International Compilation of Human Research Standards
2021 Edition

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

Asia/Pacific
ASIA/PACIFIC

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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 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 However, not all countries provided corroboration, so some of the information contain in this document may be outdated or incomplete (please see disclaimer below).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 Asia/Pacific. 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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ASIA/PACIFIC – Australia

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

### General

**Key Organizations**
- Australian Research Council (ARC): [http://www.arc.gov.au](http://www.arc.gov.au)

**Relevant Standards**

### Drugs, Biologics, and Devices

#### Drugs

**Key Organizations**

**Relevant Standards**

#### Devices

**Key Organizations**
Relevant Standards


Clinical Trials Registry

Key Organizations

- National Health and Medical Research Council and the Department of Industry, Innovation, and Science: https://www.australianclinicaltrials.gov.au
- Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/

Relevant Standards


Research Injury

Key Organizations

- Medicines Australia: https://medicinesaustralia.com.au
- National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au

Relevant Standards


Social-Behavioral Research

Key Organizations

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

Relevant Standards

Privacy/Data Protection

**Key Organizations**

**Relevant Standards**
- Privacy in Australian States and Territories: https://www.oaic.gov.au/privacy/privacy-in-your-state

Human Biological Materials

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

**Key Organizations**
- National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/

**Relevant Standards**

Genetic Research

**Key Organizations**
- National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/

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

Key Organizations

Relevant Standards

ASIA/PACIFIC – Bangladesh

General

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

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

Drugs, Biologics, and Devices

Key Organizations

Relevant Standards
- The Drugs Act (1964)
### Human Biological Materials

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

**Relevant Standards**

### ASIA/PACIFIC – China, People’s Republic of

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

**General**

**Key Organizations**

**Relevant Standards**

### Drugs, Biologics, and Devices

#### Drugs

**Key Organizations**

**Relevant Standards**


Interim Guidelines on International Multi-Regional Drug Clinical Trials (2015)


**Devices**

**Key Organizations**


**Relevant Standards**


- Templates for Medical Device Clinical Trials – Ethical Application and Approval (2016):
  1. Ethical Review Application and Review Form
  2. Informed Consent Form
  3. CRF Template
  4. Protocol Template
  5. Clinical Trial Report Template
  6. Required Documents List for Archiving
Clinical Trial Registries

Key Organizations
- Chinese Clinical Trial Registry: http://www.chictr.org.cn/enIndex.aspx

Relevant Standards

Privacy/Data Protection

Mainland

Key Organizations
- Ministry of Industry and Information Technology of People’s Republic of China

Relevant Standards

Hong Kong

Key Organizations
- Privacy Commissioner for Personal Data, Hong Kong: http://www.pcpd.org.hk

Relevant Standards

Research Injury

Key Organizations
- National Medical Products Administration: http://www.nmpa.gov.cn
Relevant Standards

- Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2016), Articles 18.5, 20.8, 36.6, and 37: [http://www.gov.cn/gongbao/content/2017/content_5227817.htm](http://www.gov.cn/gongbao/content/2017/content_5227817.htm)
- Guideline on Vaccine Clinical Trials, Part 6 (2004)
- Guideline on Ethical Review of Drug Clinical Trials, Appendix 1, Section 6.10 (2010)

Genetic Research

Key Organizations

- Ministry of Science and Technology of the People’s Republic of China (MOST): [http://www.most.cn/eng/](http://www.most.cn/eng/)

Relevant Standards


Embryos, Stem Cells, and Cloning

Mainland

Key Organizations

- Ministry of Science and Technology of the People’s Republic of China (MOST): [http://www.most.cn/eng/](http://www.most.cn/eng/)

Relevant Standards

- Administrative Measures for Clinical Application of Medical Technology (2018)


**Hong Kong**

**Key Organizations**


**Relevant Standards**


**Asia/Pacific – India**

**NOTE:** For an overview of the clinical research regulations in India, see the ClinRegs report: [http://clinregs.niaid.nih.gov/single_country.php?c_id=100](http://clinregs.niaid.nih.gov/single_country.php?c_id=100)

**General**

**Key Organizations**

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

**Relevant Standards**


**Drugs, Biologics, and Devices**

**Drugs**

**Key Organizations**


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

**Relevant Standards**


**Devices**

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

**Relevant Standards**
- CDSCO, Medical Devices Rules, 2017 General Statutory Rules 78(E) [English from page 146]: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzMzNg== (English from page 143)

**Clinical Trial Registries**

**Key Organizations**
- Indian Council of Medical Research (ICMR)

**Relevant Standards**
- Clinical Trials Registry – India: http://ctri.nic.in/
- Clinical Trials Registry – India, FAQs: http://ctri.nic.in/Clinicaltrials/faq.php

**Research Injury**

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

**Relevant Standards**
Social-Behavioral Research

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

**Relevant Standards**

Privacy/Data Protection

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

**Relevant Standards**
- ICMR, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Sections 1, 2, 4, 5, 6, 7, 9, 10, 11 and 12 (2017): [https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)

Human Biological Materials

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

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

Genetic Research

**Key Organizations**
- Department of Biotechnology (DBT): [https://dbtindia.gov.in/](https://dbtindia.gov.in/)
- Indian Council of Medical Research (ICMR): [http://www.icmr.nic.in/](http://www.icmr.nic.in/)

**Relevant Standards**
- DBT, Environmental Protection Act (1986)
- DBT, Recombinant DNA Safety Guidelines (1990)
Embryos, Stem Cells, and Cloning

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

Relevant Standards
- DBT, Biosafety Programme, Guidelines, Rules, and Regulations: [https://dbtindia.gov.in/regulations-guidelines/regulations/biosafety-programme](https://dbtindia.gov.in/regulations-guidelines/regulations/biosafety-programme)

ASIA/PACIFIC – Indonesia

General

Key Organizations

Relevant Standards
- Indonesian Health Act No. 23/1992 Section on Health Research, Article 69
- Regulation No. 39/1995 on Health Research and Development
- Presidential Decree No. 100/1993: Research by Foreigners

Drugs, Biologics, and Devices

Key Organizations
- National Agency of Drug and Food Control: [www.pom.go.id](http://www.pom.go.id)

Relevant Standards
- Ministry of Health Decree No. 56/2000: Guidelines on Clinical Trials of Traditional Drugs
- Guidelines on Good Clinical Practice (2001)
Human Biological Materials

Relevant Standards
- National Guidelines on Use of Stored Biological Materials (2005)

ASIA/PACIFIC – Japan

General

Key Organizations

Relevant Standards

Drugs, Biologics, and Devices

Drugs

Key Organizations
- Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html

Relevant Standards

Devices

Key Organizations
- Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html

Relevant Standards
- Ministerial Ordinance on Good Clinical Practice for Medical Devices (2016): https://www.mhlw.go.jp/web/t_doc?dataId=81aa6871&dataType=0&pageNo=1
Clinical Trial Registries

Key Organizations
- Japan Registry of Clinical Trials: https://jrct.niph.go.jp/

Relevant Standards
- NIPH Clinical Trials Search: https://rctportal.niph.go.jp/en/

Research Injury

Key Organizations

Relevant Standards
- Ethics Guidelines for Medical and Health Research Involving Human Subjects, Chapter 2, 3, and No. 6 (2021): https://www.mhlw.go.jp/content/000757566.pdf

Privacy/Data Protection

Key Organizations

Relevant Standards
Human Biological Materials

**Key Organizations**

**Relevant Standards**

Genetic Research

**Key Organizations**

**Relevant Standards**
- Genetic recombination experiments: [https://www.lifescience.mext.go.jp/bioethics/anzen.html#kumikae](https://www.lifescience.mext.go.jp/bioethics/anzen.html#kumikae)
- Genome editing technology: [https://www.lifescience.mext.go.jp/bioethics/anzen.html#chiryo](https://www.lifescience.mext.go.jp/bioethics/anzen.html#chiryo)

Embryos, Stem Cells, and Cloning

**Key Organizations**

**Relevant Standards**


Rules for Enforcement of Act on Safety of Regenerative Medicine (2018): [https://www.mhlw.go.jp/content/000452630.pdf](https://www.mhlw.go.jp/content/000452630.pdf)


Fundamental Philosophy on Handling of Human Embryo (2004)


ASIA/PACIFIC – Kazakhstan


**General**

**Key Organizations**


**Relevant Standards**

- Local Ethics Committees: Policy, Rules and Procedures (2014)
- Guidelines on Ethics in Biomedical Research (2015)
Drugs, Biologics, and Devices

Key Organizations

Relevant Standards
- Order of the MHSD of the RK Dated 12.11.2009 No. 697 on the Approval of Regulations on the Medical-Biological Experiments, Preclinical (Non-Clinical) and Clinical Trials
- Order of the MHSD of the RK dated 19.11.2009 No. 744 on the Approval of Regulations on the Conduct of Clinical Trials and/or Trials on Pharmaceutical and Drug Products, Medical Devices, and Medical Equipment
- Order of the MHSD Dated 20.05.2014 No.272 on the Approval of Regulations on the Implementation of the New Methods of Diagnostic, Treatment, and Rehabilitation

Privacy/Data Protection

Key Organizations

Relevant Standards

ASIA/PACIFIC – Kyrgyzstan

General

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

Relevant Standards
- Law on Health Protection of the Kyrgyz Republic (Sept. 1, 2005, No. 6), Articles 34 and 72: http://www.pharm.kg/ru/legislation
- Code of Professional Ethics of Medical Worker of the Kyrgyz Republic (2004)
- Code of Administrative Responsibility of the Kyrgyz Republic №114 from 04.08.1998г. (Updated June 11, 2008 N 115 and June 23, 2008 N 136) Chapters 7 and 10
Drugs, Biologics, and Devices

Key Organizations
- Ministry of Health, Department of Drugs and Medical Devices (DDMD): [http://www.pharm.kg](http://www.pharm.kg)
- Ministry of Health, National Bioethics Committee
- Pharmaceutical Union of Kyrgyzstan, Ethics Committee

Relevant Standards

Research Injury

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

Relevant Standards

Human Biological Materials

Key Organizations
- Ministry of Health, Department of Drug and Medical Devices Provision: [http://www.pharm.kg](http://www.pharm.kg)
- Ministry of Health, National Bioethics Committee

Relevant Standards
# Social-Behavioral Research

**Key Organizations**


**Relevant Standards**


# Privacy/Data Protection

**Key Organizations**

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

**Relevant Standards**


# ASIA/PACIFIC – Malaysia

## General

**Key Organizations**


**Relevant Standards**


**Drugs, Biologics, and Devices**

**Key Organizations**

- Medical Device Authority (MDA), Ministry of Health Malaysia: https://portal.mda.gov.my/
- Clinical Research Malaysia (CRM), Ministry of Health: https://clinicalresearch.my/

**Relevant Standards**


Clinical Trial Registries

Key Organizations

Relevant Standards

Research Injury

Key Organizations
- Attorney General’s Chambers of Malaysia (AGC)
- Department of Occupational Safety and Health (DOSH), Ministry of Human Resources: https://www.dosh.gov.my/index.php/about-us/dosh-profile

Relevant Standards

Social-Behavioral Research

Key Organizations

Relevant Standards
Privacy/Data Protection

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

Relevant Standards

Human Biological Materials

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

Relevant Standards

Genetic Research

Key Organizations
- Laws of Malaysia. Attorney General’s Chambers of Malaysia (AGC)
- Ministry of Energy and Natural Resources: https://www.mybis.gov.my/pb/4497

Relevant Standards
- Biosafety (Approval and Notification) Regulations 2010: http://bch.cbd.int/database/attachment/?id=17640
- Various Guidelines for Institutional Biosafety Committees: https://umresearch.um.edu.my/ibbc-policy-amp-guidelines
### Embryos, Stem Cells, and Cloning

#### Key Organizations
- Ministry of Health, National Stem Cell Research and Ethics Subcommittee (NSCERT)

#### Relevant Standards

### ASIA/PACIFIC – Myanmar

#### General

**Key Organizations**
- Ministry of Health, Department of Medical Research (DMR): [https://www.dmr.gov.mm/](https://www.dmr.gov.mm/)
- Ministry of Health National Ethics Committee on Clinical Research: [https://www.moh.gov.mm](https://www.moh.gov.mm)

**Relevant Standards**
- DMR, Guideline for Submission to Ethics Review Committee (2016)
### Drugs, Biologics, and Devices

**Key Organizations**

**Relevant Standards**
- National Drug Law (1992)

### Human Biological Materials

**Relevant Standards**

### ASIA/PACIFIC – Nepal

**General**

**Key Organizations**

**Relevant Standards**

### ASIA/PACIFIC – New Zealand

**NOTE:** All New Zealand acts, bills, and regulations can be found here: [http://www.legislation.govt.nz/](http://www.legislation.govt.nz/)

**General**

**Key Organizations**
International Compilation of Human Research Standards
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- Health and Disability Ethics Committees: http://www.ethics.health.govt.nz/

Relevant Standards
- Health Research Council Act 1990, Sections 24 and 25
- New Zealand Bill of Rights Act, Article 10 (1990)
- Health and Disability Commissioner Act 1994
- New Zealand Public Health and Disability Act 2000, Section 16
- Accident Compensation Act 2001
- HRC, The Role of Ethics (scroll down to Specific Considerations), various: http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval

Drugs, Biologics, and Devices

Drugs

Key Organizations
- New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz
- Medicines New Zealand: http://www.medicinesnz.co.nz/
- Health Research Council (HRC), Standing Committee on Therapeutic Trials: http://www.hrc.govt.nz/about-us/committees/standing-committee-therapeutic-trials-scott

Relevant Standards
- Medicines New Zealand, Guidelines on Clinical Trials, Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial (2015)
Devices

Key Organizations
- New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz

Relevant Standards
- Conducting Medical Device Clinical Trials in New Zealand, various: http://medsafe.govt.nz/regulatory/DevicesNew/13ConductingClinicalTrials.asp

Clinical Trial Registries

Key Organizations
- Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/

Relevant Standards

Privacy/Data Protection

Key Organizations
- Privacy Commissioner: http://www.privacy.org.nz/

Relevant Standards
- Public Records Act (2005)
- Privacy Act 1993 (2012)

Human Biological Materials

Key Organizations
- Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval
- Te Puni Kokiri (TPK): http://www.tpk.govt.nz/

Relevant Standards
- Health Act 1956 (2012)
- Human Tissue Act 2008

### Genetic Research

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

#### Relevant Standards

### Embryos, Stem Cells, and Cloning

#### Key Organizations

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

### ASIA/PACIFIC – Pakistan

#### General

#### Key Organizations

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### Drugs, Biologics, and Devices

#### Key Organizations

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### Human Biological Materials

**Key Organizations**

**Relevant Standards**

### Embryos, Stem Cells, and Cloning

**Key Organizations**

**Relevant Standards**

### ASIA/PACIFIC – Philippines

**General**

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

**Relevant Standards**

### Drugs, Biologics, and Devices

**Drugs**

**Key Organizations**
Relevant Standards

- FDA, Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products (Administrative Order No. 47-a) (2001)
- FDA, Guidelines: Regulation of Clinical Trials in the Philippines: http://www.pcrp.org.ph/pdf/GuidelinesversionLR.PDF
- FDA, Circular 2015-026: Adoption of the ICH Harmonized Tripartite Guideline, Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products Q5C

Devices

Key Organizations

- Food and Drug Administration: http://www.fda.gov.ph/

Relevant Standards

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

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards

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

Social-Behavioral Research

Key Organizations

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


Privacy/Data Protection

Relevant Standards


Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards


ASIA/PACIFIC – Singapore

General

Key Organizations


Relevant Standards


Drugs, Biologics, and Devices

Drugs

Key Organizations

- Health Sciences Authority of Singapore (HSA): https://www.hsa.gov.sg/
Relevant Standards


Research Injury

Key Organizations

- Health Sciences Authority: http://www.hsa.gov.sg

Relevant Standards

Privacy/Data Protection

Key Organizations

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Human Biological Materials

Key Organizations

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Genetic Research

Key Organizations

Relevant Standards
Embryos, Stem Cells, and Cloning

Key Organizations

Relevant Standards

ASIA/PACIFIC – South Korea

General

Key Organizations

Relevant Standards

Drugs, Biologics, and Devices

Key Organizations

Relevant Standards
- Pharmaceutical Affairs Act No. 16250 (2019.01.15): https://www.law.go.kr/LSW/eng/engLsSc.do?menuId=2&section=lawNm&query=%EC%95%BD%EC%82%AC%EB%B2%95&x=0&y=0#liBgcolor15
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- Act on In Vitro Diagnostic Medical Devices Act No. 16433 (2019.05.01):
  https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72621&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1

- Enforcement Decree of the Medical Device Act No. 1580 (2019.12.23):
  https://www.law.go.kr/LSW/eng/engLsSc.do?query=medical+device+act&menuId=2&section=lawNm&y=20&x=23#liBgcolor8

- Regulations for Clinical Trial Personnel Education and Certification for the Educational Institution Notice No. 2019-3 (2019.01.17):

- Regulation on Approval for Investigational New Drug Application of Drugs, Notice No. 2021-12 (2021.02.25):
  https://www.law.go.kr/행정규칙/의약품임상시험계획승인에관한규정/(2021-12,20210225)

  https://www.law.go.kr/행정규칙/의료기기임상시험계획승인에관한규정/(2019-33,20190430)

- Regulation for Medical Device Approvals, Notifications and Reviews No. 2021-35 (2021.04.22):
  https://www.law.go.kr/행정규칙/의료기기허가·신고·심사등에관한규정/(2021-35,20210422)

- Regulation on Medical Device Re-examination No. 2020-29 (2020.05.01):
  https://www.law.go.kr/행정규칙/의료기기재심사에관한규정/(2020-29,20200501)

- Guidelines on Human Research Protection Program 0053-01 (2014.3) 2017.5.31 고시:
  https://nedrug.mfds.go.kr/bbs/38/65

- Bioethics and Safety Act No. 16372 (2019.04.23):
  https://www.law.go.kr/LSW/IsLsInfoP.do?IsiSeq=208465&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000

- Enforcement Decree of Pharmaceutical Affairs Act No. 30141 (2019.10.22):
  https://www.law.go.kr/LSW/IsLsInfoP.do?IsiSeq=210861&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000

  https://www.law.go.kr/법령/ 생명윤리및안전에관한법률시행규칙

### Clinical Trial Registries

#### Key Organizations

- Korea Centers for Disease Control and Prevention (KCDC), Clinical Research Information Service:
  https://cris.nih.go.kr/cris/index/index.do

- Ministry of Food and Drug Safety (MFDS): https://nedrug.mfds.go.kr/searchClinic
InternationalCompilationofHumanResearchStandards
2021Edition

Relevant Standards
 Regulation on Safety of Medicinal Products, No.1576 (2019.12.06):
  https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=71487&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=2

Research Injury

Key Organizations
 Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng/index.do

Relevant Standards
 Pharmaceutical Affairs Act No.16250 (2019.01.15):
 Regulation on Safety of Pharmaceuticals, etc. No. 1576 (2019.12.12.):
  https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=71487&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=2
 Enforcement Rule of the Medical Devices Act No.1580 (2019.12.23.):
 Guidelines for Clinical Trial Indemnity and Its Process 0052-03 (2021.06.21.):
  https://www.mfds.go.kr/brd/m_1060/view.do?seq=14857&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=103
 Guidance for Sponsors; Safety Reporting Requirements 0785-02 (2020.10.30.):
  https://www.mfds.go.kr/brd/m_1060/view.do?seq=14669&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=4

Social-Behavioral Research

Key Organizations
 Ministry of the Interior and Safety: https://www.mois.go.kr/frt/a01/frtMain.do

Relevant Standards
 Bioethics and Safety Act No.16372(2019.04.):
 Enforcement Decree of the Bioethics and Safety Act No. 30141(2019.10.):
  https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙
 Personal Information Protection Act No.16930 (2020.02.):
 Enforcement Decree of the Personal Information Protection Act No.30892 (2020.08.):
Privacy/Data Protection

Key Organizations
- Ministry of the Interior and Safety (MOIS): http://www.mois.go.kr/eng/a01/engMain.do

Relevant Standards
- Standard Personal Information Protection Guidelines (2020.08.11): https://www.law.go.kr/admRulSc.do?menuId=5&subMenuId=41&tabMenuId=183&query=%ED%91%9C%EC%A4%80%EA%B0%9C%EC%9D%B8%EC%A0%95%EB%B3%B4%EB%B3%B4%ED%98%B8%EC%A7%80%EC%B9%A8#liBgcolor0
- Criteria for ensuring the Safety of Personal Information (2020.08.11): https://www.law.go.kr/admRulSc.do?menuId=5&subMenuId=41&tabMenuId=183&query=%ED%91%9C%EC%A4%80%20%EA%B0%9C%EC%9D%B8%EC%A0%95%EB%B3%B4%20%EB%98%B8%EC%A7%80%EC%B9%A8#liBgcolor7

Human Biological Materials

Key Organizations

Relevant Standards
- Guidelines on Biological material management in clinical trial (2018.08): https://www.mfds.go.kr/brd/m_218/view.do?seq=33339&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=7

### Genetic Research

**Key Organizations**

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### Embryos, Stem Cells, and Cloning

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**Relevant Standards**


**ASIA/PACIFIC – Sri Lanka**

**Drugs, Biologics, and Devices**

**Key Organizations**


**Relevant Standards**


**Clinical Trial Registries**

**Key Organizations**

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

**Relevant Standards**

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

**ASIA/PACIFIC – Taiwan**

**General**

**Key Organizations**


**Relevant Standards**


### Drugs, Biologics, and Devices

**Key Organizations**
- Taiwan Food and Drug Administration (FDA): https://www.fda.gov.tw/ENG/

**Relevant Standards**
- Regulations for Governing the Management of Medical Devices (2014)

### Research Injury

**Key Organizations**
- Food and Drug Administration (FDA), MOHW: https://www.fda.gov.tw/ENG/

**Relevant Standards**

### Social-Behavioral Research

**Key Organizations**
# Privacy/Data Protection

## Key Organizations

## Relevant Standards

# Human Biological Materials

## Key Organizations

## Relevant Standards
- Guidelines for the Collection and Use of Human Specimens for Research (2006) (Chinese): [http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1598&chk=6056f7dd-eb0a-48bf-ae7e-8a2a5875e6e0&mid=46&name=fdContent](http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1598&chk=6056f7dd-eb0a-48bf-ae7e-8a2a5875e6e0&mid=46&name=fdContent)

# Genetic Research

## Key Organizations
- Food and Drug Administration (FDA): [https://www.fda.gov.tw/ENG/](https://www.fda.gov.tw/ENG/)

## Relevant Standards

### Embryos, Stem Cells, and Cloning

#### Key Organizations

#### Relevant Standards

### ASIA/PACIFIC – Tajikistan


#### General

#### Relevant Standards
- Order of the Ministry of Public Health of the Republic Tajikistan of 10 March, 2005 No. 118: About the Assertion of the Normative Documents of Republic Committee on Medical Ethics

### ASIA/PACIFIC – Thailand


#### General

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

- NCRT, Guidance for Foreign researcher Conducting Research in Thailand, various:  
- MCT, Rule of the Medical Council on the Observance of Medical Ethics (1983):  
- FERCIT, Ethical Guidelines for Research on Human Subject in Thailand (2007):  

Drugs, Biologics, and Devices

Drugs

Key Organizations
- Food and Drug Administration, Drug Control Division:  
  https://www.fda.moph.go.th/sites/fda_en/Pages/Main.aspx
- Medical Council of Thailand (MCT):  
  https://tmc.or.th/En/

Relevant Standards
- Consumer Protection Act (2007)
- MCT, Acts and Rules, various:  
  https://tmc.or.th/En/act_rules_en.php

Devices

Key Organizations
- Food and Drug Administration, Medical Device Control Division:  
  https://www.fda.moph.go.th/sites/fda_en/Pages/Main.aspx

Relevant Standards
- 1988 Medical Device Act
- Laws and Regulations, various:
  https://www.fda.moph.go.th/sites/FDA_EN/SitePages/Medical.aspx?IDitem=LawsAndRegulations

Clinical Trial Registries

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

Relevant Standards
- FAQs:
  http://www.clinicaltrials.in.th/index.php?meun=home&smenu=4&task=home&task1=openpage&task2=view&topid=4
Privacy/Data Protection

Key Organizations


Relevant Standards


ASIA/PACIFIC – Uzbekistan

General

Key Organizations

- Ministry of Health: [https://ssv.uz/en](https://ssv.uz/en)

Relevant Standards

- Constitution of Republic of Uzbekistan, Articles 24, 26, 40, 44 (1992)

Drugs, Biologics, and Devices

Key Organizations

- Center for Expertise and standardization of medicines, medical devices and medical equipment: [http://www.minzdrav.uz](http://www.minzdrav.uz)
- Ministry of Health, National Ethics Committee
- Scientific Boards of Medical Institutes

Relevant Standards

- Law on Drugs and Pharmaceutical Activity (1997)
- Law on Narcotic and Psychoactive Drugs (2000)
- Guidelines on Conducting Clinical Trials and Determining Clinical Sites (2001)
- National Standard of Uzbekistan: Good Clinical Practice (2013)
Human Biological Materials

Key Organizations

- Ministry of Health, Pharmacological Committee of the Central Department for Quality Control of Pharmaceuticals and Medical Equipment: https://uzpharm-control.uz/
- Ministry of Health, National Ethics Committee
- Scientific Boards of Medical Institutes

Relevant Standards

- Guidelines on Conducting Clinical Trials and Determining Clinical Sites (2001)
- National Standard of Uzbekistan: Good Clinical Practice (2013)

Asia/Pacific – Vietnam


General

Key Organizations


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