

# 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)

## Asia/Pacific



Office for  
Human Research  
Protections

*International Compilation of Human Research Standards  
2024 Edition*

## **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 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].”

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**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](mailto:OHRP-Edu@hhs.gov).

**DISCLAIMER**

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or 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.

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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

- National Health and Medical Research Council (NHMRC): <http://www.nhmrc.gov.au/>
- Australian Research Council (ARC): <http://www.arc.gov.au>
- Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS): <http://aiatsis.gov.au/>

#### Relevant Standards

- National Health and Medical Research Council Act 1992 (2014): <http://www.comlaw.gov.au/Details/C2014C00364>
- National Health and Medical Research Regulation 2016: <https://www.legislation.gov.au/Details/F2016L00682>
- NHMRC, Ethical guidelines for research with Aboriginal and Torres Strait Islander Peoples (2018): <https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-and-torres-strait-islander-peoples>
- NHMRC, Australian Code for the Responsible Conduct of Research (2018): <https://nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>
- NHMRC, National Statement on Ethical Conduct in Human Research, 2007 (2018): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>
- Australian States and Territories, National Mutual Acceptance of Scientific and Ethical Review of Multi-Centre Human Research: <https://www.safetyandquality.gov.au/our-work/health-and-human-research/national-mutual-acceptance-scheme-ethical-and-scientific-review-multi-centre-research>
- AIATSIS, Code of Ethics for Aboriginal and Torres Strait Islander Research (The AIATSIS Code) and Associated Guidance for Applying It: [AIATSIS Code of Ethics and Guidance](#)

### Drugs, Biologics, and Devices

#### Key Organizations

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

#### Relevant Standards

##### Drugs

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

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### **Devices**

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

## **Clinical Trials Registry**

### **Key Organizations**

- Australian Clinical Trials: <https://www.australianclinicaltrials.gov.au/>
- Australian New Zealand Clinical Trials Registry (ANZCTR): <http://www.anzctr.org.au/>

### **Relevant Standards**

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

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

- TGA, Guidance on Good Clinical Practice (CPMP/ICH-135/95). (2018): <https://www.tga.gov.au/publication/note-guidance-good-clinical-practice>
- Medicines Australia, Indemnity & Compensation Guidelines: <https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/>
- NHMRC, National Statement on Ethical Conduct in Human Research. Paragraphs 5.1.38 and 5.1.39 (2018): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>

## **Social-Behavioral Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

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

## Human Biological Materials

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

### Key Organizations

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

### Relevant Standards

- NHMRC, National Statement on Ethical Conduct in Human Research, Chapter 3.2 (2023): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>
- TGA, Australian Regulatory Guidelines for Biologicals (2017): <http://www.tga.gov.au/industry/biologicals-argb.htm>

## Genetic Research

### Key Organizations

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

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### **Relevant Standards**

- Gene Technology Act 2000 (2016): <https://www.legislation.gov.au/Details/C2016C00792>
- Gene Technology Regulations 2001 (2016): <https://www.legislation.gov.au/Details/F2016C00615>
- NHMRC, National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2023): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>

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

### **Key Organizations**

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

### **Relevant Standards**

- Prohibition of Human Cloning for Reproduction Act 2002 (2008): <http://www.comlaw.gov.au/Details/C2008C00694>
- Research Involving Human Embryos Act 2002 (2014): <http://www.comlaw.gov.au/Details/C2014C00605>
- Research Involving Human Embryos Regulations (2017): <https://www.legislation.gov.au/Details/F2017L01213>
- NHMRC, National Statement on Ethical Conduct in Human Research, Chapter 3.2 (2023): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>
- NHMRC, Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2017): <https://nhmrc.gov.au/about-us/publications/ethical-guidelines-use-assisted-reproductive-technology>

## **ASIA/PACIFIC – Bangladesh**

### **General**

#### **Key Organizations**

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

#### **Relevant Standards**

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

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

#### **Key Organizations**

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



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### Relevant Standards

- The Drugs Act (1964)
- Drugs (Control) Ordinance 1982, Ordinance No. VIII:  
<http://bdlaws.minlaw.gov.bd/act-623.html>
- Good Clinical Practice (GCP) Guidelines: <http://www.dgdagov.info/index.php/information-center/good-clinical-practice-gcp>

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

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

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

*NOTE: For an overview of clinical research regulations in China, see the ClinRegs report:*  
<https://clinregs.niaid.nih.gov/country/china>

## General

### Key Organizations

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

### Relevant Standards

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

## Drugs, Biologics, and Devices

### Key Organizations

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

### **Relevant Standards**

- National Medical Products Administration, Laws and Regulations, Various: [https://english.nmpa.gov.cn/lawsandregulations\\_3.html](https://english.nmpa.gov.cn/lawsandregulations_3.html)
- National Medical Products Administration, Regulatory Information, Various: <https://english.nmpa.gov.cn/regulatoryinformation.html>
- Provisions for Adverse Drug Reaction Reporting and Monitoring, Decree No. 81 (2011): [http://english.nmpa.gov.cn/2019-12/14/c\\_432227.htm](http://english.nmpa.gov.cn/2019-12/14/c_432227.htm)
- Administrative Measures for the Signing and Issuing of Biological Product (2017): <http://www.nmpa.gov.cn/WS04/CL2077/300708.html>
- Guidelines on Ethical Review of Drug Clinical Trials, No. 436 (2010): [http://www.gov.cn/gzdt/2010-11/08/content\\_1740976.htm](http://www.gov.cn/gzdt/2010-11/08/content_1740976.htm)

## **Clinical Trial Registries**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Privacy/Data Protection**

### ***Mainland***

#### **Key Organizations**

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

#### **Relevant Standards**

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

### ***Hong Kong***

#### **Key Organizations**

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

### **Relevant Standards**

- Personal Data (Privacy) Ordinance (2018):
- <https://www.elegislation.gov.hk/hk/cap486!en-zh-Hant-HK.pdf?FROMCAPINDEX=Y>
- Code of Practice on the Identity Card Number and Other Personal Identifiers (2016):  
[https://www.pcpd.org.hk/english/data\\_privacy\\_law/code\\_of\\_practices/files/picode\\_en.pdf](https://www.pcpd.org.hk/english/data_privacy_law/code_of_practices/files/picode_en.pdf)
- Code of Practice on Human Resource Management (2016):  
[https://main.icmr.nic.in/sites/default/files/guidelines/guidelines\\_GTP.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/guidelines_GTP.pdf)

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

- Tort Liability law of the People's Republic of China, Chapter 7 (2009):  
[http://www.gov.cn/flfg/2009-12/26/content\\_1497435.htm](http://www.gov.cn/flfg/2009-12/26/content_1497435.htm)
- National Medical Products Administration, Laws and Regulations, Various:  
[https://english.nmpa.gov.cn/lawsandregulations\\_3.html](https://english.nmpa.gov.cn/lawsandregulations_3.html)
- National Medical Products Administration, Regulatory Information, Various:  
<https://english.nmpa.gov.cn/regulatoryinformation.html>
- Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2016), Articles 18.5, 20.8, 36.6, and 37: [http://www.gov.cn/gongbao/content/2017/content\\_5227817.htm](http://www.gov.cn/gongbao/content/2017/content_5227817.htm)

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

- People's Republic of China Human Genetic Resources Management Regulations (2019):  
[http://www.gov.cn/zhengce/content/2019-06/10/content\\_5398829.htm](http://www.gov.cn/zhengce/content/2019-06/10/content_5398829.htm)
- Service Guidelines for the Collection, Selling, Export. and Admission Application of Human Genetic Resources (2015): [http://www.most.gov.cn/tztg/201507/t20150703\\_120547.htm](http://www.most.gov.cn/tztg/201507/t20150703_120547.htm)

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

### *Mainland*

### **Key Organizations**

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

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

### **Relevant Standards**

- Ethical Principles and Conduct Norms for Human Assisted Reproductive Technologies (2003)
- Administrative Measures for Clinical Application of Medical Technology (2018)
- Interim Measures for the Administrative Measures of Stem Cell Clinical Research (2015): <http://www.nmpa.gov.cn/WS04/CL2077/300673.html>
- Ethical Guidelines for Research on Human Embryo Stem Cells (2003): [http://www.most.gov.cn/fggw/zfwj/zfwj2003/200512/t20051214\\_54948.htm](http://www.most.gov.cn/fggw/zfwj/zfwj2003/200512/t20051214_54948.htm)
- Interim Guidelines for the Quality Control of Stem Cell Preparations and Preclinical Research (2015): <http://www.nmpa.gov.cn/WS04/CL2196/324124.html>

### **Hong Kong**

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **ASIA/PACIFIC – India**

*NOTE: For an overview of the clinical research regulations in India, see the ClinRegs report:*  
<https://clinregs.niaid.nih.gov/country/india>

### **General**

#### **Key Organizations**

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

#### **Relevant Standards**

- ICMR, Guidelines, Various (scroll down to “Ethics”): <https://main.icmr.nic.in/content/guidelines-0>
- National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During Covid-19 Pandemic: [https://ethics.ncdirindia.org/asset/pdf/EC\\_Guidance\\_COVID19.pdf](https://ethics.ncdirindia.org/asset/pdf/EC_Guidance_COVID19.pdf)
- DHR, National Ethics Committee Registry for Biomedical and Health Research: <https://naitik.gov.in/DHR/Homepage#>

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

#### **Key Organizations**

- Central Drugs Standard Control Organization (CDSCO), Office of Drugs Controller General of India (DCGI): <https://cdsco.gov.in/opencms/opencms/en/>

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

### **Relevant Standards**

#### ***Drugs***

- CDSCO, Drugs and Cosmetics Act (1940 amended up to 31st December, 2016): [Drugs and Cosmetics Act \(page 584\)](#)
- CDSCO, New Drugs and Clinical Trials Rules (2019): [New Drugs and Clinical Trials Rules, 2019](#) (English from page 147)
- CDSCO, Good Clinical Practice Guidelines for Clinical Research in India (2001): <https://rgcb.res.in/documents/Good-Clinical-Practice-Guideline.pdf>
- ICMR Guidelines for Good Clinical Laboratory Practices (GCLP) (2021): [https://main.icmr.nic.in/sites/default/files/upload\\_documents/GCLP\\_Guidelines\\_2020\\_Final.pdf](https://main.icmr.nic.in/sites/default/files/upload_documents/GCLP_Guidelines_2020_Final.pdf)
- ICMR, Guidelines, Various (scroll down to “Ethics”): <https://main.icmr.nic.in/content/guidelines-0>

#### ***Devices***

- CDSCO, Medical Devices Rules, 2017 General Statutory Rules 78(E) (English from page 143): [Medical Devices Rules, 2017](#)
- ICMR, National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 7.7 (2017): [https://main.icmr.nic.in/sites/default/files/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)

### **Clinical Trial Registries**

#### **Key Organizations**

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

#### **Relevant Standards**

- Clinical Trials Registry – India: <http://ctri.nic.in/>
- Clinical Trials Registry – India, FAQs: <http://ctri.nic.in/Clinicaltrials/faq.php>

### **Research Injury**

#### **Key Organizations**

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

#### **Relevant Standards**

- CDSCO, New Drugs and Clinical Trials Rules (2019): [New Drugs and Clinical Trials Rules, 2019](#) (English from page 147)
- ICMR, National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 2.6 (2017): [https://main.icmr.nic.in/sites/default/files/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)

## Social-Behavioral Research

### Key Organizations

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

### Relevant Standards

- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 9 (2017):  
[https://main.icmr.nic.in/sites/default/files/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)

## Privacy/Data Protection

### Key Organizations

- Indian Council of Medical Research (ICMR): <http://www.icmr.nic.in/>
- National AIDS Control Organization (NACO): <http://naco.gov.in/>
- Ministry of Electronics & Information Technology (MeiTY): <https://www.meity.gov.in/home>
- National Health Authority (NHA): <https://nha.gov.in/>

### Relevant Standards

- ICMR, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017):  
[https://main.icmr.nic.in/sites/default/files/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)
- NACO, Data Protection Guidelines of the National AIDS Control Programme:  
[Data Protection Guidelines](#)
- Digital Personal Data Protection Act (2023):  
<https://www.meity.gov.in/writereaddata/files/Digital%20Personal%20Data%20Protection%20Act%202023.pdf>
- National Digital Health Mission, Health Data Management Policy:  
[https://abdm.gov.in:8081/uploads/health\\_data\\_management\\_policy\\_455613409c.pdf](https://abdm.gov.in:8081/uploads/health_data_management_policy_455613409c.pdf)
- Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare:  
[https://main.icmr.nic.in/sites/default/files/upload\\_documents/Ethical\\_Guidelines\\_AI\\_Healthcare\\_2023.pdf](https://main.icmr.nic.in/sites/default/files/upload_documents/Ethical_Guidelines_AI_Healthcare_2023.pdf)

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

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

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- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 11 (2017):  
[https://main.icmr.nic.in/sites/default/files/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)

## Genetic Research

### Key Organizations

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

### Relevant Standards

- DBT, Environmental Protection Act (1986)
- DBT, Recombinant DNA Safety Guidelines (1990)
- DBT, Regulations and Guidelines for Recombinant DNA Research and Biocontainment (2017):  
[Regulations and Guidelines for Recombinant DNA](#)
- DBT, Ethical Policies on the Human Genome, Genetic Research, and Services (2002)
- ICMR, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 10 (2017):  
[https://main.icmr.nic.in/sites/default/files/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)
- National Guidelines for Gene Therapy Product Development and Clinical Trials (2019):  
[https://main.icmr.nic.in/sites/default/files/guidelines/guidelines\\_GTP.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/guidelines_GTP.pdf)

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

- ICMR and DBT Combined, National Guidelines for Stem Cell Research (2017): [National Guidelines for Stem Cell Research](#)
- DBT, Biosafety Programme, Guidelines, Rules, and Regulations: <https://dbtindia.gov.in/regulations-guidelines/regulations/biosafety-programme>
- CDSCO, Stem Cell and Cell based Products:  
<https://cdsco.gov.in/opencms/opencms/en/biologicals/Stem-cells-and-Cell-based-Products/>
- The Surrogacy (Regulation) Act (2021):  
<https://dhr.gov.in/sites/default/files/Surrogacy%20Regulation%20ACT%202021.pdf>

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

## ASIA/PACIFIC – Indonesia

### General

#### Key Organizations

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

#### Relevant Standards

- Indonesian Health Act No. 23/1992 Section on Health Research, Article 69
- Regulation No. 39/1995 on Health Research and Development
- Presidential Decree No. 100/1993: Research by Foreigners
- National Guidelines on Ethics in Health Research (2003)

### Drugs, Biologics, and Devices

#### Key Organizations

- National Agency of Drug and Food Control: <http://www.pom.go.id>

#### Relevant Standards

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

### Human Biological Materials

#### Relevant Standards

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



## ASIA/PACIFIC – Japan

### General

#### Key Organizations

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

#### Relevant Standards

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

### Drugs, Biologics, and Devices

#### Key Organizations

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

#### Relevant Standards

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

### Clinical Trial Registries

#### Key Organizations

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

#### Relevant Standards

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

### Research Injury

#### Key Organizations

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

## **Relevant Standards**

- Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (2016): <https://elaws.e-gov.go.jp/document?lawid=335AC0000000145>
- Clinical Trials Act (2017): <https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000213334.pdf>
- Ministerial Ordinance on Good Clinical Practice for Drugs (2020), Article 14, 23: [https://elaws.e-gov.go.jp/document?lawid=409M50000100028\\_20200901\\_502M60000100155](https://elaws.e-gov.go.jp/document?lawid=409M50000100028_20200901_502M60000100155)
- Ethics Guidelines for Medical and Health Research Involving Human Subjects, Chapter 2, 3, and No. 6 (2021): <https://www.mhlw.go.jp/content/000757566.pdf>

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

- Act on the Protection of Personal Information (2020): <https://elaws.e-gov.go.jp/document?lawid=415AC0000000057>
- Act on the Protection of Personal Information, Various Laws and Policies: <https://www.ppc.go.jp/en/legal/>
- Act Regarding Anonymized Medical Data to Contribute to R&D in the Medical Field (2017): [http://www.kantei.go.jp/jp/singi/kenkouiryoku/jisedai\\_kiban/pdf/170310\\_shiryoku3.pdf](http://www.kantei.go.jp/jp/singi/kenkouiryoku/jisedai_kiban/pdf/170310_shiryoku3.pdf)
- Amendment to the Cabinet Order to Enforce the Act on the Protection of Personal Information (2016): [https://www.ppc.go.jp/files/pdf/Cabinet\\_Order.pdf](https://www.ppc.go.jp/files/pdf/Cabinet_Order.pdf)
- Enforcement Rules for the Act on the Protection of Personal Information (2016): [https://www.ppc.go.jp/files/pdf/PPC\\_rules.pdf](https://www.ppc.go.jp/files/pdf/PPC_rules.pdf)
- Regulation for Enforcement of the Clinical Trials Act, Article 20 (2018): <https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000195391.pdf>

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

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

## Genetic Research

### Key Organizations

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

### Relevant Standards

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

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

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

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

## ASIA/PACIFIC – Kazakhstan

### General

#### Key Organizations

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

#### Relevant Standards

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

### Drugs, Biologics, and Devices

#### Key Organizations

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

### **Relevant Standards**

- Code of the Republic of Kazakhstan "On People's Health and the Health Care System" (18.09.2009 No.193-IV), Articles 74 and 180 (2015): [http://online.zakon.kz/Document/?doc\\_id=30479065#pos=1;-8](http://online.zakon.kz/Document/?doc_id=30479065#pos=1;-8)
- Order of the MHSD of the RK Dated 12.11.2009 No. 697 on the Approval of Regulations on the Medical-Biological Experiments, Preclinical (Non-Clinical) and Clinical Trials
- Order of the MHSD of the RK dated 19.11.2009 No. 744 on the Approval of Regulations on the Conduct of Clinical Trials and/or Trials on Pharmaceutical and Drug Products, Medical Devices, and Medical Equipment
- Order of the MHSD Dated 20.05.2014 No.272 on the Approval of Regulations on the Implementation of the New Methods of Diagnostic, Treatment, and Rehabilitation
- Guidelines on Clinical Trials in Kazakhstan (2003)

## **Privacy/Data Protection**

### **Key Organizations**

- Ministry of Healthcare and Social Development: <https://www.gov.kg/en/post/s/21942-ministerstvo-zdravookhraneniya-soobshchaet-po-sostoyaniyu-na-utro-200922>

### **Relevant Standards**

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

## **ASIA/PACIFIC – Kyrgyzstan**

### **General**

#### **Key Organizations**

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

#### **Relevant Standards**

- Constitution of Kyrgyz Republic, Chapter II, Article 22 (2010): [http://www.gov.kg/?page\\_id=263&lang=ru](http://www.gov.kg/?page_id=263&lang=ru)
- Law on Health Protection of the Kyrgyz Republic (Sept. 1, 2005, No. 6), Articles 34 and 72: <http://www.pharm.kg/ru/legislation>
- Code of Professional Ethics of Medical Worker of the Kyrgyz Republic (2004)
- Code of Administrative Responsibility of the Kyrgyz Republic №114 from 04.08.1998г. (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>

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- Ministry of Health, National Bioethics Committee
- Pharmaceutical Union of Kyrgyzstan, Ethics Committee

### **Relevant Standards**

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

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Social-Behavioral Research**

### **Key Organizations**

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

### Relevant Standards

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

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

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

## ASIA/PACIFIC – Malaysia

### General

### Key Organizations

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

### Relevant Standards

- Malaysian Guidelines of Good Clinical Practice (2020): [Guidelines of Good Clinical Practice](#)
- Ministry of Health Malaysia, National Institutes of Health, Medical Review and Ethics Committee (MREC): [https://nih.gov.my/images/media/publication/guidelines/NIH\\_Guideline\\_2021.pdf](https://nih.gov.my/images/media/publication/guidelines/NIH_Guideline_2021.pdf)
- ASM, The Malaysian Code of Responsible Conduct in Research (2020): [The Malaysian Code of Responsible Conduct in Research](#)
- Clinical Trials and Biomedical Research (2007): <https://mmc.gov.my/wp-content/uploads/2019/11/Clinical-TrialsBiomedical-Research.pdf>
- Malaysian Guideline for Application of Clinical Trial Import License and Clinical Trial Exemption, 7th Edition (2021): <https://npra.gov.my/easyarticles/images/users/1140/Malaysian-Guideline-for-Application-of-CTIL-and-CTX-8th-Ed-Final.pdf>

## Drugs, Biologics, and Devices

### **Key Organizations**

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

### **Relevant Standards**

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

## Clinical Trial Registries

### **Key Organizations**

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

### **Relevant Standards**

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



## Research Injury

### Key Organizations

- Ministry of Health Malaysia, National Pharmaceutical Regulatory Agency (NPRA): <https://npra.gov.my/index.php/en/>
- Department of Occupational Safety and Health (DOSH), Ministry of Human Resources: <https://www.dosh.gov.my/index.php/about-us/dosh-profile>

### Relevant Standards

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

## Social-Behavioral Research

### Key Organizations

- Academy of Sciences Malaysia (ASM): <https://www.akademisains.gov.my/>
- Ministry of Health Malaysia, Institute for Health Behavioural Research (IPTK): <https://iptk.moh.gov.my/>

### Relevant Standards

- The Malaysian Code of Responsible Conduct in Research (2020): [Malaysian Code of Responsible Conduct in Research](#)

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- Act 709: Personal Data Protection Act (2010): [Personal Data Protection Act](#)

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

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

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- Malaysian Guideline on the Use of Human Biological Sample for Research (2015): [https://www.crc.gov.my/wp-content/uploads/2016/07/Guideline\\_on\\_Human\\_Tissue\\_in\\_Clinical\\_Research.pdf](https://www.crc.gov.my/wp-content/uploads/2016/07/Guideline_on_Human_Tissue_in_Clinical_Research.pdf)

## Genetic Research

### Key Organizations

- Medical Development Division, Ministry of Health (MOH): <https://www.moh.gov.my/index.php/pages/view/270?mid=248>
- Ministry of Energy and Natural Resources: <https://www.mybis.gov.my/pb/4497>
- University of Malaysia: <https://mohre.um.edu.my/>

### Relevant Standards

- Act 678. Biosafety Act 2007: <http://bch.cbd.int/database/attachment/?id=17640>
- Biosafety (Approval and Notification) Regulations 2010: <http://bch.cbd.int/database/attachment/?id=17640>
- MMC, Medical Genetics and Genetic Services. MMC Guidelines 010/2006: [http://www.npra.gov.my/images/Guidelines\\_Central/Guidelines\\_on\\_Regulatory/CGTP\\_guidelines.doc](http://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Regulatory/CGTP_guidelines.doc)
- Guidelines for Institutional Biosafety Committees, Use of Living Modified Organisms and Related Materials (2010): <https://mohre.um.edu.my/img/files/Guidelines%20For%20Institutional%20Biosafety%20Committees.pdf>
- MOH, Guidelines on Ethical Issues in the provision of Medical Genetics Services in Malaysia (2019): [Ethical Issues in the provision of Medical Genetics Services](#)
- Act 795 Access to Biological Resources and Benefit Sharing Act (2017): <https://www.mybis.gov.my/pb/3567>
- Ministry of Energy and Natural Resources, User's Guide to the Access to Biological Resources and Benefit Sharing Act 2017 (Act 795): <https://www.mybis.gov.my/pb/4497>

## Embryos, Stem Cells, and Cloning

### Key Organizations

- Ministry of Health Malaysia, National Pharmaceutical Regulatory Agency (NPR): <https://npra.gov.my/index.php/en/>
- Ministry of Health, National Institutes of Health (NIH): <http://www.nih.gov.my/>
- Ministry of Health, National Pharmaceutical Control Bureau (NPCB): <https://npra.gov.my/index.php/en/>
- Medical Development Division, Ministry of Health (MOH): <https://www.moh.gov.my/index.php/pages/view/270?mid=248>
- Malaysian Medical Council (MMC): <http://mmc.gov.my/>
- Malaysian Society of Transplantation (MST): <http://www.mst.org.my/>

### **Relevant Standards**

- NIH, Checklist for Research on Stem Cell and Cell-Based Therapies (2015): <https://nih.gov.my/mrec/wp-content/uploads/2014/11/Stem-Cell-checklist.pdf>
- NPRA, Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) in Malaysia (2016): [https://www.npra.gov.my/images/00NPRA/biologic/guidelines/CGTP\\_guidelinesbio.pdf](https://www.npra.gov.my/images/00NPRA/biologic/guidelines/CGTP_guidelinesbio.pdf)
- MOH, Medical Development Division, Guidelines for Stem Cell Research and Gene Therapy (2009): <http://www.moh.gov.my/moh/resources/auto%20download%20images/586f38d1c77ed.pdf>
- National Organ, Tissue and Cell Transplantation Policy: <http://www.mst.org.my/articles/MALAYSIA%20TRANSPLANT%20POLICY.pdf>
- MOH, National Standards for Cord Blood Banking and Transplantation: <http://www.moh.gov.my/moh/resources/auto%20download%20images/589d78e8689af.pdf>
- MOH, National Standards For Stem Cell Transplantation: Collection, Processing, Storage and Infusion of Haemopoietic Stem Cells and Therapeutic Cells (2nd Edition) (2018): [https://www.moh.gov.my/index.php/database\\_stores/store\\_view\\_page/70/70](https://www.moh.gov.my/index.php/database_stores/store_view_page/70/70)
- MOH, National Guidelines For Haemopoietic Stem Cell Therapy (2009): [https://www.moh.gov.my/index.php/database\\_stores/store\\_view\\_page/70/47](https://www.moh.gov.my/index.php/database_stores/store_view_page/70/47)
- MMC, Stem Cell Research and Stem Cell Therapy, MMC Guideline 002/2009 (2009): [Stem Cell Research and Stem Cell Therapy, MMC Guideline](#)
- MST, National Organ, Tissue and Cell Transplantation Policy: <http://www.mst.org.my/articles/MALAYSIA%20TRANSPLANT%20POLICY.pdf>

## **ASIA/PACIFIC – Myanmar**

### **General**

#### **Key Organizations**

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

#### **Relevant Standards**

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

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

#### **Key Organizations**

- Ministry of Health, Food and Drug Administration (FDA): <https://www.fda.gov.mm/>

#### **Relevant Standards**

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

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

## Human Biological Materials

### Relevant Standards

- Blood and Blood Products Law (2003): [https://www.myanmar-law-library.org/IMG/pdf/myanmar\\_laws\\_2003.pdf](https://www.myanmar-law-library.org/IMG/pdf/myanmar_laws_2003.pdf) (page 1)
- Body Organ Donation Law (2004): [https://www.myanmar-law-library.org/spip.php?page=pdfjs&id\\_document=103#page=7](https://www.myanmar-law-library.org/spip.php?page=pdfjs&id_document=103#page=7) (page 1)
- Organ Donation Law (Law No. 58/2015) (Burmese): [Organ Donation Law](#)

## ASIA/PACIFIC – Nepal

### General

#### Key Organizations

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

#### Relevant Standards

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

## Drugs, Biologics, and Devices

#### Key Organizations

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

#### Relevant Standards

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

## ASIA/PACIFIC – New Zealand

*NOTE: All New Zealand acts, bills, and regulations can be found here: <http://www.legislation.govt.nz/>*

### General

#### Key Organizations

- Health Research Council (HRC) Ethics Committee:  
<https://www.hrc.govt.nz/resources/hrc-ethics-committee>
- National Ethics Advisory Committee (NEAC): <http://www.neac.health.govt.nz/>
- Ministry of Health (MOH): <https://www.health.govt.nz/>
- Health and Disability Commissioner (HDC): <http://www.hdc.org.nz/>
- Health and Disability Ethics Committees: <http://www.ethics.health.govt.nz/>
- Ministry of Business, Innovation and Employment: <http://www.mbie.govt.nz/>

#### Relevant Standards

- Health Research Council Act 1990, Sections 24 and 25
- New Zealand Bill of Rights Act, Article 10 (1990)
- Health and Disability Commissioner Act 1994
- New Zealand Public Health and Disability Act 2000, Section 16
- Accident Compensation Act 2001
- HDC, The Code of Health and Disability Services Consumers' Rights (the Code of Rights) (2004):  
[Code of Health and Disability Services](#)
- HRC, The Role of Ethics (scroll down to Specific Considerations), various:  
<http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval>
- NEAC, National Ethical Standards, various:  
<https://neac.health.govt.nz/national-ethical-standards/>
- NEAC, Publications and Resources, various:  
<https://neac.health.govt.nz/publications-and-resources/neac-publications/>
- MOH, Standard Operating Procedures for Health and Disability Ethics Committees (2012):  
<http://www.ethics.health.govt.nz/operating-procedures>

### Drugs, Biologics, and Devices

#### Key Organizations

- New Zealand Medicines and Medical Devices Safety Authority (Medsafe):  
<http://www.medsafe.govt.nz>
- Medicines New Zealand: <http://www.medicinesnz.co.nz/>
- Health Research Council (HRC), Standing Committee on Therapeutic Trials:  
<https://www.hrc.govt.nz/resources/standing-committee-therapeutic-trials-scott#:~:text=The%20Health%20Research%20Council's%20Standing,not%20trials%20should%20be%20approved.>

## **Relevant Standards**

### **Drugs**

- Accident Compensation Act 2001, Section 32 (2010)
- Medicines Act 1981(2012)
- Medsafe, Medicines Regulations 1984:  
<http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM95668.html>
- Medsafe, Good Clinical Research Practice and Obtaining Approval for Clinical Trials (2013):  
<http://www.medsafe.govt.nz/medicines/clinical-trials.asp>
- Medicines New Zealand, Guidelines on Clinical Trials, Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial (2015)

### **Devices**

- Medicines (Database of Medical Devices) Regulations (2003):  
<http://www.legislation.govt.nz/regulation/public/2003/0325/latest/DLM224223.html>
- Standard Operating Procedures for Health and Disability Ethics Committees (2012):  
<http://www.ethics.health.govt.nz/operating-procedures>
- Conducting Medical Device Clinical Trials in New Zealand, various:  
<http://medsafe.govt.nz/regulatory/DevicesNew/13ConductingClinicalTrials.asp>

## **Clinical Trial Registries**

### **Key Organizations**

- Australian New Zealand Clinical Trials Registry: <http://www.anzctr.org.au/>

### **Relevant Standards**

- Australian New Zealand Clinical Trials Registry, FAQs: <http://www.anzctr.org.au/Faq.aspx>

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

- Official Information Act 1982 (2012)
- Public Records Act (2005)
- Privacy Act 1993 (2012)
- Health Information Privacy Code 1994: [Health Information Privacy Code](#)

## **Human Biological Materials**

### **Key Organizations**

- Ministry of Health (MOH): <https://www.health.govt.nz/>

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- Health Research Council (HRC) Ethics Committee: <http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval>
- Te Puni Kokiri (TPK): <http://www.tpk.govt.nz/>
- Office of the Health and Disability Commissioner (HDC): <http://www.hdc.org.nz>
- Ministry of Business, Innovation and Employment: <http://www.mbie.govt.nz/>

### **Relevant Standards**

- Health Act 1956 (2012)
- Human Tissue Act 2008
- MOH, Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (2007): [Human Tissue for Future Unspecified Research](#)

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

- Hazardous Substances and New Organisms Act 1996 (2012)

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

### **Key Organizations**

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

### **Relevant Standards**

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

## **ASIA/PACIFIC – Pakistan**

### **General**

#### **Key Organizations**

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

#### **Relevant Standards**

- National Bioethics Committee, Various Guidelines: <http://nbcPakistan.org.pk/guidelines.html>

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- National Bioethics Committee, Various Relevant Downloads:  
<http://nbcPakistan.org.pk/downloads.html>

### Drugs, Biologics, and Devices

#### Key Organizations

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

#### Relevant Standards

- Guidelines For Healthcare Professionals Interaction with Pharmaceutical Trade and Industry (PPI Guidelines):  
[http://nbcPakistan.org.pk/assets/ppi\\_guidelines\\_may\\_2011-1--final-copy-on-pmrc-wbsite.pdf](http://nbcPakistan.org.pk/assets/ppi_guidelines_may_2011-1--final-copy-on-pmrc-wbsite.pdf)

### Human Biological Materials

#### Key Organizations

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

#### Relevant Standards

- National Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials (2020): [Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials](#)
- Ethical Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials (2016): <http://nbcPakistan.org.pk/assets/hbm-guidelines-2016.pdf>

### Embryos, Stem Cells, and Cloning

#### Key Organizations

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

#### Relevant Standards

- Protocol/Guidelines for Stem Cell Research/Regulation in Pakistan:  
[http://nbcPakistan.org.pk/assets/guidelines\\_for\\_stem\\_cells.pdf](http://nbcPakistan.org.pk/assets/guidelines_for_stem_cells.pdf)

## ASIA/PACIFIC – Philippines

### General

#### Key Organizations

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



### **Relevant Standards**

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

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

### **Key Organizations**

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

### **Relevant Standards**

- FDA, Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products (Administrative Order No. 47-a) (2001)
- FDA, Guidelines: Regulation of Clinical Trials in the Philippines:  
<http://www.pcrp.org.ph/pdf/GuidelinesversionLR.PDF>
- FDA, Circular 2015-026: Adoption of the ICH Harmonized Tripartite Guideline, Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products Q5C
- PHREB, Orders and Memoranda, various:  
<https://ethics.healthresearch.ph/index.php/orders-and-memorandums>
- PHREB, National Ethical Guidelines for Health and Health-Related Research, Page 70 (2017):  
<https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg>

## **Clinical Trial Registries**

### **Key Organizations**

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

### **Relevant Standards**

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

## Research Injury

### Key Organizations

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

### Relevant Standards

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

## Social-Behavioral Research

### Key Organizations

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

### Relevant Standards

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

## Privacy/Data Protection

### Relevant Standards

- Republic Act No. 10173: Data Privacy Act of 2012: <http://www.officialgazette.gov.ph/2012/08/15/republic-act-no-10173/>
- Data Privacy Act Implementing Rules and Regulations (2016): [Data Privacy Act Rules and Regulations](#)

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

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

## ASIA/PACIFIC – Singapore

### General

### Key Organizations

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

### **Relevant Standards**

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

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

### **Key Organizations**

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

### **Relevant Standards**

- Health Products Act 2007: <https://sso.agc.gov.sg/Act/HPA2007>
- Medicines Act 1975: <https://sso.agc.gov.sg/Act/MA1975>
- Health Products (Clinical Trials) Regulations 2016: <https://sso.agc.gov.sg/SL/HPA2007-S331-2016>
- Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016: <https://sso.agc.gov.sg/SL/HPA2007-S332-2016>
- Medicines (Clinical Trials) Regulations 2016: <https://sso.agc.gov.sg/SL/MA1975-S335-2016>
- Medicines (Medicinal Products as Clinical Research Materials) Regulations 2016: <https://sso.agc.gov.sg/SL/MA1975-S336-2016>
- Singapore Guidance on Good Clinical Practice Compliance Inspection Framework (2021): [https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa\\_gn-ioctb-11\\_gcp\\_inspection\\_1mar2021.pdf](https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-11_gcp_inspection_1mar2021.pdf)
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH E6(R2) Good Clinical Practice Guideline, 2016: [https://database.ich.org/sites/default/files/E6\\_R2\\_Addendum.pdf](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf)
- Health Products (Medical Device) Regulations 2010: <http://sso.agc.gov.sg/SL/HPA2007-S436-2010>
- Radiation Protection Act 2007: <https://sso.agc.gov.sg/Act/RPA2007>
- Radiation Protection (Non-Ionising Radiation) Regulations 1991: <https://sso.agc.gov.sg/SL/262-RG1>
- HSA, Regulatory Overview of Clinical Trials: <https://www.hsa.gov.sg/clinical-trials/overview>

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

### Research Injury

#### Key Organizations

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

#### Relevant Standards

- Human Biomedical Research Act 2015: <https://sso.agc.gov.sg/Act/HBRA2015>
- Health Products Act (Cap 122D): <https://sso.agc.gov.sg/Act/HPA2007>
- Human Biomedical Research Regulations 2017: <https://sso.agc.gov.sg/SL/HBRA2015-S621-2017>
- Health Products (Clinical Trials) Regulations 2016: <https://sso.agc.gov.sg/SL/HPA2007-S331-2016>
- Medicines (Clinical Trials) Regulations (2016): <https://sso.agc.gov.sg/SL/MA1975-S335-2016>
- Singapore Guideline for Good Clinical Practice (2016): [http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6/E6\\_R2\\_Step\\_4\\_2016\\_1109.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step_4_2016_1109.pdf) (page under construction as of June 2024)

### Privacy/Data Protection

#### Key Organizations

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

#### Relevant Standards

- Personal Data Protection Act 2012: <https://sso.agc.gov.sg/Act/PDPA2012>
- Healthcare Sector Specific Guidelines Promulgated by PDPC: <https://www.pdpc.gov.sg/guidelines-and-consultation/2017/10/advisory-guidelines-for-the-healthcare-sector>
- Personal Information in Biomedical Research (2007): [Personal Information in Biomedical Research](#)

### Human Biological Materials

#### Key Organizations

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

### **Relevant Standards**

- Medical (Therapy, Education, and Research) Act 1972: <https://sso.agc.gov.sg/Act/MTERA1972>
- Human Biomedical Research (Tissue Banking) Regulations 2019: <https://sso.agc.gov.sg/SL-Supp/S702-2019/>
- Guidance on Prohibition against Commercial Trading of Human Tissue (2017): [Prohibition against Commercial Trading of Human Tissue](#)
- Guide on the Requirement of Appropriate Consent for the Conduct of HBR and Handling of Human Tissue (2019): [https://www.moh.gov.sg/docs/librariesprovider5/legislation/guidance-on-appropriate-consent\\_17-may-2019.pdf](https://www.moh.gov.sg/docs/librariesprovider5/legislation/guidance-on-appropriate-consent_17-may-2019.pdf)
- Bioethics Advisory Committee, Human Tissue Research (2002): <https://www.bioethics-singapore.gov.sg/files/publications/reports/human-tissue-research-full-report.pdf>
- Directive on the Use of Cell, Tissue and Gene Therapy Products Manufactured In-House by Healthcare Institutions (2020): [Directive on the Use of Cell, Tissue and Gene Therapy Products](#)

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

- Genetic Testing and Genetic Research (2005): <https://www.bioethics-singapore.gov.sg/files/publications/reports/genetic-testing-and-genetic-research-full-report.pdf>
- Directive on the Use of Cell, Tissue and Gene Therapy Products Manufactured In-House by Healthcare Institutions (2020): [Directive on the Use of Cell, Tissue and Gene Therapy Products](#)

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

### **Key Organizations**

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

### **Relevant Standards**

- Human Cloning and Other Prohibited Practices Act 2004: <https://sso.agc.gov.sg/Act/HCOPPA2004>
- Human Biomedical Research (Restricted Research) Regulations 2017: <https://sso.agc.gov.sg/SL/HBRA2015-S622-2017>
- Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning (2002): [Ethical, Legal and Social Issues in Stem Cell Research](#)
- Donation of Human Eggs for Research (2008): <https://www.bioethics-singapore.gov.sg/files/publications/reports/donation-of-human-eggs-for-research-full-report.pdf>

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- Human-Animal Combinations in Stem-Cell Research (2010):  
<https://www.bioethics-singapore.gov.sg/files/publications/reports/human-animal-combinations-in-stem-cell-research-full-report.pdf>

## ASIA/PACIFIC – South Korea

### General

#### Key Organizations

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

#### Relevant Standards

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

### Drugs, Biologics, and Devices

#### Key Organizations

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

#### Relevant Standards

- Pharmaceutical Affairs Act No. 16250 (2019.01.15): [Act No. 16250](#)
- Medical Device Act No. 16402 (2019.04.23):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?lang=ENG&hseq=50798](https://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=50798)
- Act on In Vitro Diagnostic Medical Devices Act No. 16433 (2019.05.01):  
[Act No. 16433](#)
- Enforcement Decree of the Medical Device Act No. 1580 (2019.12.23):  
<https://www.law.go.kr/LSW/eng/engLsSc.do?query=medical+device+act&menuId=2&section=lawNm&y=20&x=23#liBgcolor8>
- Regulations for Clinical Trial Personnel Education and Certification for the Educational Institution Notice No.2019-3 (2019.01.17):  
[Clinical Trial Personnel Education and Certification](#)
- Regulation on Approval for Investigational New Drug Application of Drugs, Notice No. 2021-12 (2021.02.25): [https://www.law.go.kr/행정규칙/의약품임상시험계획승인에관한규정/\(2021-12,20210225\)](https://www.law.go.kr/행정규칙/의약품임상시험계획승인에관한규정/(2021-12,20210225))
- Regulation on Approval for Investigational Device Exemption Application No. 2019-33 (2019.04.30): [https://www.law.go.kr/행정규칙/의료기기임상시험계획승인에관한규정/\(2019-33,20190430\)](https://www.law.go.kr/행정규칙/의료기기임상시험계획승인에관한규정/(2019-33,20190430))

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- Regulation for Medical Device Approvals, Notifications and Reviews No. 2021-35 (2021.04.22):  
[https://www.law.go.kr/행정규칙/의료기기허가.신고.심사등에관한규정/\(2021-35,20210422\)](https://www.law.go.kr/행정규칙/의료기기허가.신고.심사등에관한규정/(2021-35,20210422))
- Regulation on Medical Device Re-examination No. 2020-29 (2020.05.01):  
[https://www.law.go.kr/행정규칙/의료기기재심사에관한규정/\(2020-29,20200501\)](https://www.law.go.kr/행정규칙/의료기기재심사에관한규정/(2020-29,20200501))
- Guidelines on Human Research Protection Program 0053-01 (2014.3) 2017.5.31 고시:  
<https://nedrug.mfds.go.kr/bbs/38/65>
- Bioethics and Safety Act No. 16372 (2019.04.23): [Act No. 16372](#)
- Enforcement Decree of Pharmaceutical Affairs Act No. 30141 (2019.10.22):  
[Enforcement Decree of Act No. 30141](#)
- Enforcement Rule of Bioethics and Safety Act No. 733 (2020.12.31):  
<https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙>

## Clinical Trial Registries

### Key Organizations

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

### Relevant Standards

- MFDS, Various Laws, Enforcement Decrees, and Enforcement Rules:  
[https://www.mfds.go.kr/brd/m\\_203/list.do](https://www.mfds.go.kr/brd/m_203/list.do)
- MFDS, Various Regulations: [Various Regulations](#)
- Regulation on Safety of Medicinal Products, No.1576 (2019.12.06):  
[https://www.mfds.go.kr/eng/brd/m\\_18/view.do?seq=71487&srchFr=&srchTo=&srchWord=&srchTp=&itm\\_seq\\_1=0&itm\\_seq\\_2=0&multi\\_itm\\_seq=0&company\\_cd=&company\\_nm=&page=2](https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=71487&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=2)

## Research Injury

### Key Organizations

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

### Relevant Standards

- Pharmaceutical Affairs Act No.16250 (2019.01.15):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?hseq=49635&lang=ENG](https://elaw.klri.re.kr/kor_service/lawView.do?hseq=49635&lang=ENG)
- Regulation on Safety of Pharmaceuticals, etc. No. 1576 (2019.12.12.):  
[https://www.mfds.go.kr/eng/brd/m\\_18/view.do?seq=71487&srchFr=&srchTo=&srchWord=&srchTp=&itm\\_seq\\_1=0&itm\\_seq\\_2=0&multi\\_itm\\_seq=0&company\\_cd=&company\\_nm=&page=2](https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=71487&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=2)
- Enforcement Rule of the Medical Devices Act No.1580 (2019.12.23.):  
[https://elaw.klri.re.kr/eng\\_mobile/viewer.do?hseq=54331&type=part&key=36](https://elaw.klri.re.kr/eng_mobile/viewer.do?hseq=54331&type=part&key=36) [Amended 2021.06.24]

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- Guidelines for Clinical Trial Indemnity and Its Process 0052-03 (2021.06.21.):  
[Guidelines for Clinical Trial Indemnity](#)
- Guidance for Sponsors; Safety Reporting Requirements 0785-02 (2020.10.30.):  
[Safety Reporting Requirements](#)

**Social-Behavioral Research**

**Key Organizations**

- Ministry of Health and Welfare: <http://www.mohw.go.kr/eng/index.jsp>
- Ministry of the Interior and Safety: <https://www.mois.go.kr/frt/a01/frtMain.do>

**Relevant Standards**

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

**Privacy/Data Protection**

**Key Organizations**

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

**Relevant Standards**

- Personal Information Protection Act No. 16930 (2020.02.04):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?hseq=53044&lang=ENG](https://elaw.klri.re.kr/kor_service/lawView.do?hseq=53044&lang=ENG)
- Enforcement Decrees to Personal Information Protection Act No. 30892 (2020.02.04):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?hseq=54521&lang=ENG](https://elaw.klri.re.kr/kor_service/lawView.do?hseq=54521&lang=ENG)
- Bioethics and Safety Act No. 16372 (2019.04.23):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?lang=ENG&hseq=52559](https://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=52559)
- Act on Dissection and Preservation of Corpses No. 17472 (2021.04.08):  
<https://www.law.go.kr/법령/시체해부및보존등에관한법률>
- Guidelines for the Use of Health and Medical data (2021.01):  
[Use of Health and Medical data](#)



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- Standard Personal Information Protection Guidelines (2020.08.11):  
[Personal Information Protection Guidelines](#)
- Guidelines for the Pseudonymisation of Personal Information (2020.09):  
<https://www.pipc.go.kr/np/cop/bbs/selectBoardArticle.do?bbsId=BS217&mCode=D010030000&nttId=6840>

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- Bioethics and Safety Act No. 16372 (23Apr2019):  
<https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=208465&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000> (amended in 2020.09.12)
- Enforcement Rule of Bioethics and Safety Act No. 733 (2020.12.31):  
<https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙>
- Enforcement Decree of Pharmaceutical Affairs Act No. 30141 (22Oct2019):  
<https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=210861&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000>
- Guidelines on Biological Material Management in Clinical Trial (2018.08):  
[Biological Material Management in Clinical Trial](#)

## Genetic Research

### Key Organizations

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

### Relevant Standards

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

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

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

### **Relevant Standards**

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

## **ASIA/PACIFIC – Sri Lanka**

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

#### **Key Organizations**

- Cosmetics, Devices, and Drugs Regulatory Authority: Website under construction as of July 25<sup>th</sup>, 2024. In the meantime, this [link](#) provides access to important information.

### **Clinical Trial Registries**

#### **Key Organizations**

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

#### **Relevant Standards**

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

## ASIA/PACIFIC – Taiwan

### General

#### Key Organizations

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

#### Relevant Standards

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

### Drugs, Biologics, and Devices

#### Key Organizations

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

#### Relevant Standards

- Medical Care Act (2018): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020021>
- Pharmaceutical Affairs Act (2018):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001>
- Regulations on Human Trials (2016):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020162>
- Pharmaceutical Affairs Act Enforcement Rules (2016):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030002>
- Regulations for Drug Safety Monitoring (2013):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030050>

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- Regulations for Good Clinical Practice (2014):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030056>
- Regulations for Governing the Management of Medical Devices (2014)
- Regulation on Bioavailability and Bioequivalence Studies (2015):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030065>

## Research Injury

### Key Organizations

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

### Relevant Standards

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

## Social-Behavioral Research

### Key Organizations

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

### Relevant Standards

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

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

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

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- Human Biobank Management Act (2012):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020164>
- Medical Care Act (2018): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020021>

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- Regulations on Human Trials (2009):  
<https://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=L0020162>
- Administrative Regulations on the Establishment of Human Biobanks (2011):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?PCODE=L0020173>

## Genetic Research

### Key Organizations

- Ministry of Health and Welfare (MOHW): <https://www.mohw.gov.tw/mp-2.html>
- Food and Drug Administration (FDA): <https://www.fda.gov.tw/ENG/>
- Ministry of Science and Technology: <https://www.nstc.gov.tw/?l=en>

### Relevant Standards

- Human Biobank Management Act (2012): [Human Biobank Management Act](#)
- Regulations on Commercial Benefit Feedback of Human Biobanks (2010) (Chinese):  
<https://law.moj.gov.tw/LawClass/LawAll.aspx?PCODE=L0020170>
- Administrative Regulations on the Establishment of Human Biobanks (2011):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?PCODE=L0020173>
- Guidance for Information Safety of Human Biobank (2010) (Chinese):  
[http://regulation.cde.org.tw/doc\\_data\\_display?sid=1929&doctype2](http://regulation.cde.org.tw/doc_data_display?sid=1929&doctype2)

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

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

## ASIA/PACIFIC – Tajikistan

### General

### Key Organizations

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

### Relevant Standards

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

## ASIA/PACIFIC – Thailand

**NOTE:** For an overview of the clinical research regulations in Thailand, see:  
<https://clinregs.niaid.nih.gov/country/thailand>

### General

#### Key Organizations

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

#### Relevant Standards

- NCRT, Initial Registration of an REC-EC-IRB (2022): <http://deven.nrct.go.th/service/detail/194>
- NCRT, National Policy and Guidelines for Human Research (2015):  
[https://sp.mahidol.ac.th/pdf/ref/National\\_Policy\\_Guidelines\\_for\\_Human\\_Research2015.pdf](https://sp.mahidol.ac.th/pdf/ref/National_Policy_Guidelines_for_Human_Research2015.pdf)
- MCT, Various Acts and Rules: [https://tmc.or.th/En/act\\_rules\\_en.php](https://tmc.or.th/En/act_rules_en.php)
- NCRT, Regulation on the Permission of Foreign Researchers (1982):  
[https://op.mahidol.ac.th/ra/contents/research\\_fund/MU-SURF/REGULATION-FOREIGN\\_2550\\_EN.pdf](https://op.mahidol.ac.th/ra/contents/research_fund/MU-SURF/REGULATION-FOREIGN_2550_EN.pdf)
- NCRT, Guidance for Foreign researcher Conducting Research in Thailand, various:  
[https://foreignresearcher.nrct.go.th/index.php?lang=en&mod=forms&op=guidelines\\_en](https://foreignresearcher.nrct.go.th/index.php?lang=en&mod=forms&op=guidelines_en)
- FERCIT, Ethical Guidelines for Research on Human Subject in Thailand (2007):  
[http://www.fercit.org/file/Guideline\\_English\\_version.pdf](http://www.fercit.org/file/Guideline_English_version.pdf)

### Drugs, Biologics, and Devices

#### Key Organizations

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

#### Relevant Standards

- FDA, Various Laws and Regulations, Medicines:  
<https://en.fda.moph.go.th/cat2-health-products/category/lr-medicines>
- FDA, Various Laws and Regulations, Devices: <https://en.fda.moph.go.th/cat2-health-products/category/health-products-medical-devices>
- Consumer Protection Act (2007)
- FDA, Rules, Procedures and Conditions for Accepting Ethics Committee for Research Involving Human Subjects (2018)
- MCT, Acts and Rules, various: [https://tmc.or.th/En/act\\_rules\\_en.php](https://tmc.or.th/En/act_rules_en.php)
- MCT, Thailand Good Clinical Practice Guidelines (2002)
- 1988 Medical Device Act

## Clinical Trial Registries

### Key Organizations

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

### Relevant Standards

- FAQs: [Clinical Trials Registry FAQs](#)

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- Official Information Act, B.E. 2540 (1997): [Official Information Actwe](#)
- Ministerial Regulations, various:  
[https://sp.mahidol.ac.th/pdf/ref/National\\_Policy\\_Guidelines\\_for\\_Human\\_Research2015.pdf](https://sp.mahidol.ac.th/pdf/ref/National_Policy_Guidelines_for_Human_Research2015.pdf)

## ASIA/PACIFIC – Uzbekistan

### General

#### Key Organizations

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

#### Relevant Standards

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

## Drugs, Biologics, and Devices

#### Key Organizations

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

#### Relevant Standards

- Center for Pharmaceutical Products Safety, Various Laws, Decrees, Resolutions, State Standards, etc.: <https://www.uzpharm-control.uz/en/documents>
- Law on Protection of Citizens' Health (1997)
- Law on Drugs and Pharmaceutical Activity (1997)
- Law on Narcotic and Psychoactive Drugs (2000)
- Guidelines on Conducting Clinical Trials and Determining Clinical Sites (2001)
- National Standard of Uzbekistan: Good Clinical Practice (2013)

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

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

## ASIA/PACIFIC – Vietnam

*NOTE: For an overview of the clinical research regulations in Vietnam, see the ClinRegs report: <https://clinregs.niaid.nih.gov/country/vietnam>*

## General

### Key Organizations

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

### Relevant Standards

- Decision No. 111/QD-BYT – On Promulgation of Regulation on Organization and Operation of Council of Ethics in Biomedical Research at Grass-Roots Level, Chapter I (Articles 3 and 4), Chapter II, and Chapter III (2013): <http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo111-QD-BYT.pdf>
- Decision No. 460/QD-BYT – On the Promulgation of Regulations on Organization and Operation of Ethical Evaluation Committee in Biomedical Research of the Ministry of Health, Period 2012-2017, Chapters I-III (2012): <http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo460-QD-BYT.pdf>
- Circular No. 45/2017/TT-BYT – Regulation on the Establishment, Functions, Tasks, and Powers of the Ethics Committee in Biomedical Research (2017) (Vietnamese): [Circular No. 45/2017/TT-BYT](#)
- Decision No. 1122/QD-BYT – On the Establishment of the Ethics Committee in Biomedical Research of the Ministry of Health, Period 2018-2023: [http://crc.pasteurhcm.gov.vn/upload/files/1122\\_2018.pdf](http://crc.pasteurhcm.gov.vn/upload/files/1122_2018.pdf)

## Drugs, Biologics, and Devices

### Key Organizations

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



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**Relevant Standards**

- Law on Pharmacy (No. 34/2005/QH11), Chapter II (Section III, Article 20), Chapter VIII (Articles 54 and 59) (2005):  
[http://www.vertic.org/media/National%20Legislation/Vietnam/VN\\_Law\\_on\\_Pharmacy.pdf](http://www.vertic.org/media/National%20Legislation/Vietnam/VN_Law_on_Pharmacy.pdf)
- Decision No. 799/QD-BYT on the Issuance of Guideline on Good Clinical Practice, Chapter III, Articles 1 and 2 (2008): <http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo799-QD-BYT.pdf>
- Decision No. 799/QD-BYT of the Minister of Health on the Promulgation of the Guidelines on Good Clinical Practice of Clinical Trials (2008):  
<http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo799-QD-BYT.pdf>
- Circular – Guidelines for Clinical Trials on Drugs (C-ClinDrugTrial), Articles 2, 4, 5, 9, 17, 18, 31, and 39 (2012):  
<http://clinregs.niaid.nih.gov/documents/vietnam/C-ClinDrugTrial.pdf>
- Guidelines for Clinical Trials of Drugs, Chapter III, Articles 10, 16, and 17 (2012):  
<https://clinregs.niaid.nih.gov/documents/vietnam/C-ClinDrugTrial.pdf>
- Circular No. 29/2018/TT-BYT – Regulations for Clinical Trials on Drugs (Vietnamese):  
<https://thuvienphapluat.vn/van-ban/The-thao-Y-te/Circular-29-2018-TT-BYT-clinical-trial-of-drugs-401541.aspx>

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