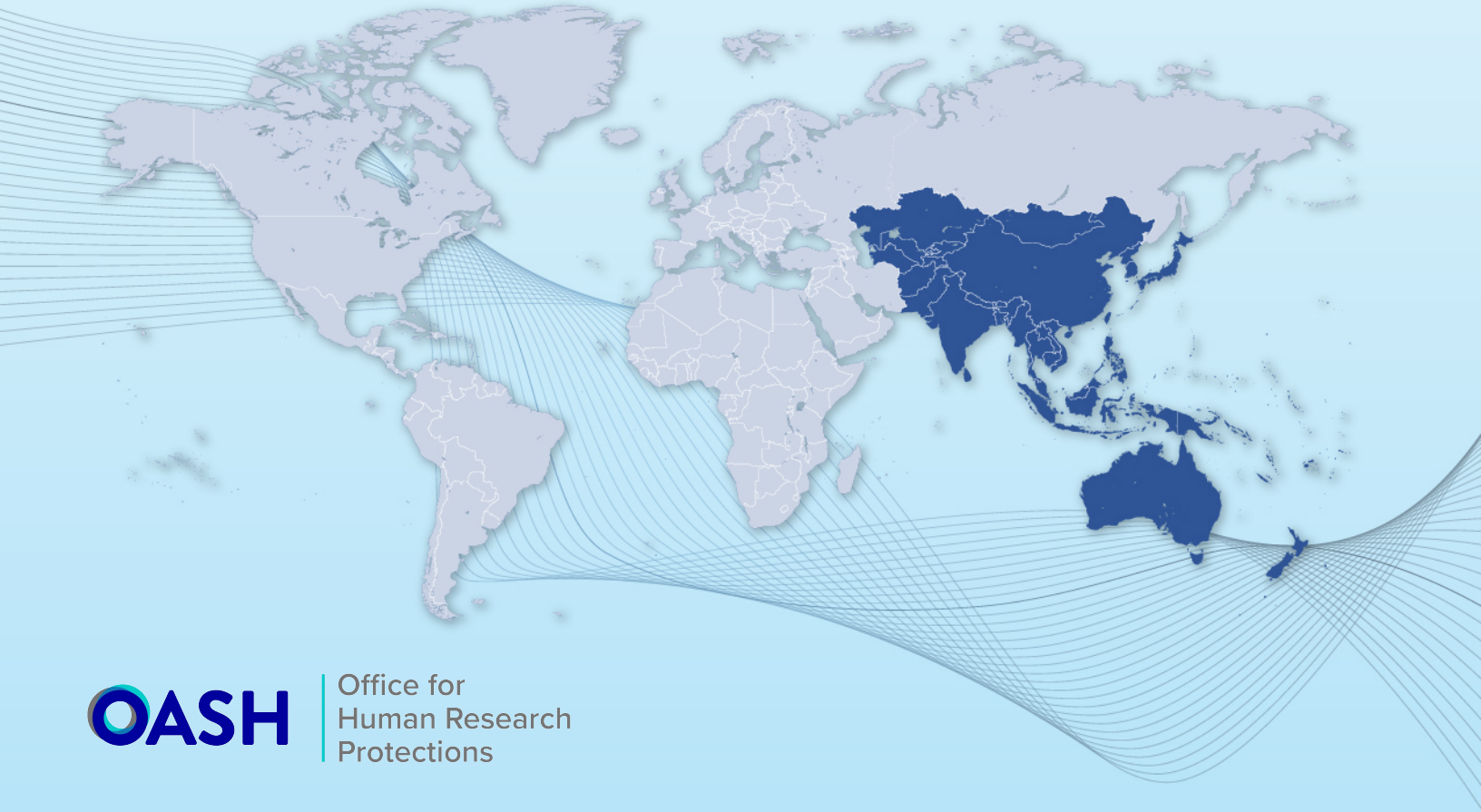
International Compilation of Human Research Standards
2021 Edition

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

Asia/Pacific



OASH | Office for Human Research Protections

ASIA/PACIFIC

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PURPOSE

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

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 However, not all countries provided corroboration, so some of the information contain in this document may be outdated or incomplete (please see disclaimer below).

ORGANIZATION

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

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

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

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

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

TOPICS NOT COVERED

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

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

NEW STANDARDS, UPDATES, AND BROKEN LINKS

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

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

DISCLAIMER

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

TABLE OF CONTENTS

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.australianclinicaltrials.gov.au/ethical-review-process-each-australian-state-and-territory
- AIATSIS, Guidelines for Ethical Research in Australian Indigenous Studies (2012): http://www.aiatsis.gov.au/research/ethics/GERAIS.html

Drugs, Biologics, and Devices

Drugs

Key Organizations

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

Relevant Standards

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

Devices

Key Organizations

- Therapeutic Goods Administration: http://www.tga.gov.au/industry/devices.htm

Relevant Standards

- Therapeutic Goods Act 1989 (2016): https://www.legislation.gov.au/Details/C2016C00269
- Therapeutic Goods (Medical Devices) Regulations 2002 (2016): https://www.legislation.gov.au/Details/F2016C00801
- Australian Regulatory Guidelines for Medical Devices (ARGMD) (2011): http://www.tga.gov.au/industry/devices-argmd.htm

Clinical Trials Registry

Key Organizations

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

Relevant Standards

- 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
- 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, Industry Standard Compensation Guidelines (2012): https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/Clnical-Trials-Compensation-Guidelines-1.pdf
- NHMRC, National Statement on Ethical Conduct in Human Research. Paragraphs 5.1.38 and 5.1.39 (2018): https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research

Social-Behavioral Research

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

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

Key Organizations

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

Relevant Standards

- NHMRC, National Statement on Ethical Conduct in Human Research, Chapter 3.2 (2018): https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research
- TGA, Australian Regulatory Guidelines for Biologicals (2017): http://www.tga.gov.au/industry/biologicals-argb.htm

Genetic Research

Key Organizations

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

Relevant Standards

- Gene Technology Act 2000 (2016): https://www.legislation.gov.au/Details/C2016C00792
- Gene Technology Regulations 2001 (2016): https://www.legislation.gov.au/Details/F2016C00615

- NHMRC, National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2018): 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 (2018): https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research
- NHMRC, Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2017): https://nhmrc.gov.au/about-us/publications/ethical-guidelines-use-assisted-reproductive-technology

ASIA/PACIFIC – Bangladesh

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- The Drugs Act (1964)
- Drugs (Control) Ordinance 1982, Ordinance No. VIII: http://bdlaws.minlaw.gov.bd/act-623.html
- Good Clinical Practice (GCP) Guidelines: http://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/registered-medical-device-list-4/129-good-clinical-practice-gcp-guidelines/file

Human Biological Materials

Key Organizations

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

Relevant Standards

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

ASIA/PACIFIC – China, People's Republic of

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

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Drugs

Key Organizations

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

Relevant Standards

- Drug Administration Law of the People's Republic of China (2019): http://www.npc.gov.cn/npc/c30834/201908/26a6b28dd83546d79d17f90c62e59461.shtml
- Vaccine Management Law of the People's Republic of China (2019): http://www.npc.gov.cn/npc/c30834/201907/11447c85e05840b9b12c62b5b645fe9d.shtml
- Regulations for Implementation of the Drug Administration Law of the People's Republic of China (2016): http://www.nmpa.gov.cn/WS04/CL2076/300567.html
- Chinese Good Clinical Practice (2003): http://www.nmpa.gov.cn/WS04/CL2077/300595.html

- Measures for the Administration of Drug Registration (2007): http://www.nmpa.gov.cn/WS04/CL2174/300629.html
- Interim Measures for the Confirmation of Clinical Trial Sites/Institutions (2004): http://www.nmpa.gov.cn/WS04/CL2079/337621.html
- Provisions for Adverse Drug Reaction Reporting and Monitoring (2011): http://english.nmpa.gov.cn/2019-12/14/c_432227.htm
- Administrative Measures for the Signing and Issuing of Biological Product (2017): http://www.nmpa.gov.cn/WS04/CL2077/300708.html
- Guideline for HIV Vaccine Research Technology (2003)
- Guideline for Vaccine Research Technology (2004)
- Guidelines on Ethical Review of Drug Clinical Trials (2010): http://www.gov.cn/gzdt/2010-11/08/content_1740976.htm
- Interim Guidelines on International Multi-Regional Drug Clinical Trials (2015)
- Interim Guidelines for Reporting and Supervision of Adverse Drug Reactions (2015): http://www.nmpa.gov.cn/WS04/CL2196/324118.html

Devices

Key Organizations

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

Relevant Standards

- Good Clinical Practice on Medical Device Clinical Trials (2016): http://www.nmpa.gov.cn/WS04/CL2077/300685.html
- Regulations on the Supervision and Administration of Medical Devices (revised 2017): http://www.nmpa.gov.cn/WS04/CL2076/331389.html
- Measures for the Registration and Administration of In Vitro Diagnostic Reagents (2014): http://www.nmpa.gov.cn/WS04/CL2077/300661.html
- Amendment of Measures for the Registration and Administration of In Vitro Diagnostic Reagents (updated Art.20 in 2017): http://www.nmpa.gov.cn/WS04/CL2077/300690.html
- Administrative Measures for Recall of Medical Devices (2017): http://www.nmpa.gov.cn/WS04/CL2186/300689.html
- Guiding Principles of the Clinical Trail Technology on In Vitro Diagnostic (IVD) Reagents (2014): http://www.nmpa.gov.cn/WS04/CL2138/299988.html
- Management Measures for the Monitoring and Re-evaluation of Adverse Events on Medical Devices (2019): http://www.nmpa.gov.cn/WS04/CL2077/330071.html
- Templates for Medical Device Clinical Trials – Ethical Application and Approval (2016):
  1. Ethical Review Application and Review Form
  2. Informed Consent Form
  3. CRF Template
  4. Protocol Template
  5. Clinical Trial Report Template
  6. Required Documents List for Archiving

Clinical Trial Registries

Key Organizations

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

Relevant Standards

- FAQs: http://www.chictr.org.cn/questionen.aspx

Privacy/Data Protection

Mainland

Key Organizations

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

Relevant Standards

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

Hong Kong

Key Organizations

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

Relevant Standards

- Personal Data (Privacy) Ordinance (2018): https://www.elegislation.gov.hk/hk/cap486!en-zh-Hant-HK.pdf?FROMCAPINDEX=Y
- Code of Practice on the Identity Card Number and Other Personal Identifiers (2016): https://www.pcpd.org.hk/english/data_privacy_law/code_of_practices/files/picode_en.pdf
- Code of Practice on Human Resource Management (2016): https://www.pcpd.org.hk/english/data_privacy_law/code_of_practices/files/PCPD_HR_Booklet_Eng_AW07_Web.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
- Chinese Good Clinical Practice, Article 43 (2003): http://www.nmpa.gov.cn/WS04/CL2077/300595.html
- Administrative Measures for Recall of Medical Devices, Article 36 (2017): http://www.nmpa.gov.cn/WS04/CL2186/300689.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
- Good Clinical Practice on Medical Device Clinical Trials (2016), Articles 10, 22, 33, and 48: http://www.nmpa.gov.cn/WS04/CL2077/300685.html
- Guideline on Vaccine Clinical Trials, Part 6 (2004)
- Guideline on Ethical Review of Drug Clinical Trials, Appendix 1, Section 6.10 (2010)

Genetic Research

Key Organizations

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

Relevant Standards

- People's Republic of China Human Genetic Resources Management Regulations (2019): http://www.gov.cn/zhengce/content/2019-06/10/content_5398829.htm
- Service Guidelines for the Collection, Selling, Export. and Admission Application of Human Genetic Resources (2015): http://www.most.gov.cn/tztg/201507/t20150703_120547.htm
- Service Guideline for the Approval of Administrative Licensing Items for Exporting Human Genetic Resources Outside of China: https://fuwu.most.gov.cn/r/cms/zwpt/web/assets/pdf/4.rlyczycjspfwzn.pdf

Embryos, Stem Cells, and Cloning

Mainland

Key Organizations

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

Relevant Standards

- Ethical Principles and Conduct Norms for Human Assisted Reproductive Technologies (2003)
- Administrative Measures for Clinical Application of Medical Technology (2018)
- Interim Measures for the Administrative Measures of Stem Cell Clinical Research (2015): http://www.nmpa.gov.cn/WS04/CL2077/300673.html

- Ethical Guidelines for Research on Human Embryo Stem Cells (2003): http://www.most.gov.cn/fggw/zfwj/zfwj2003/200512/t20051214_54948.htm
- Interim Guidelines for the Quality Control of Stem Cell Preparations and Preclinical Research (2015): http://www.nmpa.gov.cn/WS04/CL2196/324124.html

Hong Kong

Key Organizations

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

Relevant Standards

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

ASIA/PACIFIC – India

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

General

Key Organizations

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

Relevant Standards

- 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
- National Ethical Guidelines for Biomedical Research Involving Children (2017): https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf
- National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During Covid-19 Pandemic: https://ethics.ncdirindia.org//asset/pdf/EC_Guidance_COVID19.pdf

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Central Drugs Standard Control Organization (CDSCO), Office of Drugs Controller General of India (DCGI): https://cdsco.gov.in/opencms/opencms/en/
- Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/

Relevant Standards

- CDSCO, Drugs and Cosmetics Act (1940 amended up to 31st December, 2016): https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf (pages 584)

- CDSCO, New Drugs and Clinical Trials Rules (2019): https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDI2MQ== (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, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 7 (2017): https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf

Devices

Key Organizations

- Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): https://cdsco.gov.in/opencms/opencms/en/Home/
- Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/

Relevant Standards

- CDSCO, Medical Devices Rules, 2017 General Statutory Rules 78(E) [English from page 146]: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzMzNg== (English from page 143)
- ICMR, National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 7.7 (2017): https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

Clinical Trial Registries

Key Organizations

- Indian Council of Medical Research (ICMR)

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): https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDI2MQ== (English from page 147)
- ICMR, National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 2.6 (2017): https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

Social-Behavioral Research

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

- Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/
- National AIDS Control Organization (NACO): http://naco.gov.in/

Relevant Standards

- ICMR, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Sections 1, 2, 4, 5, 6, 7, 9, 10, 11 and 12 (2017): https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf
- NACO, Data Protection Guidelines of the National AIDS Control Programme: http://www.naco.gov.in/sites/default/files/Data%20Protection%20Guideline%20of%20National%20AIDS%20Control%20Programme.pdf

Human Biological Materials

Key Organizations

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

Relevant Standards

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

Genetic Research

Key Organizations

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

Relevant Standards

- DBT, Environmental Protection Act (1986)
- DBT, Recombinant DNA Safety Guidelines (1990)

- DBT, Regulations and Guidelines for Recombinant DNA Research and Biocontainment (2017): https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115134719867_Regulations-Guidelines-for-Reocminant-DNA-Research-and-Biocontainment-2017.pdf
- 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

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

Relevant Standards

- ICMR and DBT Combined, National Guidelines for Stem Cell Research (2017): https://dbtindia.gov.in/regulations-guidelines/guidelines/national-guidelines-stem-cell-research-%E2%80%93-2017
- 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/

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: www.pom.go.id

Relevant Standards

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

Human Biological Materials

Relevant Standards

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

ASIA/PACIFIC – Japan

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Drugs

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

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 Medical Devices (2016): https://www.mhlw.go.jp/web/t_doc?dataId=81aa6871&dataType=0&pageNo=1

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/index_en.html
- Japan Registry of Clinical Trials: https://jrct.niph.go.jp/

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- Act on the Protection of Personal Information (2020): https://elaws.e-gov.go.jp/document?lawid=415AC0000000057
- Act on the Protection of Personal Information, Various Laws and Policies: https://www.ppc.go.jp/en/legal/
- Act Regarding Anonymized Medical Data to Contribute to R&D in the Medical Field (2017): http://www.kantei.go.jp/jp/singi/kenkouiryou/jisedai_kiban/pdf/170310_shiryou3.pdf
- Amendment to the Cabinet Order to Enforce the Act on the Protection of Personal Information (2016): https://www.ppc.go.jp/files/pdf/Cabinet_Order.pdf
- Enforcement Rules for the Act on the Protection of Personal Information (2016): https://www.ppc.go.jp/files/pdf/PPC_rules.pdf

- Regulation for Enforcement of the Clinical Trials Act, Article 20 (2018): https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000195391.pdf

Human Biological Materials

Key Organizations

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

Relevant Standards

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

Genetic Research

Key Organizations

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

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

ASIA/PACIFIC – Kazakhstan

NOTE: For an overview of human subject protections in Kazakhstan, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 5: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

- Ministry of Healthcare and Social Development: http://www.mzsr.gov.kz/en

Relevant Standards

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

ASIA/PACIFIC – Kyrgyzstan

General

Key Organizations

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

Relevant Standards

- Constitution of Kyrgyz Republic, Chapter II, Article 22 (2010): http://www.gov.kg/?page_id=263&lang=ru
- Law on Health Protection of the Kyrgyz Republic (Sept. 1, 2005, No. 6), Articles 34 and 72: http://www.pharm.kg/ru/legislation
- Code of Professional Ethics of Medical Worker of the Kyrgyz Republic (2004)
- Code of Administrative Responsibility of the Kyrgyz Republic №114 from 04.08.1998г. (Updated June 11, 2008 N 115 and June 23, 2008 N 136) Chapters 7 and 10

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

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

Social-Behavioral Research

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

ASIA/PACIFIC – Malaysia

General

Key Organizations

- Ministry of Health Malaysia, National Institutes of Health, Medical Review and Ethics Committee (MREC): https://www.nih.gov.my/mrec/
- Malaysian Industry-Government Group For High Technology (MIGHT): https://www.might.org.my/
- Academy of Sciences Malaysia (ASM): https://www.akademisains.gov.my/

Relevant Standards

- Malaysian Guidelines of Good Clinical Practice (2020): https://www.npra.gov.my/easyarticles/images/users/1059/NPRA-GUIDELINES-FOR-GCP-INPECTION-IN-MSIA-ED2.1.pdf
- ASM, The Malaysian Code of Responsible Conduct in Research (2020): https://www.akademisains.gov.my/asm-publication/the-malaysian-code-of-responsible-conduct-in-research-2nd-edition/
- 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://www.npra.gov.my/easyarticles/images/users/1069/CTIL%20Guidelines%20Ed%207%20&%20Form%20Version%2001/Malaysian-Guideline-for-Application-of-CTIL-and-CTX-7.1-Edition-16.09.2pdf

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health Malaysia, National Pharmaceutical Regulatory Agency (NPRA): https://npra.gov.my/index.php/en/
- National Committee for Clinical Research (NCRC): http://www.nccr.gov.my/
- Ministry of Health, National Institutes of Health (NIH): http://www.nih.gov.my/
- Medical Device Authority (MDA), Ministry of Health Malaysia: https://portal.mda.gov.my/
- National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia: https://npra.gov.my/index.php/en/
- Clinical Research Malaysia (CRM), Ministry of Health: https://clinicalresearch.my/
- Society of Clinical Research Professionals Malaysia (SCRPM): https://scrpm.ucoz.com/

Relevant Standards

- Malaysian Guidelines of Good Clinical Practice (2020): https://www.npra.gov.my/easyarticles/images/users/1059/NPRA-GUIDELINES-FOR-GCP-INPECTION-IN-MSIA-ED2.1.pdf
- Malaysian Guideline for Phase I Unit Inspection and Accreditation Program (2018): https://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Clinical_Trial/MALAYSIAN GUIDELINEFORPHASEIUNITINSPECTION.pdf
- Malaysian Phase I Clinical Trial Guidelines: https://clinicalresearch.my/wp-content/uploads/2020/11/Malaysian-Phase-I-Clinical-Trial-Guidelines.pdf
- NIH, Guidelines for Conducting Research in Ministry of Health Institutions and Facilities (2015): https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/nih-guidelines-conducting-research-moh-institutions-facilities-revision-01-2015.pdf
- A Guide To Conducting Clinical Trials in Malaysia (2016): https://clinicalresearch.my/wp-content/uploads/2020/11/A-Guide-to-Conduct-Clinical-Trials-in-Malaysia.pdf
- Medical Device Act 2012: https://portal.mda.gov.my/documents/regulation/685-medical-device-act-2012-eng/file.html
- Medical Device Authority Act 2012: https://portal.mda.gov.my/documents/regulation/685-medical-device-act-2012-eng/file.html
- Medical Device Regulations 2012: https://portal.mda.gov.my/documents/regulation/688-medical-device-regulations-2012/file.html
- Medical Device (Exemption) Order 2016 https://portal.mda.gov.my/documents/medical-device-exemption-order-2016.html

- Medical Device Guidance Document Notification of Exemption from Registration of Medical Devices For The Purpose Of Clinical Research Or Performance Evaluation (Medical Device Guidance) (2017): https://portal.mda.gov.my/documents/guidance-documents/807-16-notification-for-clinical-research-or-performance-evaluation/file.html

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/
- Attorney General's Chambers of Malaysia (AGC)
- Department of Occupational Safety and Health (DOSH), Ministry of Human Resources: https://www.dosh.gov.my/index.php/about-us/dosh-profile
- National Committee for Clinical Research (CRC): http://www.nccr.gov.my/

Relevant Standards

- Occupational Safety and Health Act 1994: Section 32: https://www.dosh.gov.my/index.php/legislation/acts-legislation/23-02-occupational-safety-and-health-act-1994-act-514/file
- Malaysian Guidelines of Good Clinical Practice (2020): https://www.npra.gov.my/easyarticles/images/users/1059/NPRA-GUIDELINES-FOR-GCP-INPECTION-IN-MSIA-ED2.1.pdf

Social-Behavioral Research

Key Organizations

- Malaysian Industry-Government Group For High Technology (MIGHT): https://www.might.org.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): https://www.akademisains.gov.my/asm-publication/the-malaysian-code-of-responsible-conduct-in-research-2nd-edition/

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): Section 38, 39 and 40 (https://www.pdp.gov.my/jpdpv2/laws-of-malaysia-pdpa/personal-data-protection-act-2010/?lang=en)

Human Biological Materials

Key Organizations

- National Committee for Clinical Research (NCRC): http://www.nccr.gov.my/
- Laws of Malaysia. Attorney General's Chambers of Malaysia (AGC)

Relevant Standards

- Act 130, Human Tissues Act (1974): Section 2 Removal of parts of bodies for therapeutic purpose: http://www.agc.gov.my/agcportal/uploads/files/Publications/LOM/EN/Act%20130.pdf
- Act 699, DNA Identification Act 2009. Malaysian Government Gazette of 3 September 2009: http://www.agc.gov.my/agcportal/uploads/files/Publications/LOM/EN/Act%20699%209_7_2015.pdf
- Act 795 Access to Biological Resources and Benefit Sharing Act (2017): https://www.mybis.gov.my/pb/3567
- Malaysian Guideline on the Use of Human Biological Sample for Research (2015) https://www.crc.gov.my/wp-content/uploads/2016/07/Guideline_on_Human_Tissue_in_Clinical_Research.pdf

Genetic Research

Key Organizations

- Malaysian Medical Council: http://mmc.gov.my/
- Laws of Malaysia. Attorney General's Chambers of Malaysia (AGC)
- 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

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
- Various Guidelines for Institutional Biosafety Committees: https://umresearch.um.edu.my/ibbc-policy-amp-guidelines

- Guidelines on Ethical Issues in the provision of Medical Genetics Services in Malaysia (2019) https://www.moh.gov.my/moh/resources/Penerbitan/Garis%20Panduan/Garis%20panduan%20Umum%20(Awam)/Guidelines_On_Ethical_Issues_In_The_Provision_Of_Medical_Genetics_Services_In_Malaysia_(1).pdf
- 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, 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
- Ministry of Health, National Stem Cell Research and Ethics Subcommittee (NSCERT)

Relevant Standards

- 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
- 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
- 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
- National Standards for Cord Blood Banking and Transplantation: http://www.moh.gov.my/moh/resources/auto%20download%20images/589d78e8689af.pdf
- 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
- National Guidelines For Haemopoietic Stem Cell Therapy (2009): https://www.moh.gov.my/index.php/database_stores/store_view_page/70/47

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: http://www.fdamyanmar.gov.mm/

Relevant Standards

- National Drug Law (1992)

Human Biological Materials

Relevant Standards

- Blood and Blood Products Law (2003) (Burmese): http://www.moh.gov.mm/file/Law/Blood%20and%20Blood%20Product%20Law%20(2003).pdf
- Body Organ Donation Law (2004)

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: http://www.hrc.govt.nz/

- National Ethics Advisory Committee (NEAC): http://www.neac.health.govt.nz/
- Ministry of Health (MOH): http://www.moh.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): https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/
- 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

Drugs

Key Organizations

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

Relevant Standards

- 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

Key Organizations

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

Relevant Standards

- 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

- 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: http://www.privacy.org.nz/assets/Files/Codes-of-Practice-materials/Health-Information-Privacy-Code-1994-including-Amendment.pdf

Human Biological Materials

Key Organizations

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

Relevant Standards

- Health Act 1956 (2012)

- Human Tissue Act 2008
- MOH, Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (2007): http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes

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/
- Advisory Committee on Assisted Reproductive Technology (ACART): http://ecart.health.govt.nz/
- Ministry of Health: http://www.moh.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

- Various: http://nbcpakistan.org.pk/guidelines.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/?page_id=61

Human Biological Materials

Key Organizations

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

Relevant Standards

- Ethical Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials (HBM): http://nbcpakistan.org.pk/assets/hbm-nbc-guidelines-final-18june-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/?page_id=61

ASIA/PACIFIC – Philippines

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Drugs

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

Devices

Key Organizations

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

Relevant Standards

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

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards

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

Social-Behavioral Research

Key Organizations

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

Relevant Standards

- 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): https://privacy.gov.ph/implementing-rules-and-regulations-of-republic-act-no-10173-known-as-the-data-privacy-act-of-2012/

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- National Ethical Guidelines for Health and Health-Related Research, Pages 91, 157 and 163 (2017): http://www.ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=96:2017-national-ethical-guidelines-for-health-and-health-related-research

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

Drugs

Key Organizations

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

Relevant Standards

- Health Products Act 2007: https://sso.agc.gov.sg/Act/HPA2007
- Medicines Act 1975: https://sso.agc.gov.sg/Act/MA1975
- Health Products (Clinical Trials) Regulations 2016: https://sso.agc.gov.sg/SL/HPA2007-S331-2016
- Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016: https://sso.agc.gov.sg/SL/HPA2007-S332-2016
- Medicines (Clinical Trials) Regulations 2016: https://sso.agc.gov.sg/SL/MA1975-S335-2016
- Medicines (Medicinal Products as Clinical Research Materials) Regulations 2016: https://sso.agc.gov.sg/SL/MA1975-S336-2016
- Singapore Guidance on Good Clinical Practice Compliance Inspection Framework (2021): https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-11_gcp_inspection_1mar2021.pdf
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH E6(R2) Good Clinical Practice Guideline, 2016: https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
- Health Products (Medical Device) Regulations 2010: http://sso.agc.gov.sg/SL/HPA2007-S436-2010
- Directive on the Use of Cell, Tissue and Gene Therapy Products Manufactured In-House by Healthcare Institutions (2020): https://www.moh.gov.sg/licensing-and-regulation/regulations-guidelines-and-circulars/details/directive-on-the-use-of-cell-tissue-and-gene-therapy-products-manufactured-in-house-by-healthcare-institutions
- 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

Research Injury

Key Organizations

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

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/-/media/Files/PDPC/PDF-Files/Sector-Specific-Advisory/advisoryguidelinesforthehealthcaresector28mar2017.pdf?la=en
- Personal Information in Biomedical Research (2007): https://www.bioethics-singapore.gov.sg/files/publications/reports/personal-informations-in-biomedical-research-full-report.pdf

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): https://www.moh.gov.sg/docs/librariesprovider5/legislation/guidance-on-prohibition-against-commercial-trading-of-human-tissue-under-hbra---february-2017.pdf
- Guide on the Requirement of Appropriate Consent for the Conduct of HBR and Handling of Human Tissue (2019): https://www.moh.gov.sg/docs/librariesprovider5/legislation/guidance-on-appropriate-consent_17-may-2019.pdf
- Bioethics Advisory Committee, Human Tissue Research (2002): https://www.bioethics-singapore.gov.sg/files/publications/reports/human-tissue-research-full-report.pdf

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

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): https://www.bioethics-singapore.gov.sg/files/publications/reports/ethical-legal-and-social-issues-in-human-stem-cell-research-reproduction-full-report.pdf
- Donation of Human Eggs for Research (2008): https://www.bioethics-singapore.gov.sg/files/publications/reports/donation-of-human-eggs-for-research-full-report.pdf
- Human-Animal Combinations in Stem-Cell Research (2010): https://www.bioethics-singapore.gov.sg/files/publications/reports/human-animal-combinations-in-stem-cell-research-full-report.pdf

ASIA/PACIFIC – South Korea

General

Key Organizations

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Pharmaceutical Affairs Act No. 16250 (2019.01.15): https://www.law.go.kr/LSW/eng/engLsSc.do?menuId=2&section=lawNm&query=%EC%95%BD%EC%82%AC%EB%B2%95&x=0&y=0#liBgcolor15
- Medical Device Act No. 16402 (2019.04.23): https://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=50798

- Act on In Vitro Diagnostic Medical Devices Act No. 16433 (2019.05.01): https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72621&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1
- Enforcement Decree of the Medical Device Act No. 1580 (2019.12.23): https://www.law.go.kr/LSW/eng/engLsSc.do?query=medical+device+act&menuId=2&section=lawNm&y=20&x=23#liBgcolor8
- Regulations for Clinical Trial Personnel Education and Certification for the Educational Institution Notice No.2019-3 (2019.01.17): https://www.law.go.kr/행정규칙/의약품임상시험종사자교육및교육실시기관지정에관한규정/(2019-3,20190117)
- Regulation on Approval for Investigational New Drug Application of Drugs, Notice No. 2021-12 (2021.02.25): https://www.law.go.kr/행정규칙/의약품임상시험계획승인에관한규정/(2021-12,20210225)
- Regulation on Approval for Investigational Device Exemption Application No. 2019-33 (2019.04.30): https://www.law.go.kr/행정규칙/의료기기임상시험계획승인에관한규정/(2019-33,20190430)
- Regulation for Medical Device Approvals, Notifications and Reviews No. 2021-35 (2021.04.22): https://www.law.go.kr/행정규칙/의료기기허가·신고·심사등에관한규정/(2021-35,20210422)
- Regulation on Medical Device Re-examination No. 2020-29 (2020.05.01): https://www.law.go.kr/행정규칙/의료기기재심사에관한규정/(2020-29,20200501)
- Guidelines on Human Research Protection Program 0053-01 (2014.3) 2017.5.31 고시: https://nedrug.mfds.go.kr/bbs/38/65
- Bioethics and Safety Act No. 16372 (2019.04.23): https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=208465&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000
- Enforcement Decree of Pharmaceutical Affairs Act No. 30141 (2019.10.22): https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=210861&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000
- 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

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

Research Injury

Key Organizations

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

Relevant Standards

- Pharmaceutical Affairs Act No.16250 (2019.01.15): https://elaw.klri.re.kr/kor_service/lawView.do?hseq=49635&lang=ENG
- Regulation on Safety of Pharmaceuticals, etc. No. 1576 (2019.12.12.): https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=71487&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=2
- Enforcement Rule of the Medical Devices Act No.1580 (2019.12.23.): https://elaw.klri.re.kr/eng_mobile/viewer.do?hseq=54331&type=part&key=36 [Amended 2021.06.24]
- Guidelines for Clinical Trial Indemnity and Its Process 0052-03 (2021.06.21.): https://www.mfds.go.kr/brd/m_1060/view.do?seq=14857&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=103
- Guidance for Sponsors; Safety Reporting Requirements 0785-02 (2020.10.30.): https://www.mfds.go.kr/brd/m_1060/view.do?seq=14669&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=4

Social-Behavioral Research

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- Personal Information Protection Act No. 16930 (2020.02.04): https://elaw.klri.re.kr/kor_service/lawView.do?hseq=53044&lang=ENG
- Enforcement Decrees to Personal Information Protection Act No. 30892 (2020.02.04): https://elaw.klri.re.kr/kor_service/lawView.do?hseq=54521&lang=ENG
- Bioethics and Safety Act No. 16372 (2019.04.23): https://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=52559
- Act on Dissection and Preservation of Corpses No. 17472 (2021.04.08): https://www.law.go.kr/법령/시체해부및보존등에관한법률
- Guidelines for the Use of Health and Medical data (2021.01): http://www.mohw.go.kr/react/al/sal0101vw.jsp?PAR_MENU_ID=04&MENU_ID=040101&CONT_SEQ=363309&page=1
- Standard Personal Information Protection Guidelines (2020.08.11): https://www.law.go.kr/admRulSc.do?menuId=5&subMenuId=41&tabMenuId=183&query=%ED%91%9C%EC%A4%80%EA%B0%9C%EC%9D%B8%EC%A0%95%EB%B3%B4%EB%B3%B4%ED%98%B8%EC%A7%80%EC%B9%A8#liBgcolor0
- Criteria for ensuring the Safety of Personal Information (2020.08.11): https://www.law.go.kr/admRulSc.do?menuId=5&subMenuId=41&tabMenuId=183&query=%ED%91%9C%EC%A4%80%20%EA%B0%9C%EC%9D%B8%EC%A0%95%EB%B3%B4%20%EB%B3%B4%ED%98%B8%EC%A7%80%EC%B9%A8#liBgcolor7
- 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): https://www.mfds.go.kr/brd/m_218/view.do?seq=33339&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=7

Genetic Research

Key Organizations

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- Bioethics and Safety Act No.16372(2019.04.): https://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=52559
- Enforcement Decree of the Bioethics and Safety Act No. 30141(2019.10.): https://elaw.klri.re.kr/kor_service/lawView.do?hseq=52561&lang=ENG
- Enforcement Rule of Bioethics and Safety Act No. 733 (2020.12.31): https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙
- Enforcement Rule of the Safety and Support of Advanced Regenerative Medicine No. 746 (2020.08.28): https://www.law.go.kr/법령/첨단재생의료안전및지원에관한규칙
- Advanced Regenerative Medicine and Advanced Biopharmaceuticals Safety and Support Act No. 17472 (2020.8.11.): https://www.law.go.kr/법령/첨단재생의료및첨단바이오의약품안전및지원에관한법률
- Enforcement Decree of Advanced Regenerative Medicine and Advanced Biopharmaceuticals Safety and Support Act No. 30979 (2020.08.28): https://www.law.go.kr/법령/첨단재생의료및첨단바이오의약품안전및지원에관한법률시행령

- Enforcement Rule of Advanced Biopharmaceuticals Safety and Support No. 1641 (2020.09.07): https://www.law.go.kr/법령/첨단바이오의약품안전및지원에관한규칙
- Guideline on Quality Assessment for Gene-Editing Based Advanced Therapy Medicinal Products (2018.12): https://www.mfds.go.kr/eng/brd/m_27/view.do?seq=71877

ASIA/PACIFIC – Sri Lanka

Drugs, Biologics, and Devices

Key Organizations

- Cosmetics, Devices, and Drugs Regulatory Authority, Subcommittee on Clinical Trials: http://www.cdda.gov.lk/index.php?option=com_content&view=article&id=78&Itemid=115&lang=en

Relevant Standards

- Legislation, various: http://nmra.gov.lk/index.php?option=com_content&view=article&id=263&Itemid=190&lang=en
- Guidelines, various: http://nmra.gov.lk/index.php?option=com_content&view=article&id=441:general-guideline-topics&catid=42&Itemid=331&lang=en#medicines-regulatory-division

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

ASIA/PACIFIC – Taiwan

General

Key Organizations

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

Relevant Standards

- Human Subjects Research Act (2019) (Chinese): https://law.moj.gov.tw/LawClass/LawAll.aspx?pcode=L0020176
- Medical Care Act (2018): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020021
- Regulations on Human Trials (2016): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020162
- Enforcement Rules of the Medical Care Act (2017) (Chinese): http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0020023
- Regulations for the Organization and Operation of Human Research Ethics Review Boards (2018): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020179
- Exempt Review Categories for Human Research (2012): https://gazette.nat.gov.tw/egFront/e_detail.do?metaid=54295

- Informed Consent Exemptions for Human Research (2012): https://gazette.nat.gov.tw/egFront/e_detail.do?metaid=54273
- Expedited Review Categories for Human Research (2012): https://gazette.nat.gov.tw/egFront/e_detail.do?metaid=54277
- Regulations Governing the Organization and Operation of the Human Research Ethics Review Board (2018): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020179

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Medical Care Act (2018): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020021 ‘
- Pharmaceutical Affairs Act (2018): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001
- Regulations on Human Trials (2016): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020162
- Pharmaceutical Affairs Act Enforcement Rules (2016): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030002
- Regulations for Drug Safety Monitoring (2013): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030050
- Regulations for Good Clinical Practice (2014): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030056
- Regulations for Governing the Management of Medical Devices (2014)
- Regulation on Bioavailability and Bioequivalence Studies (2015): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030065

Research Injury

Key Organizations

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

Relevant Standards

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

Social-Behavioral Research

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

- Human Biobank Management Act (2012): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020164
- Medical Care Act (2018): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020021
- Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162
- Administrative Regulations on the Establishment of Human Biobanks (2011): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020173
- Good Tissue Practice (2002) (Chinese): http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1153&chk=342a5c73-c206-4756-ade9-9c63265c859d&mid=46&name=fdContent
- Guidelines for the Collection and Use of Human Specimens for Research (2006) (Chinese): http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1598&chk=6056f7dd-eb0a-48bf-ae7e-8a2a5875e6e0&mid=46&name=fdContent

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.most.gov.tw/en/public

Relevant Standards

- Human Biobank Management Act (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020164

- Regulations on Commercial Benefit Feedback of Human Biobanks (2010) (Chinese): https://law.moj.gov.tw/LawClass/LawAll.aspx?pcode=L0020170
- Administrative Regulations on the Establishment of Human Biobanks (2011): https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020173
- Guidance for Information Safety of Human Biobank (2010) (Chinese): http://regulation.cde.org.tw/doc_data_display?sid=1929&doctype2

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

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

ASIA/PACIFIC – Tajikistan

NOTE: For an overview of human subject protections in Tajikistan, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 9: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf

General

Key Organizations

- Ministry of Public Health: http://www.health.tj/

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/single_country.php?c_id=213

General

Key Organizations

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

Relevant Standards

- Medical Professions Act (2009), Articles 47-50: http://www.fercit.org/SIDCER-FERCAP/Handout_10/4.%20Accreditation-update_surveyor_aj.Sopit.pdf
- NCRT, Regulation on the Permission of Foreign Researchers (1982): https://foreignresearcher.nrct.go.th/index.php?lang=th&mod=forms&op=regulations_en

- NCRT, Guidance for Foreign researcher Conducting Research in Thailand, various: https://foreignresearcher.nrct.go.th/index.php?lang=en&mod=forms&op=guidelines_en
- MCT, Rule of the Medical Council on the Observance of Medical Ethics (1983): http://thailaws.com/law/t_laws/tlaw0510.pdf
- MCT, National Guideline for Ethical Research on Human Subjects (2002)
- FERCIT, Ethical Guidelines for Research on Human Subject in Thailand (2007): http://www.fercit.org/file/Guideline_English_version.pdf

Drugs, Biologics, and Devices

Drugs

Key Organizations

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

Relevant Standards

- Consumer Protection Act (2007)
- FDA, Rules, Procedures and Conditions for Accepting Ethics Committee for Research Involving Human Subjects (2018)
- MCT, Acts and Rules, various: https://tmc.or.th/En/act_rules_en.php
- MCT, Thailand Good Clinical Practice Guidelines (2002)

Devices

Key Organizations

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

Relevant Standards

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

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

Privacy/Data Protection

Key Organizations

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

Relevant Standards

- Official Information Act, B.E. 2540 (1997): http://www.oic.go.th/web2017/en/ACTOfficial_Information.htm.
- Ministerial Regulations, various: http://www.oic.go.th/web2017/en/bookshell_law.htm?title=Ministerial%20Regulations&cid=142

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

Relevant Standards

- 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)
- State standard of the Republic of Uzbekistan. Good Clinical Practice (GCP) (2018): https://uzpharm-control.uz/uploads/documents/GCP_2765-2018.pdf.
- Model rules of ethical conduct of the Agency for the Development of the Pharmaceutical Industry under the Ministry of Health of the Republic of Uzbekistan (Order No. 90 of July 26, 2018): https://uzpharm-control.uz/en/documents/category/9

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/single_country.php?c_id=233

General

Key Organizations

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

Relevant Standards

- Decision No. 111/QD-BYT – On Promulgation of Regulation on Organization and Operation of Council of Ethics in Biomedical Research at Grass-Roots Level, Chapter I (Articles 3 and 4), Chapter II, and Chapter III (2013): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo111-QD-BYT.pdf
- Decision No. 460/QD-BYT – On the Promulgation of Regulations on Organization and Operation of Ethical Evaluation Committee in Biomedical Research of the Ministry of Health, Period 2012-2017, Chapters I-III (2012): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo460-QD-BYT.pdf
- Circular No. 45/2017/TT-BYT – Regulation on the Establishment, Functions, Tasks, and Powers of the Ethics Committee in Biomedical Research (2017) (Vietnamese): https://thuvienphapluat.vn/van-ban/The-thao-Y-te/Thong-tu-45-2017-TT-BYT-nhiem-vu-quyen-han-Hoi-dong-dao-duc-nghien-cuu-y-sinh-hoc-354849.aspx
- Decision No. 1122/QD-BYT – On the Establishment of the Ethics Committee in Biomedical Research of the Ministry of Health, Period 2018-2023: http://crc.pasteurhcm.gov.vn/upload/files/1122_2018.pdf

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

- Law on Pharmacy (No. 34/2005/QH11), Chapter II (Section III, Article 20), Chapter VIII (Articles 54 and 59) (2005): http://www.vertic.org/media/National%20Legislation/Vietnam/VN_Law_on_Pharmacy.pdf

- Decision No. 799/QD-BYT on the Issuance of Guideline on Good Clinical Practice, Chapter III, Articles 1 and 2 (2008): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo799-QD-BYT.pdf
- Decision No. 799/QD-BYT of the Minister of Health on the Promulgation of the Guidelines on Good Clinical Practice of Clinical Trials (2008): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo799-QD-BYT.pdf
- Circular – Guidelines for Clinical Trials on Drugs (C-ClinDrugTrial), Articles 2, 4, 5, 9, 17, 18, 31, and 39 (2012): http://clinregs.niaid.nih.gov/documents/vietnam/C-ClinDrugTrial.pdf
- Guidelines for Clinical Trials of Drugs, Chapter III, Articles 10, 16, and 17 (2012): https://clinregs.niaid.nih.gov/documents/vietnam/C-ClinDrugTrial.pdf
- Circular No. 29/2018/TT-BYT – Regulations for Clinical Trials on Drugs (Vietnamese): https://thuvienphapluat.vn/van-ban/The-thao-Y-te/Circular-29-2018-TT-BYT-clinical-trial-of-drugs-401541.aspx

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