097
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- LP143 Din 19.07.18, MO309-320/17.08.18 Article 482
- Decision of Government No. 1123 Dated 14.12.2010 on the Approval of the Requirements for the Assurance of Personal Data Security at their Processing within the Information Systems of Personal Data: http://old.datepersonale.md/no.1123
- Law on personal data protection (2011); The Law on enunciation of certain declarations to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data by the Republic of Moldova: https://datepersonale.md/en/legislation/national-legislation/law/

Human Biological Materials

Key Organizations

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

Relevant Standards

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

Genetic Research

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- REGULATION No. 902 of 09.02.2000 on the manner of issuing licenses for conducting research in the field of genetics and microbiology in the Republic of Moldova: http://www.vertic.org/regulation902

EUROPE – Montenegro

General

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards

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

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Relevant Standards

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

Genetic Research

Key Organizations

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Relevant Standards

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

EUROPE – Netherlands

General

Key Organizations

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

Relevant Standards

- Population Screening Act (1996): https://wetten.overheid.nl/BWBR0005699/2021-07-01

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- VWS, Medicines Act (2007): http://wetten.overheid.nl/medicinesact
- VWS, Medicines Act Decree (2007): https://wetten.overheid.nl/medicinesactdecree
- VWS, Medicines Act Regulation (2007): http://wetten.overheid.nl/medicinesactregulation
- CCMO, Clinical Trials with Medicinal Products (CTR), Various Standards and Relevant Information: https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr
- CCMO, Clinical Trials with Medical Devices (MDR), Various Standards and Relevant Information: https://english.ccmo.nl/investigators/clinical-investigations-with-medical-devices
- CCMO Memorandum, Definition of Medical Research: https://english.ccmo.nl/investigators/publications/publications/2005/11/25/ccmo-memorandum-definition-of-medical-research

Clinical Trial Registries

Key Organizations

- Netherlands Trial Register: https://www.onderzoekmetmensen.nl/en
- CCMO Register: https://www.toetsingonline.nl/to/ccmo_search.nsf/Searchform?OpenForm

Research Injury

Key Organizations

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

Relevant Standards

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

Social-Behavioral Research

Key Organizations

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

Relevant Standards

- Netherlands Code of Conduct for Research (2018): https://www.nwo.nl/researchcodeofconduct
- CCMO, Memorandum Behavioural Research: https://english.ccmo.nl/investigators/publications/publications/2002/01/01/ccmo-memorandum-behavioural-research

Privacy/Data Protection

Key Organizations

- Dutch Data Protection Authority: https://cbpweb.nl/en

Relevant Standards

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

Human Biological Materials

Relevant Standards

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

Genetic Research

Key Organizations

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Relevant Standards

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

EUROPE – North Macedonia, Republic of

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Research Injury

Relevant Standards

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

Social-Behavioral Research

Key Organizations

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- Law on Ratification on Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2005)
- Law on Ratification on Additional Protocol to the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2008)

- Law on Personal Data Protection, Consolidated (2016): https://www.dzlp.mk/personaldatalaw and amendments (2021): https://www.dzlp.mk/amendments
- Regulations on Protection of Personal Data: https://dzlp.mk/personaldataregulation
- Rule book for the Manner of Performing Inspection Supervision: https://www.dzlp.mk/inspectionsupervision
- Rulebook on transfer of personal data: https://dzlp.mk/sites/default/files/052e8e10cf2e4bd48e7827e7bc85fb62.pdf

Human Biological Materials

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Law on Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, With Additional Protocol on the Prohibition of Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (2009): https://www.coe.int/humanrightsdignitybiologyandmedicine
- Health Care Law (Official Gazette No. 43/2012) and Laws Amending and Supplementing the Law (2012-2016): https://zdravstvo.gov.mk/zakon-za-zdravstvenata-zashtita/
- Law on Taking and Transplanting of the Human Body for Treatment (Official Gazette No. 47/2011) and Laws Amending and Supplementing the Law (2011-2016): https://zdravstvo.gov.mk/no.47
- Regulation on Criteria Relating to Space, Personnel and Equipment for Collection, Transplantation and Exchange of Organs and Tissues, the Necessary Space, Equipment and Staff Required to be Provided by the Health Institution for the Collection, Transfer, Exchange and Storage of Organs and Tissues from Human Body for Treatment Purposes (2012): http://zdravstvo.gov.mk/regulationorgansandtissues

Genetic Research

Key Organizations

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

Relevant Standards

- Law on Patient Rights Protections, Article 21: Action on Human Genome (2012): http://zdravstvo.gov.mk/article21

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

EUROPE – Norway

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

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

Devices

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

Research Injury

Key Organizations

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

Relevant Standards

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

Social-Behavioral Research

Key Organizations

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

Relevant Standards

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

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

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

Genetic Research

Key Organizations

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

Relevant Standards

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

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

EUROPE – Poland

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Relevant Standards

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

Genetic Research

Key Organizations

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

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

Relevant Standards

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

EUROPE – Portugal

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

Research Injury

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Relevant Standards

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

Genetic Research

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Portuguese Law on Assisted Reproductive Technologies, Articles 7 and 9 (2006)
- Opinion 15/CNECV/95 on Embryo Research (1995)
- Opinion 47/CNECV/2005 on Stem Cell Research (2005)

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

EUROPE – Romania

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Order 904/25July 2006 on Approval of Rules Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use – Transposition of 2001/20/EC Directive, and various legislation for CTs
- Clinical Trials, Legislation, Various: https://www.anm.ro/studii-clinice/legislatie/
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use (2014): https://eur-lex.europa.eu/no.536

Clinical Trial Registries

Key Organizations

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

Research Injury

Relevant Standards

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

Social-Behavioral Research

Key Organizations

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

Privacy/Data Protection

Key Organizations

- National Supervisory Authority for Personal Data Processing: https://www.dataprotection.ro/

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Law No. 667/2001 On the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data: https://legislatie.just.ro/Public/DetaliiDocumentAfis/32733

Human Biological Materials

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Law No. 95/2006 Regarding the Reform in Health Field. Title VI. Performing of Sampling and Transplant of Organs, Tissues and Human Origin Cells with Therapeutic Purpose: http://legislatie.just.ro/Public/DetaliiDocument/71139
- ORDER no. 1,527 of December 16, 2014, On the Methodological Norms for the Application of Title VI "Carrying out the Collection and Transplantation of Organs, Tissues and Cells of Human Origin for Therapeutic Purposes": http://legislatie.just.ro/Public/DetaliiDocument/164199
- ORDER no. 855 of July 26, 2017, For the Approval of Therapeutic Protocols for the Removal of Organs, Tissues and Cells of Human Origin from Living and/or Deceased Donors: http://legislatie.just.ro/Public/DetaliiDocument/192507
- Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on Standards of Quality and Safety of Human Organs Intended for Transplantation: https://eur-lex.europa.eu/directive53

Genetic Research

Key Organizations

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

Relevant Standards

- ORDER no. 1.358 of November 13, 2014 on the establishment of the medical genetics network: http://legislatie.just.ro/Public/DetaliiDocument/163135

Embryos, Stem Cells, and Cloning

Relevant Standards

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

EUROPE – Russia

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

General

Key Organizations

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

Relevant Standards

- Constitution of the Russian Federation, Article 21 (1993): http://www.constitution.ru/article21
- Federal Law #FZ 323 "On Foundations of Protection of Citizen's Health in the Russian Federation" (2011): http://acto-russia.org/en/index.php?option=com_content&task=view&id=105
- Federal Law #FZ55 "On Introduction of Changes in FZ "On Foundations of Protection of Citizens' Health in the Russian Federation" with Regard to Questions of Organization of Medical Aid Administered in the Course of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation" (2015): http://www.consultant.ru/document/cons_doc_LAW_176159
- Ministry of Health Order 433n (July 10, 2015) "On Adoption of the Regulations on Organization of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation (Including Order of Patients' Assignment for Administering Such Medical Help), Standard Form of Protocol for Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment, and Rehabilitation": http://base.consultant.ru/order433n
- Ministry of Health Order 435h "On Ethics Committee of the Ministry of Health of the Russian Federation" (July 10, 2015): http://base.consultant.ru/order435h

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Healthcare of the Russian Federation (MOH): http://www.rosminzdrav.ru
- Association of Clinical Trials Organizations: http://acto-russia.org/en/
- Federal Agency for Technical Regulation and Metrology (Rosstandart): http://government.ru/en/department/56/

Relevant Standards

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

- Ministry of Health Order on Procedure for Suspension of Use of Medicine for Medical Application, No. 758n (2010): https://cis-legislation.com/no758n
- MOH, "On Assertion of Order of Organization and Carrying out of Ethical Review…" (Russian): http://base.garant.ru/12178437/
- Ministry of Health Order No. 774n (August 31, 2010) "On Council of Ethics" (Russian): http://www.rg.ru/2013/02/22/etika-dok.html
- Ministry of Health Order of April 1, 2016, No. 200н "On Approval of the Rules of Good Clinical Practice": http://acto-russia.org/files/prikaz_200n.docx
- GOST, Good Clinical Practice. GOST-R 52379-2005 (September 27, 2005): http://acto-russia.org/index.php?option=com_content&task=view&id=17
- Government Decree No. 673 of September 3, 2010 "Approval of Rules for Import and Export of Biological Materials Obtained in Clinical Trials of a Medicinal Product for Medical Use Into and From the Russian Federation": http://acto-russia.org/decree673

Research Injury

Relevant Standards

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

Privacy/Data Protection

Relevant Standards

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

Genetic Research

Key Organizations

- Interdepartmental Commission on Genetic-Engineering Activity

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Relevant Standards

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

EUROPE – San Marino

General

Key Organizations

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

Relevant Standards

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

Research Injury

Relevant Standards

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

Human Biological Materials

Relevant Standards

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

EUROPE – Serbia

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

- Rulebook on the Contents of the Application, and/or Documentation on the Approval of Clinical Trials for Medicines and Medical Devices, as well as the Method of Implementation for Clinical Trials of Medicines and Medical Devices, Official Gazette of RS, 64/2011, 91/2013, 60/2016, and 9/2018: https://www.alims.gov.rs/english/wp-content/uploads/2022/01/7-Rules-on-clinical-trials.pdf

Clinical Trial Registries

Key Organizations

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

Research Injury

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Law on Medicines and Medical Devices, Article 72: https://www.alims.gov.rs/Law-on-Medicines-and-Medical-Devices-2010.pdf
- Law on Patients' Rights, Article 25 Official Gazette of RS, 45/2013 and 25/2019: https://www.paragraf.rs/propisi/zakon_o_pravima_pacijenata.html

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Genetic Research

Relevant Standards

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

Human Biological Materials

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Relevant Standards

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

EUROPE – Slovak Republic

General

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Additional Protocol on Biomedical Research (2005)
- Act No. 576/2004 Coll on Health Care, As Amended by Acts No. 350/2005, 282/2006, 662/2007, 345/2009 Coll.

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Research Injury

Relevant Standards

- Law 277/1994 on Health Care, Section 44Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Act No. 576/2004 Coll. on Health Care, Sections 35-39, and 26.10.a.
- Act No. 489/2008 Coll. on Drugs and Medical Devices, Section 18 (29b).
- Governmental Regulation No. 20/2007 Coll. on Tissue and Cell Collection

Embryos, Stem Cells, and Cloning

Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Act No. 576/2004 Coll. on Health Care, Sections 35-39, and 26.10.a
- Act No. 489/2008 Coll. on Drugs and Medical Devices, Section 18 (29b)
- Governmental Regulation No. 20/2007 Coll. on Tissue and Cell Collection

EUROPE – Slovenia

General

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Health Services Act: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO214
- Decree Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research (2005): http://pisrs.si/Pis.web/pregledPredpisa?id=URED3728
- Patient Rights Act, Official Gazette No. 15/2008 55/2017: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO4281 and https://www.uradni-list.si/glasilo-uradni-list-rs/vsebina/2017-01-2526?sop=2017-01-2526
- Mental Health Act, Official Gazette Nos. 77/2008 and 46/2015: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO2157

- Code of Medical Ethics (2016): https://www.zdravniskazbornica.si/codemedicalethics

Drugs, Biologics, and Devices

Key Organizations

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/NMEC
- Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP): https://www.jazmp.si/en/

Relevant Standards

- Ministry of Health, Various Legislation (scroll down to "Medicines and medical devices"): https://www.gov.si/drzavni-organi/ministrstva/ministrstvo-za-zdravje/zakonodaja/
- Rules on Clinical Testing of Medicinal Products, Official Gazette, No. 54/2006 and 17/2014: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV6611
- Rules on Medical Devices, Official Gazette Nos. 37/2010 and 66/2012: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV9508
- JAZMP, General Information about Medical Devices, Various Legislation: https://www.jazmp.si/en/medical-devices/general-information-on-medical-devices/legislation/

Research Injury

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Decree ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research: http://pisrs.si/Pis.web/pregledPredpisa?id=URED3728
- Rules on Clinical Testing of Medicinal Products, Official Gazette, No. 54/2006 and 17/2014: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV6611
- Rules on Medical Devices, Official Gazette Nos. 37/2010 and 66/2012: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV9508

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

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

Genetic Research

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Infertility Treatment and Procedures of Biomedically-Assisted Procreation Act, Official Gazette No. 70/2000, Section 9 (Slovenian): http://www.uradni-list.si/1/objava.jsp?sop=2000-01-3307

EUROPE – Spain

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

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Law 14/2007 on Biomedical Research, Article 18: https://www.isciii.es/biomedicalresearch
- Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536&qid=1722524150296
- Royal Decree 1090/2015 Regulating Clinical Trials with Medicinal Products, Ethics Committees for Investigation with Medicinal Products and the Spanish Clinical Studies Registry: https://www.aemps.gob.es/decree1090

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Law 14/2007 on Biomedical Research, Title I, Article 5: https://www.isciii.es/biomedicalresearch
- Organic Law 3/2018 of December 5 on the Protection of Personal Data and Guaranteeing Digital Rights: https://www.boe.es/law3
- Royal Decree 1720/2007 Approving Organic Law 15/1999 for the Protection of Personal Data (2008): https://www.boe.es/buscar/pdf/2008/BOE-A-2008-979-consolidado.pdf
- AEMPS, Revised Instructions for Updating the Section "Protection of Personal Data in the Subject Information Sheet (HIP /CI) Regarding the Regulation (EU) No. 2016/679 General Data Protection (2018): https://www.aemps.gob.es/AEMPSdataprotection

Human Biological Materials

Key Organizations

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

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: https://www.isciii.es/biomedicalresearch
- Royal Decree 1716/2011 on Biobanks: https://www.boe.es/decree1716
- Royal Decree 9/2014 on Quality and Security Rules Regarding Donating, Gathering, Evaluation, Processing, Storage, Preservation, and Distribution of Human Cells and Tissues and Rules Regarding Coordination and Functioning of their Use in Human Beings: http://www.boe.es/decree9

Genetic Research

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168
- Law 14/2006 on Methods of Assisted Human Reproduction, Chapters IV and V
- Law 14/2007 of July 3 on Biomedical Research, Title III: https://www.isciii.es/LawonBiomedicalResearch
- Royal Decree 1527/2010 By Which the Guarantees Commission for the Donation and Use of Human Cells and Tissues and Registration Research Projects is Regulated: http://www.boe.es/decree1527

EUROPE – Sweden

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

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

Drugs

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

Devices

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

Social-Behavioral Research

Key Organizations

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

Relevant Standards

- Good Research Practice: Observational Studies Conducted Through Participating, Observing, and Recording (2017) (currently being updated. New report expected in 2024): https://www.vr.se/goodresearchpractice
- Research Review 2023, Humanities and social sciences: https://www.vr.se/humanities-and-social-sciences

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Patient Data Act (2008:355): https://www.riksdagen.se/act355
- Publicity and Privacy Act (2009:400): https://www.riksdagen.se/act400
- Act on Certain Health Research Registers (2013:794): https://www.riksdagen.se/act794
- Act Complement to the GDPR (2018:218): https://www.riksdagen.se/act218
- Public Access to Information and Secrecy Ordinance (2009:641): http://www.notisum.se/rnp/sls/lag/20090641.htm
- General Data Protection Regulation (2018): https://www.datainspektionen.se/lagar--regler/dataskyddsforordningen/
- Transmission to Third Countries (2018): https://www.datainspektionen.se/lagar--regler/dataskyddsforordningen/tredjelandsoverforing/

Human Biological Materials

Key Organizations

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

Relevant Standards

- Biobanks in Medical Care Act (2002:297): https://www.riksdagen.se/biobanksno.297
- Regulation on Biobanks in Health Care, etc. (2002:746): http://www.notisum.se/rnp/sls/lag/20020746.htm
- The National Board of Health and Welfare's regulations on amendments to the regulations and general guidelines (SOSFS 2009: 32) on the use of tissues and cells in health care and clinical research, etc. (2018:52) (updated 2021): https://www.socialstyrelsen.se/2018-12-31.pdf

Genetic Research

Key Organizations

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Relevant Standards

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

EUROPE – Switzerland

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

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

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

Research Injury

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Federal Act on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 19-20 (2011) (current as of September, 2023): http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Articles 8, 12, 13, and 15, and Annexes 1-2 (2013): https://www.admin.ch/opc/en/classified-compilation/20121179/index.html
- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance CLinO), RS 810.305, Articles 7, 10-13, 25, and 71, and Annexes 2-3 (2013): https://www.admin.ch/opc/en/classified-compilation/20121176/index.html

Privacy/Data Protection

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

Key Organizations

- Federal Data Protection and Information Commissioner (FDPIC): https://www.edoeb.admin.ch/edoeb/en/home.html

Relevant Standards

- Federal Act on Data Protection (FADP), RS 235.1 (1992): http://www.admin.ch/opc/en/classified-compilation/19920153/index.html
- Federal Act on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 2, 3, 8, 16-18, 31-35, 41-45, 47, 49, 58-60, and 63 (2011): http://www.admin.ch/opc/en/classified-compilation/20061313/index.html

- Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 5 - 8, 10, 15, 21, 24-34, 37-39, 41, and 44-45, and Annex 2 (2013): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305 Articles 5, 7, 9, 12, 16-18, and 25, and Annexes 2-3 (2013): https://www.admin.ch/opc/en/classified-compilation/20121176/index.html

Human Biological Materials

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Federal Act on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 2, 3, 17, 18, 31, 32 - 35, 41-43, 45, 47, 49, and 63 (2011): http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance on Human Genetic Testing, RS 810.122.1 (2007): http://www.admin.ch/opc/fr/classified-compilation/20051790/index.html
- Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301 Articles 5 - 8, 10, 15, 21, 24-30, 33-34, 37 - 39, 41, 44-45 and Annex 2) (2013): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 7, 9, 12, 16 - 18 and Annex 2 (2013): http://www.admin.ch/opc/en/classified-compilation/20121176/index.html

Genetic Research

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Federal Act on Research Involving Human Beings (Human Research Act, HRA), RS 810.30 Articles 2, 25 - 27, 39, 40, 44, and 62 (2011): http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Federal Act on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), RS 810.31 (2003): http://www.admin.ch/opc/en/classified-compilation/20022165/index.html
- Ordinance on Research involving Embryonic Stem Cells (Stem Cell Research Ordinance, SCRO), RS 810.311 (2005): http://www.admin.ch/opc/en/classified-compilation/20042542/index.html
- Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 44–46, and Annex 2 (2013): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 49, 53, 55, and 56, and Annexes 3 and 4 (2013): http://www.admin.ch/opc/en/classified-compilation/20121176/index.html
- Research Involving Human Embryos and Fetuses, Opinion No. 11 (2006): https://www.nek-cne.admin.ch/inhalte/Themen/Stellungnahmen/en/embryonen_en.pdf
- Pre-Implantation Genetic Diagnosis II, Opinion No. 14 (2007): https://www.nek-cne.admin.ch/no.14

EUROPE – Ukraine

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

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

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

EUROPE – United Kingdom

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

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

General

Key Organizations

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

- Department of Health and Social Care (DHSC): https://www.gov.uk/government/organisations/department-of-health-and-social-care
- Medical Research Council (MRC): https://www.mrc.ac.uk/
- National Institute for Health Research (NIHR): http://www.nihr.ac.uk/
- UK Research Integrity Office (UKRIO): https://ukrio.org/
- Integrated Research Application System (IRAS): https://www.myresearchproject.org.uk/

Relevant Standards

- HRA, Various Policies, Standards, and Legislation Applicable to Research and Clinical Trials: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/
- HRA, Governance Arrangements for Research Ethics Committees: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/
- HRA, Policies, Standards & Legislation, Prison Research: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/prison-research/
- HRA, Policies, Standards & Legislation, Research Involving Children: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-involving-children/
- HRA, Policies, Standards & Legislation, Public Health Emergency Research: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/public-health-emergency-research/
- HRA, Policies, Standards & Legislation, Research in Emergency Settings: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-emergency-settings/
- HRA, Guidance for Health and Social Care Researchers at the End of the Transition Period: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/guidance-health-and-social-care-researchers-end-transition-period/
- DHSC, Mental Capacity Act (2005) (England and Wales only): http://www.legislation.gov.uk/ukpga/2005/9/contents
- DHSC, Health and Social Care Act (2012): http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted
- DHSC, Care Act (2014): http://www.legislation.gov.uk/ukpga/2014/23/contents/enacted/data.htm
- DHSC, Ionising Radiation (Medical Exposure) Regulations (2017): http://www.legislation.gov.uk/uksi/2017/1322/contents/made
- MRC, Good Research Practice, Various Policies and Guidance: https://www.ukri.org/who-we-are/mrc/our-policies-and-standards/research/
- NHS, Participant Information Quality Standards (2023): https://www.hra.nhs.uk/participant-information-quality-standards/
- NHS, Participant Information Design and Review Principles (2023): https://www.hra.nhs.uk/participant-information-design-and-review-principles/
- ABPI, Clinical Trials Best Practice Guide: Helping to Improve Clinical Trial Set-Up Processed in the UK (2024): https://www.abpi.org.uk/publications/clinical-trials-best-practice-guide-2024/

Scotland

Key Organizations

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

Relevant Standards

- Adults with Incapacity (Scotland) Act 2000, Section 51: https://www.legislation.gov.uk/asp/2000/4/body
- Adults with Incapacity (Ethics Committee) (Scotland) Amendment Regulations (2002): https://www.legislation.gov.uk/ssi/2002/302/contents/made
- CSO, Research Governance Framework for Health and Community Care (2006): http://www.cso.scot.nhs.uk/RGF-Second-Edition-February-06.pdf

Wales

Key Organizations

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

Relevant Standards

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

Northern Ireland

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

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

Relevant Standards

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

Drugs

- Medicines Act (1968): http://www.legislation.gov.uk/ukpga/1968/67/contents
- Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument, No. 1031 (2004): http://www.legislation.gov.uk/uksi/2004/1031/contents/made
- Medicines for Human Use (Clinical Trials) Amendment Regulations No. 1928 (2006): http://www.legislation.gov.uk/uksi/2006/1928/contents/made
- Amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 and Adults with Incapacity (Scotland) Act 2000 to Facilitate Clinical Research in Emergency Settings No. 2984 (2006): http://www.legislation.gov.uk/uksi/2006/2984/pdfs/uksi_20062984_en.pdf
- Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations, No. 941 (2008): http://www.legislation.gov.uk/uksi/2008/941/contents/made
- Genetically Modified Organisms (Deliberate Release) Regulations, No. 2443 (2002): http://www.legislation.gov.uk/uksi/2002/2443/contents/made
- Genetically Modified Organisms (Contained Use) Regulations, No. 1663 (2014) (England, Scotland and Wales): http://www.legislation.gov.uk/uksi/2014/1663/part/1/made
- Genetically Modified Organisms (Contained Use) Regulations, No. 339 (Northern Ireland) (2015): http://www.legislation.gov.uk/nisr/2015/339/contents/made
- ABPI, Guidelines for Phase I Clinical Trials (2018): https://www.abpi.org.uk/publications/guidelines-for-phase-i-clinical-trials-2018-edition/
- National Institute for Health Research, Clinical Trials Toolkit: http://www.ct-toolkit.ac.uk/

Devices

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

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

Clinical Trial Registries

Key Organizations

- International Standard Randomized Controlled Trial Number (ISRCTN): http://www.isrctn.com/
- Health Research Authority (HRA): http://www.hra.nhs.uk/

Relevant Standards

- ISRCTN, FAQs: http://www.isrctn.com/page/faqs
- HRA, Transparency: Researchers' Responsibilities: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/

Research Injury

Key Organizations

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

Relevant Standards

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

Social-Behavioral Research

Key Organizations

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

Relevant Standards

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

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

Privacy/Data Protection

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

United Kingdom

Key Organizations

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

Relevant Standards

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

Human Biological Materials

United Kingdom

Key Organizations

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

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

Relevant Standards

- The Human Tissue Act (2004) (Applies to England, Wales, and Northern Ireland. Section 45 also applies in Scotland): http://www.legislation.gov.uk/ukpga/2004/30/contents
- Regulation 2006 No. 1260, The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) (Applies to England, Wales, and Northern Ireland): http://www.legislation.gov.uk/uksi/2006/1260/contents/made
- Regulation 2006 No. 1659, The Human Tissue Act 2004 (Persons Who Lack Capacity to Consent and Transplants) (Different provisions apply to England, Wales, Northern Ireland, and/or Scotland): http://www.legislation.gov.uk/uksi/2006/1659/contents/made
- HTA, Guidance for Professionals: https://www.hta.gov.uk/guidance-professionals
- MRC, Human Tissue and Biological Samples for Use in Research (2019): https://www.ukri.org/publications/human-tissue-and-biological-samples-for-use-in-research/
- HRA, Use of Human Tissue in Research: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/use-tissue-research/
- HRA, Research Tissue Banks and Research Databases: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/
- HRA, Research Data and Tissue Resources: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-data-and-tissue-resources/

Scotland

Key Organizations

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

Relevant Standards

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

Genetic Research

Key Organizations

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- Human Fertilisation and Embryology Act (1990): http://www.legislation.gov.uk/ukpga/1990/37/contents

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

International Compilation of Human Research Standards
2024 Edition

Latin America and the Caribbean

LATIN AMERICA AND THE CARIBBEAN – Regionwide

General

Caribbean Public Health Agency (CARPHA): https://carpha.org/

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://www.paho.org/en/documents/good-clinical-practices-work-group
- 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 Organizations

- 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: https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-1480-2011-187206

Drugs, Biologics, and Devices

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: https://www.argentina.gob.ar/normativa/nacional/disposici%C3%B3n-6677-2010-174557
- Provision ANMAT 12.792/2016: Request for Import of Medication /Treatment and Materials – Procedure (2016): https://www.argentina.gob.ar/normativa/nacional/disposici%C3%B3n-12792-2016-267853
- Provision ANMAT 828/2017: Authorization of Expanded Access Programs: https://www.argentina.gob.ar/normativa/nacional/disposici%C3%B3n-828-2017-271208

- Provision ANMAT 4008/2017: Ministerial agreement No. 491-2020, Rules of the National Committee on Research in Health
- Substitution of Article 2° of Provision ANMAT NO. 6677/10: https://www.argentina.gob.ar/normativa/nacional/disposici%C3%B3n-4008-2017-274332/texto
- Provision ANMAT 4009/2017: Health Care Institutions: Requirements and Conditions of Authorization for Conducting Phase I and/or Bioequivalence Clinical Pharmacology Studies: https://www.argentina.gob.ar/normativa/nacional/disposici%C3%B3n-4009-2017-274331
- 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/anexos/275000-279999/279820/norma.htm
- Provision ANMAT No. 969/97, Approving the Regime Applicable to Clinical Studies of Medical Technology (1997): https://www.argentina.gob.ar/normativa/nacional/disposici%C3%B3n-969-1997-42205/actualizacion

Clinical Trial Registries

Key Organizations

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

Relevant Standards

- 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

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://ceic.org.ar/integrated_chart_Act_25326.pdf
- Decree 1558/2001, Regulation of the Personal Data Protection Act: http://servicios.infoleg.gob.ar/infolegInternet/anexos/70000-74999/70368/norma.htm
- Provision 60 - E/2016, Regulation on International Transfers of Personal Data (2016): http://servicios.infoleg.gob.ar/infolegInternet/anexos/265000-269999/267922/norma.htm

Human Biological Materials

Key Organizations

- Ministry of Health: https://www.argentina.gob.ar/salud

Relevant Standards

- Resolution 2940/2020, Guidelines for biobanks of human biological samples for research purposes: https://www.argentina.gob.ar/normativa/nacional/resolución-2940-2020-345977

LATIN AMERICA AND THE CARIBBEAN – Barbados

General

Key Organizations

- 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

LATIN AMERICA AND THE CARIBBEAN – Bermuda

General

Key Organizations

- Department of Health: https://www.gov.bm/department/health

Relevant Standards

- Research Governance Framework (2008): https://www.gov.bm/sites/default/files/doh_research_governance_framework_2008_0.pdf

LATIN AMERICA AND THE CARIBBEAN – Bolivia

General

Key Organizations

- 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: https://faolex.fao.org/docs/pdf/bol198341.pdf
- New Political Constitution of the State, Article 44 (2009): https://www.oas.org/dil/esp/constitucion_bolivia.pdf
- Rules and Regulations of the National Bioethics Committee
- MHS, Guidelines for the Development of Health Research and Ethical Norms (2002)

Drugs, Biologics, and Devices

Key Organizations

- State Agency of Drugs and Medical Technology (AGEMED): https://www.agemed.gob.bo/

Relevant Standards

- Circular MS/AGEMED/CR/1 00/2020 related to the use of investigational medicines and other products: https://www.agemed.gob.bo/circulares/2020/CIRCULAR-100-2020.pdf
- Rule for Clinical Studies (2004): https://www.agemed.gob.bo/reg-far/doc_reg_far/T-N-28-RM-0834-E.CLINICOS.pdf

- AGEMED Regulations: https://www.agemed.gob.bo/#regulacion/normas_nacionales

LATIN AMERICA AND THE CARIBBEAN – Brazil

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

Brazil's Federal Council of Medicine (CFM) provides a platform to search a variety of standards on a variety of topics: https://portal.cfm.org.br/buscar-normas-cfm-e-crm/. The Ministry of Science, Technology and Innovation has a similar legal research platform for various laws and codes here: https://www4.planalto.gov.br/legislacao.

General

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

Relevant Standards

- Resolution CNS 196/96, Rules on Research Involving Human Subjects (including other resolutions): https://conselho.saude.gov.br/biblioteca/livros/Normas_Pesquisa.pdf
- Resolution CNS No. 240/97 - Defining "Participating User" According to IRB: https://bvsms.saude.gov.br/bvs/saudelegis/cns/1997/res0240_05_06_1997.html
- Operations Manual for Ethics Committees, 4th Edition (2008): https://bvsms.saude.gov.br/bvs/publicacoes/manual_operacional_comites_pesquisa_4ed.pdf
- Resolution CNS No. 292/99 on Research with Foreign Cooperation (1999): https://bvsms.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
- Resolution CNS No. 346/2005 on Multicenter Research: 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: https://conselho.saude.gov.br/resolucoes/reso_07.htm
- Resolution CNS No. 446/2011on Composition of the National Commission on Research Ethics: http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Resoluo_n_446_-_2011_-__Sobre_composio_da_CONEP.pdf
- Resolution CNS No. 466/2012 on Guidelines and Rules for Research Involving humans Subjects: 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
- Resolution CNS No. 563/2017 on Research Participant's Right in Ultra-rare Diseases: Resolution CNS No. 563/2017
- 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: Normative 001/2013
- Various: http://plataformabrasil.saude.gov.br/login.jsf

Drugs, Biologics, and Devices

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/

Relevant Standards

- CFM, Code of Medical Ethics, Regulation CFM No. 2.217 (2018): https://cem.cfm.org.br/#NovoCodigo
- Law No. 9782/99 Defining the National Health Surveillance System: http://www.planalto.gov.br/ccivil_03/leis/L9782.htm
- Resolution CNS No. 251/1997: On Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests: 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
- 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
- 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): Requirements for Biological Products Used in Clinical Trials
- 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
- Manual for Submission of Modifications, Amendments, Suspensions and Cancellations, 5th edition (2021): Submission of Modifications, Amendments, Suspensions and Cancellations

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

- 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/l6360.htm
- Resolution CNS No. 251/97, Standards Survey of New Drugs, Medicines, Vaccines, and Diagnostic Tests Involving Human Beings: 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
- Resolution MS/CNS No. 466/2012 - Guidelines and Rules for Research Involving Human Subjects: 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
- Manual of Adverse Event Notification and Safety Monitoring in Clinical Trials Involving Drugs (2016): Adverse Event Notification and Safety Monitoring in Drug Trials
- 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

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, Standards Applicable to Research in Human and Social Sciences: http://conselho.saude.gov.br/resolucoes/2016/Reso510.pdf

Privacy/Data Protection

Key Organizations

- 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
- 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#art2
- 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, providing technical standards for computerized systems that store and handle medical records: https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2007/1821

Human Biological Materials

Key Organizations

- National Health Council (CNS): http://www.conselho.saude.gov.br/
- Ministry of Health (MS) – National Institute of Cancer (INCA): https://www.inca.gov.br/en

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
- CNS, Resolution No. 441 of 12 May 2011: Storage of Human Biological Material or Use of Material Stored in Previous Research: Resolution CNS No. 441
- CNS, Decree No. 2.201 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
- CNS, 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

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.mctic.gov.br/inicio
- 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/l11105.htm
- Decree No. 5,591 (2005): http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/Decreto/D5591.htm
- 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
- 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
- Instruction CTNBio No.9 (1997): Normative CTNBio No.9
- Resolution CNS No. 340/2004: On Research on Human Genetics (2004): http://conselho.saude.gov.br/resolucoes/2004/Res340_en.pdf
- Circular Letter No. 041/2015/CONEP/CNS/MS; 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: CONEP Communication No. 011/2012
- Normative Resolution No. 33, of August 2, 2021: Normative Resolution No. 33/2021

Embryos, Stem Cells, and Cloning

Key Organizations

- National Biosafety Technical Commission: http://ctnbio.mctic.gov.br/inicio

Relevant Standards

- Biosafety Law 11.105/05 (2005): http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/lei/l11105.htm
- Decree No. 5,591, of November 22, 2005: 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
- Resolution RDC No. 29, 12 May 2008: http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2008/rdc0029_12_05_2008.html
- 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

LATIN AMERICA AND THE CARIBBEAN – Chile

General

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
- 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
- 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 (updated 2013): http://www.leychile.cl/Navegar?idNorma=1032919
- 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 (2013): http://www.leychile.cl/Navegar?idNorma=1048008&

Drugs, Biologics, and Devices

Key Organizations

- 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
- 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
- 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
- Exempt Resolution 2263, July 30th 2015 Modifying Resolution Nº 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

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

- 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
- General Technical Rule No. 140 Regarding the National System of Pharmacovigilance of Pharmaceutical Products for Human Use. June 20, 2012: https://www.ispch.cl/sites/default/files/u53/normatecnica_140.pdf
- Resolution No. 441, Notification of Adverse events in Clinical Research in Chile, February13, 2012: http://www.ispch.cl/sites/default/files/res_441.pdf

Privacy/Data Protection

Key Organizations

- 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): https://www.bcn.cl/leychile/navegar?idNorma=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

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
- 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

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
- 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 Organizations

- 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/

- Ministry of Science, Technology and Innovation (MINCIENCIAS): https://minciencias.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
- Policy on Ethical Research, Bioethics, and Scientific Integrity (2018): http://www.colciencias.gov.co/sites/default/files/ckeditor_files/PDF%20Pol%C3%ADtica.pdf

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Various Standards, Regulations for the Approval and Monitoring of Clinical Studies, Adverse Events and Safety Reports, Protocol-related Documents, Procedures, and Guides: https://www.invima.gov.co/productos-vigilados/medicamentos-y-productos-biologicos/autorizacion-y-monitoreo-de-estudios-clinicos
- 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

Relevant Standards

- Records of clinical research protocols in Colombia: Records of clinical research protocols
- 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

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

- GDI-DIE-PL009, Privacy policy for the Use of and Access to Information from the IBVIMA website (2018): https://www.invima.gov.co/sites/default/files/normatividad/politica-lineamiento-y-manuales/politicas/politica-de-privacidad-condiciones-de-uso-y-acceso-a-la-informacion-del-sitio-web-del-instituto-nacional-de-vigilancia-de-medicamentos-y-alimentos-invima.pdf
- Political Constitution of Colombia (updated with legislative acts until 2015), Article 15 (2003): http://www.corteconstitucional.gov.co/inicio/Constitucion%20politica%20de%20Colombia%20-%202015.pdf
- Law 1581 of 2012: General Regimen of Protection of Personal Data: https://www.funcionpublica.gov.co/eva/gestornormativo/norma.php?i=49981
- 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

- Various standards applicable to blood banks: https://www.invima.gov.co/productos-vigilados/medicamentos-y-productos-biologicos/bancos-de-sangre
- 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

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 Organizations

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

Relevant Standards

- Ministry of Health, Various Standards: https://www.ministeriodesalud.go.cr/conis/index.php/legislacion

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)
- Regulatory Decree NO. 39061-S (2016) on the Regulatory Law of Biomedical Research No. 39533-S
- Reforms to the Regulatory Decree No. 39533-S (2016) Regulatory Law of Biomedical Research No. 9234
- 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

General

Key Organization

- Ministry of Public Health: https://salud.msp.gob.cu/

Relevant Standards

- Draft (not yet signed into law) New Public Health Law, Art's. 13, 16.1, 31, 48, 183-84 (2023): https://salud.msp.gob.cu/wp-content/Documentos/Anteproyecto%20de%20Ley%20de%20Salud.pdf

Drugs, Biologics, and Devices

Key Organizations

- Center for State Control of the Quality of Medications (CECMED): http://www.cecmed.cu/

Relevant Standards

- Evaluation of Clinical Trials, Approved Regulatory Dispositions, Various: http://www.cecmed.cu/ensayos-clinicos/autorizos
- Draft (not yet signed into law) New Public Health Law, Fourth Section (Art's. 185-87): Clinical Trials (2023): https://salud.msp.gob.cu/wp-content/Documentos/Anteproyecto%20de%20Ley%20de%20Salud.pdf
- MSP, Resolution No. 435, Regulation of Clinical Trials in Cuba (2017): https://instituciones.sld.cu/cencec/files/2017/12/Resolución-435-del-MINSAP-Reglamento-de-los-Ensayos-Clínicos-en-Cuba.pdf
- CECMED, Good Clinical Practice in Cuba: https://www.cecmed.cu/sites/default/files/adjuntos/Reglamentacion/Dir_BPC.pdf

Clinical Trial Registries

Key Organizations

- Public Cuban Registry of Clinical Trials: https://rpcec.sld.cu/

Genetic Research

Key Organizations

- Ministry of Public Health: https://salud.msp.gob.cu/

Relevant Standards

- Draft (not yet signed into law) New Public Health Law, Art. 155 (2023): https://salud.msp.gob.cu/wp-content/Documentos/Anteproyecto%20de%20Ley%20de%20Salud.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Public Health: https://salud.msp.gob.cu/

Relevant Standards

- Draft (not yet signed into law) New Public Health Law, Art. 137 (2023): https://salud.msp.gob.cu/wp-content/Documentos/Anteproyecto%20de%20Ley%20de%20Salud.pdf

LATIN AMERICA AND THE CARIBBEAN – Dominica

General

Key Organizations

- Ministry of Health: https://health.gov.dm/

Relevant Standards

- Guidelines for the Conduct of Research on Human Subjects (2005)

LATIN AMERICA AND THE CARIBBEAN – Dominican Republic

General

Key Organizations

- State's Secretariat of Public Health and Social Assistance (SESPAS)
- National Council on Health Bioethics (CONABIOS): http://conabios.gob.do/

Relevant Standards

- SESPAS, Administrative Disposition No. 013620, Creating SESPAS' Bioethics Committee (2000): https://conabios.gob.do/wp-content/uploads/2019/12/DISPOSICIONES-CONABIOS.pdf
- SESPA, Resolution No. 0000012, Incorporating All Prior Bioethics Materials and Creating an Independent National Council on Health Bioethics (CONABIOS)(2008): https://conabios.gob.do/wp-content/uploads/2019/12/Resolución-Conabios.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 (2008): http://www.asambleanacional.gob.ec/sites/default/files/documents/old/constitucion_de_bolsillo.pdf
- Organic Health Law of 22 December 2006, Articles 207-208: https://faolex.fao.org/docs/pdf/ecu154951.pdf
- Code on Childhood and Adolescence. Law 100 Official Register 737 of January 3, 2003 (2019)
- Regulation on Health Research, Ministerial Agreement No. 66, Public Registry No. 292 (March 11, 2008): Law 100/2008
- 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): Regulation on Ethics Committees
- National Policy on Scientific Research. Ministerial Agreement 209, Public Registry No. 87 of August 23, 2005

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, Ministerial Accord No. 4889 (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): Ministerial Agreement No. 0066/2011
- 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/constitucion_de_bolsillo.pdf
- Ministerial Agreement No. 005216, Public Registry No. 427, Confidential Information in National Health System (January 29, 2015): https://www.salud.gob.ec/wp-content/uploads/2016/09/AM-5216-A-Confidencialidad.pdf

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: https://faolex.fao.org/docs/pdf/ecu154951.pdf
- Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells (2011): Law on Organs, Tissues, and Cells
- 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): Ministerial Agreement No. 0088/2017

Genetic Research

Key Organizations

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

Relevant Standards

- Organic Health Law, December 22, 2006, Articles 209-210: https://faolex.fao.org/docs/pdf/ecu154951.pdf

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): https://faolex.fao.org/docs/pdf/ecu154951.pdf
- Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells (2011): Law on Organs, Tissues, and Cells

LATIN AMERICA AND THE CARIBBEAN – El Salvador

General

Key Organizations

- 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
- Regulations 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
- Decree No. 927 (2024) Reforms to the Law on the Comprehensive Protection of Childhood and Adolescence, Article 19 (2009): https://www.asamblea.gob.sv/sites/default/files/documents/decretos/643D1361-AAD7-47AE-8253-EADCAC45609B.pdf
- Decree No. 302, Law on the Integrated National System of Health, Article 28 (2019): https://www.asamblea.gob.sv/sites/default/files/documents/decretos/64AD0BF7-BABA-47AF-8574-B5B914F4A414.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
- Operating Manual 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

Drugs, Biologics, and Devices

Key Organizations

- National Directorate of Medications: https://www.medicamentos.gob.sv/

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
- Guide on Good Clinical Practices (2016): https://cssp.gob.sv/wp-content/uploads/2017/02/Guia-de-BPC.pdf
- National Directorate of Medications, Searchable Database of Relevant Standards (some in English): https://www.medicamentos.gob.sv/?wpdmcategory=descargas

LATIN AMERICA AND THE CARIBBEAN – Grenada

General

Key Organizations

- St. George's University/Windward Islands Office of Research: https://mycampus.sgu.edu/web/office-of-research/home
- U.S. 45 CFR 46: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

LATIN AMERICA AND THE CARIBBEAN – Guyana

General

Key Organizations

- 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

LATIN AMERICA AND THE CARIBBEAN – Guatemala

General

Key Organizations

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

Relevant Standards

- Accreditation for Ethics Committees: https://tramites.gob.gt/servicio/3201/

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Public Health and Social Assistance, Department of Regulation and Control of Pharmaceutical Products: https://medicamentos.mspas.gob.gt/

Relevant Standards

- Ministerial Accord 206-2021, Law Regulating Clinical Trials in Humans: https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/acuerdos?download=336%3Aacuerdo-ministerial-206-2021

- Governmental Accord 712-99, Articles 91-94 (1999): https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/acuerdos?download=7%3Aag-712-99
- 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 – Honduras

General

Key Organizations

- 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): https://www.tsc.gob.hn/web/leyes/Ley_donacion_transp_organos_2014.pdf

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 Organizations

- Ministry of Health & Wellness: 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): https://laws.moj.gov.jm/library/statute/the-food-and-drugs-act
- Food and Drugs Regulations (1975): https://www.moa.gov.jm/sites/default/files/pdfs/Food%20and%20Drugs%20Act%201975.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 Organizations

- 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
- Regulation on the General Health Law in the Matter of Health Research (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf
- 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
- 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
- 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
- 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

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
- 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
- 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
- Guidelines for the Submission of Human Research Protocols – Observational Studies (2016)
- 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_MODIFICACI_N.pdf

Privacy/Data Protection

Key Organizations

- Federal Institute on Access to Public Information: https://www.infocdmx.org.mx/

Relevant Standards

- Laws related to personal data, various standards: https://www.infocdmx.org.mx/index.php/protege-tus-datos-personales/normatividad.html
- Federal Law for the Protection of Personal Data in Possession of Private Individuals (2017): http://www.diputados.gob.mx/LeyesBiblio/pdf/LGPDPPSO.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
- Regulations to1. General Health Law, Title XIV, Articles 313-342 (2018): 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

Genetic Research

Key Organizations

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

Relevant Standards

- Biosafety Law on Genetically Modified Organisms (2020), updated 2022: https://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM.pdf
- Regulations to the Biosafety Law on Genetically Modified Organisms (2009): 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

LATIN AMERICA AND THE CARIBBEAN – Nicaragua

General

Key Organizations

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

Relevant Standards

- General Health Law, No. 423 Republica de Nicaragua (2002): http://www.vertic.org/media/National%20Legislation/Nicaragua/I_Ley_423_General_de_Salud_2002.pdf

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health, Directorate of Sanitary Regulations: http://www.minsa.gob.ni
- National Committee on Research in Health

Relevant Standards

- Law of Medicines and Pharmacies, No. 292 (1998): http://legislacion.asamblea.gob.ni/Normaweb.nsf/($All)/10B9BC0F73CCA7FD062570A10057793D?OpenDocument
- Normative-064, Standard for the registration of medical devices: Normative-064
- Ministerial agreement No. 491-2020, Rules of the National Committee on Research in Health
- Ministerial agreement No. 492-2020, Rule 166 for the regulation of clinical trials on drugs involving human beings

Clinical Trial Registries

Key Organizations

- Ministry of Health, Directorate of Sanitary Regulations: http://www.minsa.gob.ni

LATIN AMERICA AND THE CARIBBEAN – Panama

General

Key Organizations

- Ministry of Health (MINSA): 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-investigación.pdf
- MINSA, Executive Decree Nº1, January 21, 2013: https://cnbi.senacyt.gob.pa/wp-content/uploads/2019/07/Decreto-Ejecutivo-NO.1-del-21-de-Enero-de-2013.pdf
- MINSA, Executive Decree NO.1843 on the National Research Ethics Committee of Panama (2014): http://gacetas.procuraduria-admon.gob.pa/27681-A_2014.pdf
- MINSA, Executive Decree NO. 6 on the National Research Ethics Committee of Panama (2015): 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: https://docs.panama.justia.com/federales/leyes/1-de-2001-jan-12-2001.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
- Executive Directive No. 1458 of 6 November 2012: 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
- Executive Directive No. 179 of 8 June 2018: https://www.gacetaoficial.gob.pa/pdfTemp/28546_A/68013.pdf
- Executive Decree Nº179, 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 Organizations

- Research and Strategic Studies Directorate, Ministry of Public Health and Social Welfare: https://www.mspbs.gov.py/planificacion/diee.html

Relevant Standards

- Resolution S.G. No. 905, National Policy of Health Research Ethics: Resolution S.G. No. 905
- Statute and Operating Procedures (2017): https://www.mspbs.gov.py/dependencias/cnbioetica/adjunto/a03ba4-CEIINS.VersionFinal.pdf

Drugs, Biologics, and Devices

Key Organizations

- National Directorate of Health Surveillance: https://dinavisa.gov.py

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: https://clinregs.niaid.nih.gov/country/peru

General

Key Organizations

- National Institute of Health, Directorate in Research and Innovation in Health (DIIS): https://www.gob.pe/37752-instituto-nacional-de-salud-direccion-de-investigacion-e-innovacion-en-salud-diis

Relevant Standards

- General Health Law No. 26842, Article 28 (1997): https://www.gob.pe/institucion/minsa/normas-legales/256661-26842
- Ministerial Resolution No. 233-2020, Ethical Considerations in Health Research with Human Beings: https://www.gob.pe/institucion/minsa/normas-legales/541139-233-2020-minsa
- Supreme Decree No. 011.2011-JUS Guaranteeing the exercise of Bioethics as Recognition of Human Rights (2011): http://blog.pucp.edu.pe/blog/wp-content/uploads/sites/39/2011/09/DS-N-011-2011-JUS-EL-PERUANO.pdf

Drugs, Biologics, and Devices

Key Organizations

- National Institute of Health, Clinical Trials: https://www.gob.pe/institucion/ins/tema/ensayos-clinicos
- National Directorate of Medicines, Supplies, and Drugs (DIGEMID): www.digemid.minsa.gob.pe
- Peruvian Registry of Clinical Trials: https://ensayosclinicos-repec.ins.gob.pe/

Relevant Standards

- National Institute of Health, Standards and Documents, Various: https://www.gob.pe/institucion/ins/normas-y-documentos
- Supreme Decree No. 021-2017-SA. Regulation of Clinical Trials (2017): https://www.gob.pe/institucion/minsa/normas-legales/189280-021-2017-sa
- 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)
- Peruvian Registry of Clinical Trials, Various Regulations: https://ensayosclinicos-repec.ins.gob.pe/regulacion/normatividad-vigente

Clinical Trial Registries

Key Organizations

- 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
- Peruvian Registry of Clinical Trials, 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

- Supreme Decree No. 021-2017-SA. Regulation of Clinical Trials, Articles 27-29: https://cdn.www.gob.pe/uploads/document/file/189787/189280_DS_021-2017-SA.pdf20180823-24725-cfjcm1.pdf

Privacy/Data Protection

Key Organizations

- National Directorate of Medicines, Supplies, and Drugs (DIGEMID): www.digemid.minsa.gob.pe

Relevant Standards

- Law 29733 for the Protection of Personal Information (2011): https://www.leyes.congreso.gob.pe/Documentos/Leyes/29733.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.pdf

LATIN AMERICA AND THE CARIBBEAN – Saint Lucia

Drugs, Biologics, and Devices

Relevant Standards

- Clinical Trials Act (2016): https://attorneygeneralchambers.com/laws-of-saint-lucia/clinical-trials-act

LATIN AMERICA AND THE CARIBBEAN – Trinidad and Tobago

General

Key Organizations

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

Relevant Standards

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

LATIN AMERICA AND THE CARIBBEAN – Uruguay

General

Key Organizations

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

Relevant Standards

- Order No. 1.588/020< Rules of the Bioethics Commission (2020): https://www.gub.uy/ministerio-salud-publica/institucional/normativa/ordenanza-1588020-reglamentacion-comision-bioetica
- Decree 189/998, Application of International Agreements for the Regulation of Good Clinical Practices in Pharmaceutical Research: https://www.impo.com.uy/bases/decretos/189-1998
- Decree 158/019, Approving the Bioethics Commission Project Related to Research with Human Beings (2019): https://www.impo.com.uy/diariooficial/2019/06/12/3
- Decree 379/008, Approving the Bioethics Commission Project Related to Research with Human Beings (2008): http://www.impo.com.uy/bases/decretos-originales/379-2008

Drugs, Biologics, and Devices

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: https://www.impo.com.uy/bases/decretos/189-1998

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: https://www.impo.com.uy/bases/decretos/189-1998
- 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/
- National Institute on Donation and Transplantation: 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

LATIN AMERICA AND THE CARIBBEAN – Venezuela

General

Key Organizations

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

Relevant Standards

- Constitution, Article 46 (3): http://www.cne.gob.ve/web/normativa_electoral/constitucion/indice.php
- Resolution No. 48 (1998)

- FONACIT, Code on Bioethics and Biosecurity (2002)

Drugs, Biologics, and Devices

Relevant Standards

- Medicines Act, Title III, Chapter II

Genetic Research

Key Organizations

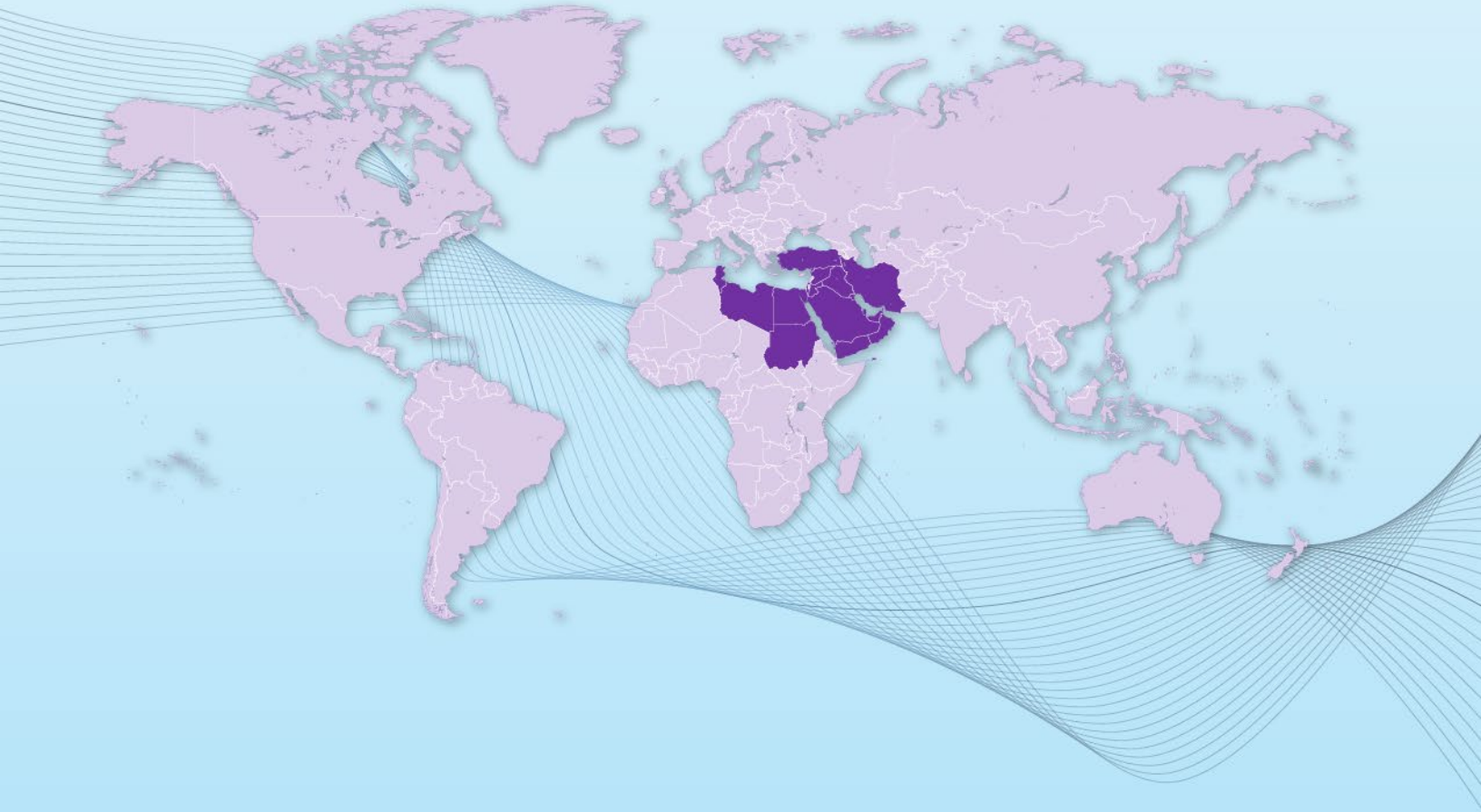
- Venezuelan Institute of Scientific Research (IVIC): https://www.ivic.gob.ve/

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
2024 Edition

Middle East/North Africa



MIDDLE EAST/NORTH AFRICA – Egypt

General

Key Organizations

- Medical Professionals Union
- Supreme Standing Committee for Human Rights (SSCHR): https://sschr.gov.eg/en

Relevant Standards

- SSCHR, Constitution of the Arab Republic of Egypt, Articles 18 and 23: https://sschr.gov.eg/en/the-egyptian-constitution/
- Professional Ethics Regulations, Conducting Medical Research on Human Beings, Articles 52-61 (2003)

Drugs, Biologics, and Devices

Key Organizations

- Egyptian Drug Authority: https://gs1eg.org/eda-egyptian-drug-authority/

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: Ministerial Resolutions

MIDDLE EAST/NORTH AFRICA – Iran

General

Key Organizations

- 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 Organizations

- Iranian Registry of Clinical Trials: http://www.irct.ir/

MIDDLE EAST/NORTH AFRICA – Israel

General

Key Organizations

- Ministry of Health: http://www.health.gov.il/english/
- The Israel Academy of Sciences and Humanities: https://www.academy.ac.il/?nodeId=808

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

- 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
- The Israel Academy of Sciences and Humanities, Committees to Approve Clinical Trials in Humans: https://www.academy.ac.il/RichText/GeneralPage.aspx?nodeId=1417

Privacy/Data Protection

Key Organizations

- The Privacy Protection Authority: 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
- The Israel Academy of Sciences and Humanities, Big Data: https://www.academy.ac.il/RichText/GeneralPage.aspx?nodeId=1419

Genetic Research

Relevant Standards

- Genetic Information Law (2000): https://www.jewishvirtuallibrary.org/jsource/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)
- The Israel Academy of Sciences and Humanities, Embryo Research: https://www.academy.ac.il/RichText/GeneralPage.aspx?nodeId=1418

MIDDLE EAST/NORTH AFRICA – Jordan

Drugs, Biologics, and Devices

Key Organizations

- 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): Law No. 2
- Drug and Pharmacy Law No. 12 (2013): Law No. 12
- Narcotic and Psychotropic Law No. 23 (2016): Law No. 23

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

Embryos, Stem Cells, and Cloning

Relevant Standards

- Stem Cell By-law No. 10 (2014)

MIDDLE EAST/NORTH AFRICA – Kuwait

General

Key Organizations

- Ministry of Health: https://www.moh.gov.kw/en/
- Ministry of Health, Food and Drug Development: https://www.moh.gov.kw/en/Pages/DRUGCA.aspx

Relevant Standards

- Ethical Guidelines for Biomedical Research

MIDDLE EAST/NORTH AFRICA – Qatar

General

Key Organizations

- Ministry of Public Health, Health Research Governance Department: https://research.moph.gov.qa/en/Pages/ResearchHome.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: Guidelines on Reviewing and Reporting Unanticipated Problems Involving Risks to Subject or Others and Adverse Events
- 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: Guidance for the Use of Stored Data and Biological Specimens
- 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: Guidance for Genomic Research
- Guidelines for Gene Transfer Research in Humans: Guidelines for Gene Transfer Research

- Human Research Policies & Regulations, various: https://research.moph.gov.qa/en/Pages/HumanResearch.aspx?csrt=16566705229134832818

MIDDLE EAST/NORTH AFRICA – Saudi Arabia

General

Key Organizations

- National Committee of BioEthics: https://ncbe.kacst.edu.sa/en/

Relevant Standards

- Law of Ethics of Research on Living Creatures (2016)
- Implementing Regulations of the Law of Ethics of Research on Living Creatures, Version 3 (2022): Implementing Regulations
- Rules and Regulations, Various: Rules and Regulations

MIDDLE EAST/NORTH AFRICA – Sudan

General

Key Organizations

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

Relevant Standards

- National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008)
- Accreditation Guidelines for Research Ethics Committees in Sudan (2017)
- Operation Guidelines, Functions, and Procedures (2016)
- Federal Ministry of Health, Sudan National Health Policy (2017-2030): https://extranet.who.int/countryplanningcycles/sites/default/files/public_file_rep/SDN_Sudan_National-Health%20Policy_2017-2030.pdf

Drugs, Biologics, and Devices

Key Organizations

- 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

- 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

Relevant Standards

- Guidelines for Genetics Research on Sudanese Subjects (2005)

MIDDLE EAST/NORTH AFRICA – Tunisia

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Public Health, Institut Pasteur: 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 Organizations

- 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 (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Update on the Law of the Support of Research and Development Activities (2021): 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

Key Organizations

- Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr
- Clinical Research Association (CRA): 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 TITCK legislation: https://www.titck.gov.tr/mevzuat
- Regulation on Clinical Trials with Drugs and Biological Products (2015): An Update of 2014 Clinical Trials Regulation
- 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)
- Draft Regulation on Clinical Research of Traditional and Complementary Medicine Practices (2020): https://shgmgetatdb.saglik.gov.tr/EN-68837/clinical-research-regulation-general-preamble-and-justification-of-articles.html
- 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)
- Guidelines on Application for Good Clinical Practice Inspections (2021): Guidelines on GCP Inspection Application
- Guideline on Risk-Based Good Clinical Practice Inspections (2022): https://titck.gov.tr/storage/Archive/2022/contentFile/Guideline%20On%20Risk-Based%20Good%20Clinical%20Practice%20Inspections_3dbaf7d9-c321-4e85-958b-9b6c63c1bfb1.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
- Regulation on Research on Medical Devices (2014): https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=20028&MevzuatTur=7&MevzuatTertip=5
- New Medical Device Regulations: https://titck.gov.tr/storage/Archive/2021/contentFile/Ek-2.1%20Duyuru%20metni-eng_2e87c6cd-5d45-43d9-9a35-0a94ffee8547.pdf

Research Injury

Key Organizations

- Turkish Medicines and Medical Devices Agency (TMMDA): https://www.titck.gov.tr/mevzuat

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- 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)
- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98

- Good Clinical Practice Guidelines for Advanced Therapy Medicinal Products (2011)
- Regulation on the Registration of Medicinal Products for Human Use: https://titck.gov.tr/storage/legislation/QEv7VEBH.pdf
- Law on Removal, Storage and Transplantation of Organs and Tissues: Storage and Transplantation of Organs and Tissues

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

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Regulation on Centers for Medically Assisted Procreation, No. 19551 (1987)
- Regulation on Cordon Blood Banks (2005)
- Circular on Research of Embryonic Stem Cells (2005)
- Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)
- 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
- 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 Organizations

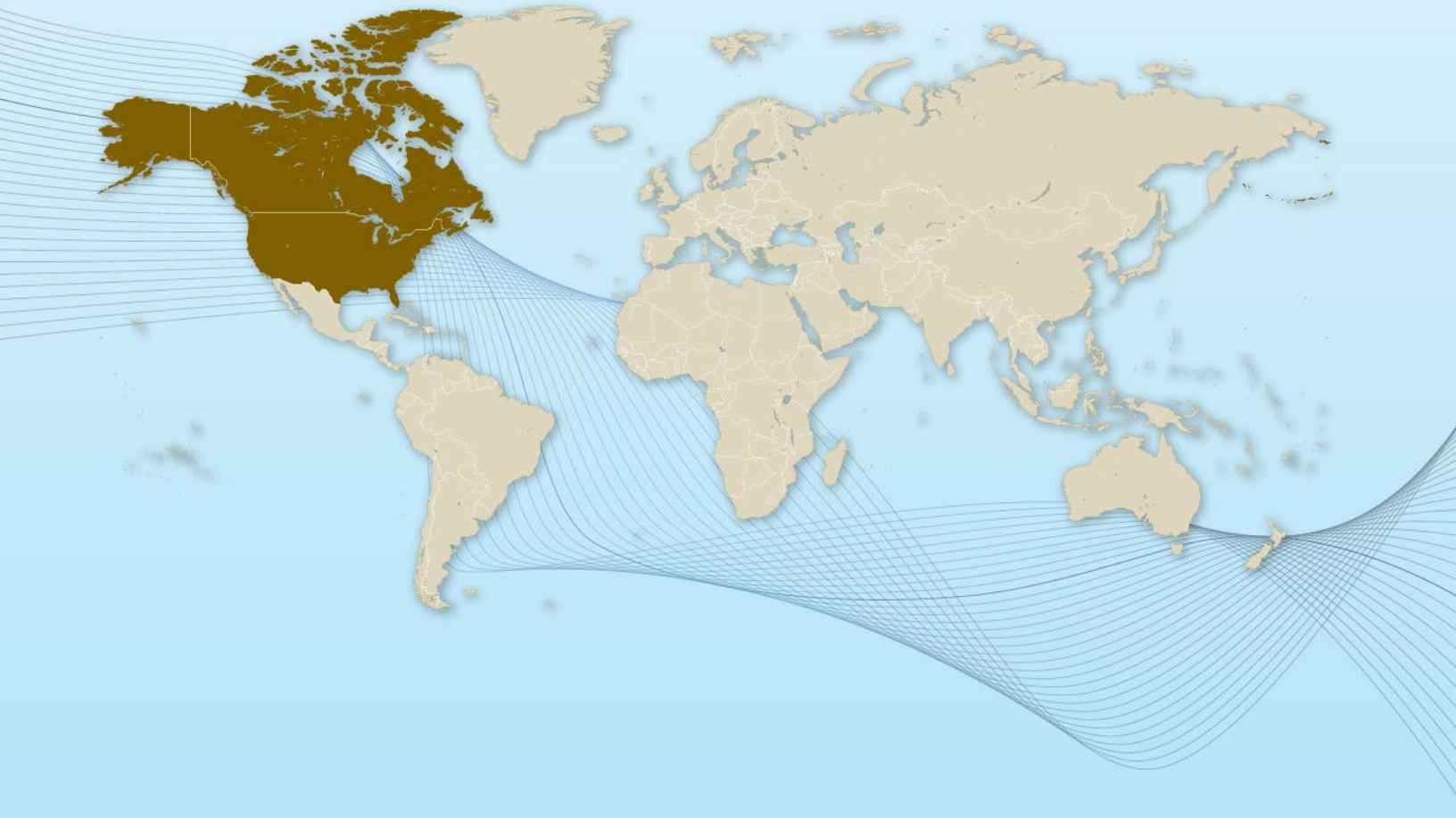
- Health Authority - Abu Dhabi: http://www.haad.ae/haad/

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
2024 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
- Health Canada: https://www.canada.ca/en/health-canada.html

Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition (2018): http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf
- Defence Administrative Orders and Directives (DAOD) 5061-0, Research Involving Human Subjects (1998): DAOD 5061-0
- Correctional Service of Canada: Commissioner's Directive - Research: DCOO9 (2017): https://www.canada.ca/en/correctional-service/corporate/acts-regulations-policy/commissioners-directives/009.html

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Health Canada, Pharmaceutical Drugs 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
- Health Canada, Good Clinical Practices, 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, 2nd 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): https://www.canlii.org/en/ca/laws/regu/sor-2001-6/latest/sor-2001-6.html

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 5: Privacy and Confidentiality (2018): http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf
- CIHR Best Practices for Protecting Privacy in Health Research (2005): 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, 2nd 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 Strategy (CBS): http://www.hc-sc.gc.ca/sr-sr/biotech/role/strateg-eng.php
- Health Canada, Biologic and Radiopharmaceutical Drugs Directorate (BRDD): 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, 2nd 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):
  https://laws-lois.justice.gc.ca/eng/acts/A-13.4/page-1.html
  http://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-137/index.html
- PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd 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 Organizations and Relevant Standards

- Public Health Service Act:
  https://www.govinfo.gov/content/pkg/COMPS-8773/pdf/COMPS-8773.pdf
- HHS, Food and Drug Administration (FDA): https://www.fda.gov/
- Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP): 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
- Each Common Rule Federal department or agency has jurisdiction over the non-exempt, human subjects research that they support or conduct (FDA is *not* a Common Rule agency). Some of the relevant standards by Common Rules departments and agencies other than HHS 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/2022-12/200mbe.pdf
     b. CFR Citation: 22 CFR Part 225
  2. Department of Agriculture: https://www.usda.gov/
     a. Office of the Chief Scientist (OCS), Research, Education and Economics Action Plan (2012): https://www.usda.gov/sites/default/files/documents/usda-ree-science-action-plan.pdf
     b. CFR Citation: 7 CFR Part 1c: https://www.ecfr.gov/current/title-7/subtitle-A/part-1c
  3. Bureau of Prisons, US Department of Justice: 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
     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
  4. Central Intelligence Agency: https://www.cia.gov/index.html

a. Executive Order 12333, adopting 45 CFR 46 Subparts A, B, C, and D: https://www.archives.gov/federal-register/codification/executive-order/12333.html

5. 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: DOD Title 10, Section 980
   b. DoDI 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (2011): https://rcb.tamu.edu/humans/resources/DOD%20Directive%20321602p.pdf
6. Department of Education: https://www.ed.gov/
   a. Protection of Pupil Rights Amendment (PPRA) (1974): https://studentprivacy.ed.gov/faq/what-protection-pupil-rights-amendment-ppra
   b. Family Educational Rights and Privacy Act (FERPA) (1974): https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html
   c. 34 CFR 98: https://www.ecfr.gov/current/title-34/subtitle-A/part-98
   d. 34 CFR 99: https://www.ecfr.gov/current/title-34/subtitle-A/part-99?toc=1
7. Department of Energy: http://science.energy.gov/ber/human-subjects/
   a. DOE Order 443.1B: https://www.directives.doe.gov/directives-documents/400-series/0443.1-BOrder-b
   b. DOE Order 481.1D: https://www.directives.doe.gov/directives-documents/400-series/0481.1-BOrder-d
   c. CFR Citation: 10 CFR Part 745
8. Environmental Protection Agency: https://www.epa.gov/
   a. EPA, Program in Human Research Ethics: https://www.epa.gov/osa/basic-information-about-human-subjects-research-0
   b. EPA, 40 CFR 26, Human Subjects Research, Various Subparts: EPA, 40 CFR 26
   c. Scientific and Ethical Approaches for Observational Exposure Studies (2008): https://nepis.epa.gov/Exe/ZyPDF.cgi/P10012LY.PDF?Dockey=P10012LY.PDF
   d. 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
9. Federal Bureau of Investigation, Department of Justice: https://www.justice.gov/doj/federal-bureau-investigation
   a. Human Subjects Protection: https://nij.ojp.gov/funding/human-subjects-protection
   b. CFR Citation: 28 CFR Part 46; CPD 0737D
10. Department of Homeland Security: https://www.dhs.gov/
    a. Public Law 108-458, Section 8306
    b. DHS Directive 026-04, Human Subjects Research (2018): DHS Directive 026-04
    c. CFR Citation: 6 CFR Part 46
11. Department of Housing and Urban Development: https://www.hud.gov/

a. CFR Citation: 24 CFR Part 60

12. Office of Justice Programs, Department of Justice: https://www.ojp.gov/
    a. CFR Citation: 28 CFR Part 46
13. Department of Labor: https://www.dol.gov/
    a. CFR Citation: 29 CFR Part 21
14. National Aeronautics and Space Administration: https://www.nasa.gov/
    a. Human Research Program (HRP): https://www.nasa.gov/hrp/
    b. CFR Citation: 29 CFR Part 21
15. National Science Foundation: https://www.nsf.gov/
    a. Research Involving Human Subjects: https://new.nsf.gov/funding/research-involving-human-subjects
    b. CFR Citation: 45 CFR Part 690
16. Office of the Director of National Intelligence: https://www.dni.gov/
    a. Executive Order 12333 (2008)
17. Social Security Administration: https://www.ssa.gov/
    a. CFR Citation: 20 CFR Part 431
18. Department of Transportation: https://www.transportation.gov/
    a. CFR Citation: 49 CCFR Part 11
19. Department of Veterans Affairs (VA)
    a. Office of Research Oversight (ORO): http://www.va.gov/oro/
    b. Office of Research and Development: http://www.research.va.gov
    c. CFR Citation: 38 CFR 17.85 (1998)
    d. VA, Policies, Human Research, various: https://www.research.va.gov/resources/policies/human_research.cfm
    e. CFR Citation: 38 CFR Part 16

Drugs, Biologics, and Devices

The Office for Human Research Protections (OHRP) may share jurisdiction with FDA over non-exempt, human subjects research on an FDA regulated product if the research is also supported or conducted by HHS. See, USA-General, supra.

Key Organizations

- Food and Drug Administration (FDA): https://www.fda.gov/drugs
- Food and Drug Administration (FDA), Vaccines, Blood & Biologics: https://www.fda.gov/vaccines-blood-biologics
- Food and Drug Administration (FDA), Center for Devices and Radiological Health: https://www.fda.gov/Medical-Devices

Relevant Standards

- For a search engine of all FDA guidance documents, see: https://www.fda.gov/regulatory-information/search-fda-guidance-documents
- 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
- 21st 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: regulations-good-clinical-practice-and-clinical-trials
- FDA, Clinical Trials and Human Subject Protection: 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
- FDA, Medical Devices and Radiation-Emitting Products, 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 (FDA) ClinicalTrials.gov Information: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrialsgov-information
- National Institutes of Health (NIH) ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/home
- Office of Research Oversight (ORO): https://www.va.gov/oro/

Relevant Standards

- FDA Modernization Act, Section 113 (1997): https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-modernization-act-fdama-1997
- FDA 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, FAQs (2015): 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

Relevant Standards

- Department of Health and Human Services (HHS), 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, Directive 1200.05, Appendix F, Paragraph 2a(11)

Social-Behavioral Research

Relevant Standards

- Department of Health and Human Services (HHS), 45 CFR 46 and applicable subparts: https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf
- All other Common Rule departments and agencies per their adoption of the Common Rule: *See*, USA-General, *supra*
- 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
- 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): https://www.hhs.gov/hipaa/for-professionals/privacy/index.html
- HIPAA Security Rule, 45 CFR parts 160, 162, and 164 (2009): https://www.hhs.gov/hipaa/for-professionals/security/index.html
- HIPAA Breach Notification Rule, 45 CFR §164.400-414: https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html
- 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

- 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://grants.nih.gov/policy/humansubjects/coc.htm
- 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 (HHS), 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, National Institutes of Health (NIH), Office of Science Policy: https://osp.od.nih.gov/
- 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): guidance-informed-consent-vitro-diagnostic-device-using-leftover-human-specimens

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- 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
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- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2019): 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 (NIH) Stem Cell Information: 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://www.hhs.gov/ohrp/regulations-and-policy/guidance/public-law-103-43/index.html
- 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
- 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

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