LATIN AMERICA and the CARIBBEAN

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)

PURPOSE

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

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 However, not all countries provided corroboration, so some of the information contain in this document may be outdated or incomplete (please see disclaimer below).

ORGANIZATION

This document only includes Latin America and the Caribbean. To access the complete International Compilation, please visit: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html. You may jump to a specific country by clicking its name in the Table of Contents.

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

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

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

Where possible, a link has been provided to specific Key Organizations and Relevant Standards. In many cases, the documents and webpages are available in English. When the URL links to a non-English website or document, an online language translator usually can render an English version. Many operating systems may also be able to translate a document or webpage. For example, in Chrome, you may be able to right click a document or page and select “translate to [your native language].”
TOPICS NOT COVERED

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

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

NEW STANDARDS, UPDATES, AND BROKEN LINKS

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

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

DISCLAIMER

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

**General**


- PAHO, Regional Program on Bioethics, various resources: [https://www.paho.org/en/bioethics](https://www.paho.org/en/bioethics)

**Drugs, Biologics, and Devices**


LATIN AMERICA AND THE CARIBBEAN – Argentina

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

**General**

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

**Relevant Standards**

**Drugs, Biologics, and Devices**

**Drugs**

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

**Relevant Standards**


Devices

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

Relevant Standards

Clinical Trial Registries

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

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

Privacy/Data Protection

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

Relevant Standards
### Human Biological Materials

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

**Relevant Standards**

### LATIN AMERICA AND THE CARIBBEAN – Barbados

**General**

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

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

### LATIN AMERICA AND THE CARIBBEAN – Bermuda

**General**

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

**Relevant Standards**

### LATIN AMERICA AND THE CARIBBEAN – Bolivia

**General**

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

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

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

Drugs, Biologics, and Devices

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

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

LATIN AMERICA AND THE CARIBBEAN – Brazil

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

General

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

Relevant Standards
- Resolution CNS No. 370/07 on Registration and Accreditation or Renewal of Registration and Accreditation of CEP: http://conselho.saude.gov.br/resolucoes/2007/Reso370.doc

Last Updated: November 2021

**Drugs, Biologics, and Devices**

**Drugs and Biologics**

**Key Organizations**


**Relevant Standards**

- Law No. 9782/99 Defining the National Health Surveillance System: [http://www.planalto.gov.br/ccivil_03/leis/L9782.htm](http://www.planalto.gov.br/ccivil_03/leis/L9782.htm)
Manual for Submission of “Drug Clinical Development Dossier” (DDCM) (2017): http://portal.anvisa.gov.br/documents/33836/2492465/Manual+para+Submiss%C3%A3o+de+Dossi%C3%AA+de+Desenvolvimento+C%C3%ADnico+de+Medicamento+%28DDCM%29+e+Dossi%C3%AA+Espec%C3%ADfico+de+Ensaio+C%C3%ADnico+-+3%C2%A9+29e9c5b1-2942-4bb9-a4dd-4fccc6fceda3


Devices

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

Relevant Standards

Clinical Trial Registries

Key Organizations
- Brazilian Clinical Trials Registry: http://www.ensaiosclinicos.gov.br/

Relevant Standards
- FAQs: https://ensaiosclinicos.gov.br/faq

Research Injury

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

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

Social-Behavioral Research

Key Organizations


Relevant Standards


Privacy/Data Protection

Key Organizations


Relevant Standards

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

Key Organizations

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

Relevant Standards

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

Genetic Research

Key Organizations

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

Relevant Standards

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

 resolution RDC No. 29, 12 May 2008:  
 resolution RDC No.260, 21 December 2018: Regulation for Conducting Clinical Trials with Investigational Advanced Therapy Product in Brazil, and Makes Other Arrangements:  
 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:  

LATIN AMERICA AND THE CARIBBEAN – Chile

General

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

Relevant Standards
  - Law No. 20.584. 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
  - Supreme Decree No. 30/2013, modifying Decree No. 114 of 2010 and Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning Official Diary January 14, 2013: http://www.leychile.cl/Navegar?idNorma=1048008&

Drugs, Biologics, and Devices

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

Relevant Standards


### Research Injury

**Key Organizations**

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

**Relevant Standards**


### Privacy/Data Protection

**Key Organizations**

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

**Relevant Standards**


### Genetic Research

**Key Organizations**

- Ministry of Health: [http://www.minsal.cl](http://www.minsal.cl)
Relevant Standards


Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Health: [http://www.minsal.cl](http://www.minsal.cl)

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Colombia

General

Key Organization

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

Relevant Standards

Drugs, Biologics, and Devices

Drugs

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- Resolution 1403 of 2007 - Which determines the Pharmaceutical Service Management Model, adopts the Essential Conditions and Procedures Manual and establishes other provisions: [https://www.invima.gov.co/documents/20143/453029/Resoluci%C3%B3n+1403+de+2007.pdf/6b2e1ce1-bb34-e17f-03ef-34e35c126949](https://www.invima.gov.co/documents/20143/453029/Resoluci%C3%B3n+1403+de+2007.pdf/6b2e1ce1-bb34-e17f-03ef-34e35c126949)

- Decree 780 of 2016 - By which the Sole Regulatory Decree of the Health and Social Protection Sector is issued. Chapter 10 Drugstores and pharmaceutical service: [https://www.invima.gov.co/documents/20143/453029/Decreto+0780+de+2016.pdf/1a19484b-e3f1-f7f8-8b66-aaac81849a7a](https://www.invima.gov.co/documents/20143/453029/Decreto+0780+de+2016.pdf/1a19484b-e3f1-f7f8-8b66-aaac81849a7a)

- Resolution 839 of 2017 - By which Resolution 1995 of 1999 is amended: [https://www.invima.gov.co/documents/20143/453029/Resoluci%C3%B3n+839+de+2017.pdf/9b129af5-d943-fde8-78f7-0f07364753af?t=1540842229176](https://www.invima.gov.co/documents/20143/453029/Resoluci%C3%B3n+839+de+2017.pdf/9b129af5-d943-fde8-78f7-0f07364753af?t=1540842229176)

- Resolution 3100 of 2019 - By which the procedures and conditions for the registration of Health Service Providers and the authorization of health services are defined and the Health Service Provider Registration and Authorization Manual is adopted: [https://normograma.invima.gov.co/docs/resolucion_minsaludps_3100_2019.htm?q=resolucion+3100](https://normograma.invima.gov.co/docs/resolucion_minsaludps_3100_2019.htm?q=resolucion+3100)


- Circular 600-9915-15 - Research Ethics Committees October 2015: [https://www.invima.gov.co/documents/20143/453029/Circular_600-9915-15_Comit%C3%A9s_de_ethica_en_investigaci%C3%B3n_Octubre2015.pdf/1c5049a4-e2c2-6825-1aff-811b09c61e3f](https://www.invima.gov.co/documents/20143/453029/Circular_600-9915-15_Comit%C3%A9s_de_ethica_en_investigaci%C3%B3n_Octubre2015.pdf/1c5049a4-e2c2-6825-1aff-811b09c61e3f)


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

Circular 600-3950-17 - National Adverse Event Reporting May 2017: https://www.invima.gov.co/documents/20143/453029/Circular-Externa-600-3950-17.pdf/7f033df3-1c1f-c2a3-a6d3-6f75d1e29ae6


Exceptional clinical research measures applicable under the national contingency for COVID-19 to reduce risks to subjects participating in clinical trials: https://www.invima.gov.co/documents/20143/1251430/Circular+Medidas+exceptionales+investigaciones.pdf

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

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

**Devices**

**Key Organizations**

Relevant Standards

- Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapters I and III (1993):

Clinical Trial Registries

Key Organizations

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

Relevant Standards

- Publication of clinical studies with drugs in humans developed in Colombia 2014-2021. Consolidated clinical studies from 2014 - 2021:

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):

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- Constitution of Colombia, Article 15 (2003):
- Law 1581 of 2012: General Regimen of Protection of Personal Data:
- Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Article 8 (1993):
Human Biological Materials

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

Relevant Standards

Genetic Research

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

Relevant Standards

LATIN AMERICA AND THE CARIBBEAN – Costa Rica

General

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

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

Drugs, Biologics, and Devices

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

- Regulatory Law of Biomedical Research No. 9234 (2014):
  TC&nValor1=1&nValor2=77070&nValor3=96424&strTipM=TC
- Regulatory Decree NO. 39061-S (2016) on the Regulatory Law of Biomedical Research No. 39533-S:
  TC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC
- Reforms to the Regulatory Decree No. 39533-S (2016) Regulatory Law of Biomedical Research No. 9234:
  TC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC
- Requirements for Accreditation, various:
  https://www.ministeriodesalud.go.cr/conis/index.php/servicios/requisitos-de-creacion
- Good Practices for Biomedical Research, various:
  https://www.ministeriodesalud.go.cr/conis/index.php/servicios/buenas-practicas-en-investigacion-
  biomedica

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

LATIN AMERICA AND THE CARIBBEAN – Cuba

Drugs, Biologics, and Devices

Key Organizations

- Center for State Control of Medications: http://www.cecméd.com/medicinas

Relevant Standards

- Various: http://www.cecméd.com/ensayos-clinicos/autorizados

Clinical Trial Registries

Key Organizations

- Public Cuban Registry of Clinical Trials: https://rpcec.sld.cu/

LATIN AMERICA AND THE CARIBBEAN – Dominica

General

Key Organization

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Dominican Republic

General

Key Organization


Relevant Standards

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

LATIN AMERICA AND THE CARIBBEAN – Ecuador

General

Key Organization

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

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

Genetic Research

Key Organizations

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


Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – El Salvador

General

Key Organization

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

Relevant Standards


Drugs, Biologics, and Devices

Key Organizations

Relevant Standards

- Medication Law, Articles 29 and 66 (2012): 
- User’s Guide for the Application of Clinical Investigation Protocols: 
  http://www.medicamentos.gob.sv/index.php/es/servicios-m/descargables/ensayos-clinicos

LATIN AMERICA AND THE CARIBBEAN – Grenada

General

Key Organization

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

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Guyana

General

Key Organization


Relevant Standards

- Medical Research Involving Human Subjects Regulations (2007): 

LATIN AMERICA AND THE CARIBBEAN – Guatemala

General

Key Organization

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

Relevant Standards

- Ministerial Accords and Amendments, various: 
  https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/acuerdos
- Internal Regulations of the National Committee on Health Ethics (2018): 

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

- Clinical Trials, various: [https://medicamentos.mspas.gob.gt/index.php/formularios/formensayos](https://medicamentos.mspas.gob.gt/index.php/formularios/formensayos)

LATIN AMERICA AND THE CARIBBEAN – Haiti

**General**

**Key Organization**

**Relevant Standards**
- Internal Regulations (2010)

LATIN AMERICA AND THE CARIBBEAN – Honduras

**General**

**Key Organization**
- Secretariat of Health: [http://www.salud.gob.hn/](http://www.salud.gob.hn/)

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

**Drugs, Biologics, and Devices**

**Key Organizations**
- Secretariat of Health: [http://www.salud.gob.hn/](http://www.salud.gob.hn/)

**Relevant Standards**

**Human Biological Materials**

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

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Jamaica

General

Key Organization


Relevant Standards


Drugs, Biologics, and Devices

Key Organizations


Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Mexico

NOTE: For an overview of clinical research regulations in Mexico, see the ClinReg report: https://clinregs.niaid.nih.gov/country/mexico

General

Key Organization

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

Relevant Standards


**Drugs, Biologics, and Devices**

**Relevant Standards**

**Privacy/Data Protection**

**Key Organizations**

**Relevant Standards**
Human Biological Materials

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

Relevant Standards

Genetic Research

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

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

LATIN AMERICA AND THE CARIBBEAN – Nicaragua

General

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

Relevant Standards
Drugs, Biologics, and Devices

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

Relevant Standards
- Law of Medicines and Pharmacies, No. 292:
  http://legislacion.asamblea.gob.ni/Normaweb.nsf/($All)/10B9BC0F73CCA7FD062570A10057793D?OpenDocument
- Normative-064, Standard for the registration of medical devices:
  http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Normativa-064%E2%80%92%80%9CNorma-para-el-registro-de-dispositivos-m%C3%A9dicos%E2%80%92%80%9D/

Clinical Trial Registries

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

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

LATIN AMERICA AND THE CARIBBEAN – Panama

General

Key Organization
- Ministry of Health (MINSA): http://www.minsa.gob.pa/
- National Committee of Research Bioethics: https://cnbi.senacyt.gob.pa

Relevant Standards

Drugs, Biologics, and Devices

Relevant Standards
Privacy/Data Protection

Relevant Standards

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

Human Biological Materials

Relevant Standards


Embryos, Stem Cells, and Cloning

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Paraguay

General

Key Organization

- National Institute of Health, Research Ethics Committee: http://www.ins.gov.py/

Relevant Standards


Drugs, Biologics, and Devices

Key Organization


Relevant Standards

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

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

### General

**Key Organization**
- National Institute of Health: [http://www.ins.gob.pe/](http://www.ins.gob.pe/)

**Relevant Standards**

### Drugs, Biologics, and Devices

**Key Organization**
- National Directorate of Drugs and Medical Devices (MINSA): [www.digemid.minsa.gob.pe](http://www.digemid.minsa.gob.pe)

**Relevant Standards**
- Procedures Manual for Clinical Trials (2017)

### Clinical Trial Registries

**Key Organization**
- Peruvian Registry of Clinical Trials: [https://ensayosclinicos-repec.ins.gob.pe/](https://ensayosclinicos-repec.ins.gob.pe/)

**Relevant Standards**
- Various regulations: [https://ensayosclinicos-repec.ins.gob.pe/regulacion/normatividad-vigente](https://ensayosclinicos-repec.ins.gob.pe/regulacion/normatividad-vigente)

### Research Injury

**Key Organizations**
- National Institute of Health: [http://www.ins.gob.pe/](http://www.ins.gob.pe/)
Relevant Standards


Privacy/Data Protection

Key Organizations

- National Directorate of Drugs and Medical Devices: [www.digemid.minsa.gob.pe](http://www.digemid.minsa.gob.pe)

Relevant Standards

- Law for Electronic Medical Charts (2013): [http://elperuanolegal.blogspot.com/2013/05/ley-30024-ley-que-crea-el-registro.html](http://elperuanolegal.blogspot.com/2013/05/ley-30024-ley-que-crea-el-registro.html)

LATIN AMERICA AND THE CARIBBEAN – Saint Lucia

Drugs, Biologics, and Devices

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Trinidad and Tobago

General

Key Organization

- University of the West Indies (UWI), St. Augustine: [https://sta.uwi.edu/research/ethics.asp](https://sta.uwi.edu/research/ethics.asp)

Relevant Standards

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

LATIN AMERICA AND THE CARIBBEAN – Uruguay

General

Key Organization

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organization

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

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards


Human Biological Materials

Key Organizations

- Ministry of Public Health: http://www.msp.gub.uy/
Latin America and the Caribbean – Venezuela

General

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

Relevant Standards
- Resolution No. 48 (1998)
- IVIC, Legal Norms, various: https://www.ivic.gob.ve/institucion-2/normativa-legal-26

Drugs, Biologics, and Devices

Key Organization
- National Institute of Hygiene “Rafael Rangel”: http://www.inhrr.gob.ve/

Relevant Standards
- Medicines Act, Title III, Chapter II

Genetic Research

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

Relevant Standards
- Contract for Accessing Genetic Resources (2003)
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