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)

Latin America and the Caribbean

OASH | Office for Human Research Protections

LATIN AMERICA and the CARIBBEAN

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PURPOSE

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

ORGANIZATION

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

This document is organized by country in alphabetical order. Before the world regions, there is a section for standards provided by several international organizations. Under each section, you will find the countries or international organizations organized also in alphabetical order. For each country or international organization, the information is then categorized as it relates to:

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

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

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

TOPICS NOT COVERED

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

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

GENERAL REQUEST FOR PUBLIC INPUT AND COMMENTS

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

DISCLAIMER

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

TABLE OF CONTENTS

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)

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