

Country	Key Organizations	Legislation	Regulations	Guidelines
Malaysia				
1. General	Society of Clinical Research Professionals Malaysia (SCRPM) in Malaysia https://scrpm.ucoz.com/	-	-	SCRPM: A Guide To Conducting Clinical Trials In Malaysia http://www.clinicalresearch.my/wp-content/uploads/2017/03/A-Guide-to-Conduct-Clinical-Trials-in-Malaysia.pdf
	Ministry of Health Malaysia, Medical Review & Ethics Committee (MREC)	-	-	MREC: Guidelines For Ethical Review Of Clinical Research Or Research Involving Human Subjects http://www.nccr.gov.my/view_file.cfm?fileid=16
	Malaysian Industry-Government Group For High Technology (MIGHT), National Science Council 2017 https://www.might.org.my/download/the-malaysian-code-of-responsible-conduct-in-research/	-	-	MIGHT: The Malaysian Code Of Responsible Conduct In Research https://uitmethics.uitm.edu.my/v1/images/stories/guidelines/my_code.pdf
	Ministry of Health Malaysia, National Pharmaceutical Regulatory Agency (NPRA) https://npra.gov.my/index.php/en/	-	-	NPRA: Malaysian Guideline for Good Clinical Practice, 4 TH Edition https://www.crc.gov.my/wp-content/uploads/2018/03/Malaysian_gcp_4th_Edition28Final_29.pdf Malaysian Guideline for Phase I Unit Inspection & Accreditation Programme

				https://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Clinical_Trial/MALAYSIANGUIDELINEFORPHASEIUNITINSPECTION.pdf
	The Academy of Science Malaysia (ASM) https://www.akademisains.gov.my/	-	-	ASM: Malaysian Educational Module On Responsible Conduct Of Research https://www.akademisains.gov.my/rcr-book-online/
	National Committee For Clinical Research, Clinical Research Malaysia (CRC) http://www.nccr.gov.my/	-	-	CRC: Malaysian Phase I Clinical Trial Guidelines https://clinicalresearch.my/mp1g/
	Ministry of Health, National Institutes of Health (NIH) http://www.nih.gov.my/	-	-	NIH: National Institutes of Health (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
2. <i>Drugs, Biologics, and Devices</i>	<u>Drugs</u> Laws of Malaysia. Attorney General's Chambers of Malaysia (AGC) http://www.agc.gov.my/agcportal/index.php?r=portal2	AGC: Act 368: Sale Of Drugs Act 1952 (REVISED - 1989) https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/sales-drug-act-1952-act-368.pdf	AGC: Regulation 7(1) of the Control of Drugs and Cosmetics Regulations 1984 https://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Clinical_Trial/CTILC	The Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption, edition 6.4 http://npra.moh.gov.my/images/Guidelines_Central/Guidelines_on_Clinical

		<p>Act 366: Poison Act 1952 (REVISED - 1989) https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/poisons-act-1952-act-366.pdf</p> <p>Act 234: Dangerous Drugs Act 1952 (REVISED 1980) http://www.agc.gov.my/agcportal/uploads/files/Publications/LOM/EN/Act%20234.pdf</p>	<p>TXGuidelineEdn64updated07082017cleanTSC.pdf</p> <p>Regulation 15(5): Clinical Trial Exemption (CTX) https://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Clinical_Trial/CTILCTXGuidelineEdn64updated07082017cleanTSC.pdf</p> <p>Regulation 18A of the Control of Drugs and Cosmetics Regulations 1984 https://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Clinical_Trial/CTILCTXGuidelineEdn64updated07082017cleanTSC.pdf</p> <p>The Poison Regulations (Psychotropic Substances) 1989 https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/poisons-psychotropic-substances-regulations-1989.pdf</p>	<p>Trial/CTILCTXGuidelineEdn64updated07082017cleanTSC.pdf</p>
	<p>Ministry of Health, National Pharmaceutical Control Bureau (NPCB)</p>			<p>NPCB: Malaysian Guideline for Safety Reporting of Investigational Products http://www.nccr.gov.my/view_file.cfm?fileid=34</p>

	<p>Ministry of Health Malaysia, National Pharmaceutical Regulatory Agency (NPRA) https://npra.gov.my/index.php/en/</p>	-	-	<p>NPRA: Malaysian Guideline for Good Clinical Practice, 4TH Edition: (2018) https://www.crc.gov.my/wp-content/uploads/2018/03/Malaysian_gcp_4th_Edition28Final_29.pdf</p> <p>The Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption, edition 6.4 https://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Clinical_Trial/CTILCTXGuidelineEdn64updated07082017cleanTSC.pdf</p>
	<p>Ministry of Health Malaysia, Pharmaceutical Services Programme https://www.pharmacy.gov.my/v2/en</p>	-	-	<p>Pharmaceutical Services Programme: Malaysia National Medicines Policy https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/bukudunas.pdf</p> <p>Pharmacy Research Priorities in Malaysia https://www.pharmacy.gov.my/v2/en/documents/pharmacy-research-priorities-malaysia.html</p>
	<p><u>Biologic</u> Ministry of Health Malaysia, Medical Review & Ethics Committee (MREC)</p>	-	-	<p>MREC: Guidelines for Ethical Review of Clinical Research or Research Involving Human Subjects (2006): http://www.nccr.gov.my/view_file.cfm?fileid=16</p>

	<p>Ministry of Health Malaysia, Institute for Medical Research (IMR) https://www.imr.gov.my/index.php/en/</p>			<p>IMR: Standard Operating Procedure For Transport Of Biological Specimens In Malaysia http://www.hkl.gov.my/content/patologi/SOP_For_Transportation_of_Biological_Specimens.pdf</p>
	<p><u>Devices</u> 1. Medical Device Authority (MDA) https://portal.mda.gov.my/ 2. Laws of Malaysia. Attorney General's Chambers of Malaysia (AGC) http://www.agc.gov.my/agcportal/index.php?r=portal2</p>	<p>AGC: Act 737: Medical Device Act 2012 https://portal.mda.gov.my/index.php?option=com_docman&view=download&alias=685-medical-device-act-2012-eng&category_slug=regulation&Itemid=476</p>	<p>AGC: Medical Device Regulations 2012 https://portal.mda.gov.my/doc-list/legislation.html</p>	<p>MDA: Guidelines for the implementation of medical device regulatory system under Medical Act 2012 (Act 737) https://portal.mda.gov.my/doc-list/guideline.html</p>
3. <i>Clinical Trial Registries</i>	<p>National Medical Research Register (NMRR) https://www.nmrr.gov.my/fwblog/inPage.jsp</p>	-	-	<p>NMRR Frequently Asked Questions FAQs https://www.nmrr.gov.my/doc/FREQUENTLY_ASKED_QUESTIONS_FAQ.pdf</p>
4. <i>Research Injury</i>	<p>Ministry of Health Malaysia, National Pharmaceutical Regulatory Agency (NPRA) https://nptra.gov.my/index.php/en/</p>	-	-	<p>NPRA: Malaysian Guideline for Good Clinical Practice, 4TH Edition, Section 5.8: Compensation to Subjects and Investigators https://www.crc.gov.my/wp-content/uploads/2018/03/Malaysian_gcp_4th_Edition28Final_29.pdf</p>

	<p>Laws of Malaysia. Attorney General's Chambers of Malaysia (AGC)</p> <p>http://www.agc.gov.my/agcportal/index.php?r=portal2</p>	<p>AGC: Act 514: Occupational Safety and Health Act 1994, Section 35</p> <p>http://www.dosh.gov.my/index.php/en/legislation/acts/23-02-occupational-safety-and-health-act-1994-act-514/file</p>	-	-
<p>5. <i>Social-Behavioral Research</i></p>	<p>Malaysian Industry-Government Group For High Technology (MIGHT), National Science Council 2017</p> <p>Ministry of Health Malaysia, Institute for Health Behavioural Research (IPTK)</p> <p>http://iptk.moh.gov.my/iptk/index.php/home</p>	-	-	<p>MIGHT: The Malaysian Code of Responsible Conduct MCRC, Section 8</p> <p>https://uitmethics.uitm.edu.my/v1/images/stories/guidelines/my_code.pdf</p>
<p>6. <i>Privacy/Data Protection</i></p>	<p>Laws of Malaysia. Attorney General's Chambers of Malaysia (AGC)</p> <p>http://www.agc.gov.my/agcportal/index.php?r=portal2</p>	<p>AGC: Act 709: Personal Data Protection (PDPA) Act: (2010) Section 39. Extent of disclosure of personal data</p> <p>http://www.pdp.gov.my/images/LAWS_OF_MALAYSIA_PDPA.pdf</p> <p>Act 709: Personal Data Protection Act 2010: Section 40. Processing of sensitive personal data</p>	-	

		http://www.pdp.gov.my/images/LAWS_OF_MALAYSIA_PDPA.pdf		
	Ministry of Communications and Multimedia (KKMM), Personal Data Protection Commissioner Malaysia. http://www.pdp.gov.my/index.php/en/			KKMM: Compliance to Personal Data Protection Act (PDPA): a quick guide http://www.pdp.gov.my/images/slaid-seminar/PDPA-Compliance---Jan-2019.pdf
	Ministry of Health Malaysia, National Pharmaceutical Regulatory Agency (NPRA) https://npra.gov.my/index.php/en/	-	-	NPRA: Malaysian Guideline for Good Clinical Practice, 4 TH Edition, Pg 82, 83 Confidential Information https://www.crc.gov.my/wp-content/uploads/2018/03/Malaysian_gcp_4th_Edition28Final_29.pdf
7. <i>Human Biological Materials</i>	National Committee for Clinical Research (NCCR) http://www.nccr.gov.my/	-	-	NCCR: Guideline on the Use of Human Biological Tissues for Research (2016) https://www.nmrr.gov.my/doc/Guideline-on-Human-Tissue-in-Clinical-Research.pdf
	Laws of Malaysia. Attorney General's Chambers of Malaysia (AGC) http://www.agc.gov.my/agcportal/index.php?r=portal2	AGC: Act 342: Prevention and Control of Infectious Disease Act 1988 http://www.moh.gov.my/index.php/database_stores/attachment/download/317/19	Prevention and Control of Infectious Diseases (Importation and Exportation of Human Remains, Human tissues and Pathogenic Organisms or Substances) Regulations 2005	-

			http://www.bloomcomm.com/sites/ISAKOS-2017/supportLetters/SD.AP.2.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 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	DNA Identification Regulations 2012. Malaysian Government Gazette of 30 Aug 2012.	-
8. Genetic Research	Malaysian Medical Council:	-	-	Medical Genetics and Genetic Services. MMC Guidelines 010/2006: http://www.mmc.gov.my/images/contents/ethics/Medical-GeneticsGenetic-Services.pdf
	Laws of Malaysia. Attorney General's Chambers of Malaysia (AGC) http://www.agc.gov.my/agcportal/index.php?r=portal2	AGC: 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	

	<p>The Ministry of Water, Land, and Natural Resources, Department of Biosafety, National Biosafety Board (NBB)</p> <p>http://www.biosafety.gov.my/en-my/Pages/default.aspx</p>			<p>NBB: Guidelines For Institutional Biosafety Committees</p> <p>https://um.edu.my/docs/default-source/institutional-biosafety-committee-(ibc)/ibc-guidelines.pdf?sfvrsn=2</p>
	<p>The Ministry of Water, Land, and Natural Resources, Department of Biosafety, Genetic Modification Advisory Committee (GMAC)</p> <p>http://www.biosafety.gov.my/en-my/Pages/default.aspx</p>			<p>GMAC: Biosafety Guidelines Risk Assessment Of Genetically Modified Microorganisms</p> <p>http://www.rmc.upm.edu.my/dokumen/92272_Risk_Assessment_of_GM_Microorganisms.pdf</p>
<p>9. Embryos, Stem Cells and Cloning</p>	<p>Ministry Of Health Malaysia, National Pharmaceutical Control Bureau (NPCB)</p> <p>https://npra.gov.my/index.php/en/</p>			<p>NPCB: Checklist for Research on Stem Cell and Cell-Based Therapies (2014):</p> <p>http://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Regulatory/CGTP_guidelines.doc</p> <p>Guidance Document And Guidelines For Registration Of Cell And Gene Therapy Products (CGTPs) In Malaysia (2016)</p> <p>https://www.npra.gov.my/images/00N/PRA/biologic/guidelines/CGTP_guidelinesbio.pdf</p>

	<p>Ministry of Health, Medical Development Division http://www.moh.gov.my/index.php?mid=5</p>			<p>Medical Development Division: Guidelines for Stem Cell Research and Gene Therapy (2009): http://www.moh.gov.my/moh/resources/auto%20download%20images/586f38d1c77ed.pdf</p> <p>National Organ, Tissue and Cell Transplantation Policy http://www.mst.org.my/articles/MALAYSIA%20TRANSPLANT%20POLICY.pdf</p> <p>National Standards For Cord Blood Banking And Transplantation http://www.moh.gov.my/moh/resources/auto%20download%20images/589d78e8689af.pdf</p> <p>National Standards For Stem Cell Transplantation http://www.moh.gov.my/moh/resources/Arkib/National_Standards_For_Stem_cell_Transplatation.pdf</p>
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