TABLE OF CONTENTS

Country	Key Organizations	Legislation	Regulations	Guidelines
ASIA/PACIFIC				
Australia				
General	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Australian Research Council (ARC): http://www.arc.gov.au	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: 1. Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) http://www.nhmrc.gov.au/guidelines/publications/e52 2. Keeping Research on Track: A Guide for Aboriginal and Torres Strait Islander Peoples about Health Research Ethics (2006): http://www.nhmrc.gov.au/guidelines/publications/e65 NHMRC, ARC, and Universities Australia: 1. Australian Code for the Responsible Conduct of Research (2007): http://www.nhmrc.gov.au/guidelines/publications/r39 2. National Statement on Ethical Conduct in Human Research, 2007 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72
	Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS): http://aiatsis.gov.au/			Guidelines for Ethical Research in Australian Indigenous Studies (2012): http://www.aiatsis.gov.au/research/ethics/GERAIS.html
Drugs and Devices	*Drugs*			
	Therapeutic Goods Administration (TGA): http://www.tga.gov.au	Therapeutic Goods Act 1989 (2016): https://www.legislation.gov.au/Details/C2016C00269	Therapeutic Goods Regulations 1990 (2016): https://www.legislation.gov.au/Details/F2016C00801	TGA: 1. Human Research Ethics Committees and the Therapeutic Goods Administration (2001): http://www.tga.gov.au/hp/access-hrec.htm 2. Australian Clinical Trial Handbook (2006): https://www.tga.gov.au/sites/default/files/clinical-trials-handbook.pdf NHMRC, ARC, and UA: 1. National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2015): http://www.nhmrc.gov.au/guidelines/publicatio

Country	Key Organizations	Legislation	Regulations	Guidelines
				ns/e72 2. Mutual Acceptance of Ethical Review of Clinical Trials: http://www.health.vic.gov.au/clinicaltrials/mutual-acceptance.htm
	Devices			
	Therapeutic Goods Administration: http://www.tga.gov.au/industry/devices.htm	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	1. National Health and Medical Research Council and the Department of Industry, Innovation, and Science: https://www.australianclinicaltrials.gov.au/ 2. Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/			1. National Statement on Ethical Conduct in Human Research, 3.3.12 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72 2. FAQs: http://www.anzctr.org.au/Faq.aspx
Research Injury	1. Therapeutic Goods Administration (TGA): http://www.tga.gov.au/ 2. Medicines Australia https://medicinesaustralia.com.au 3. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au			TGA: Guidance on Good Clinical Practice (CPMP/ICH-135/95). Paragraphs 5.8.1, 5.11.1, 8.2.5 , 8.2.7 (2000): https://www.tga.gov.au/publication/note-guidance-good-clinical-practice Medicines Australia: Industry Standard Compensation Guidelines, Section 4 (2012): https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/ NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research. Paragraphs 3.3.24 and 3.3.25 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72
Privacy/Data Protection Note: All Australian states and territories have privacy/data protection laws: http://www.oaic.gov.au	Office of the Australian Information Commissioner: http://www.oaic.gov.au/	Privacy Act 1988 (2016): https://www.legislation.gov.au/Details/C2016C00838	1. Australian Privacy Principles Guidelines (2014): http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles 2. Guidelines under Section 95 of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr1	1. Australian Privacy Principles Guidelines (2014): http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles 2. Guidelines under Section 95 of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr1

Country	Key Organizations	Legislation	Regulations	Guidelines
/privacy/other-privacy-jurisdictions/state-and-territory-privacy-law			3. Guidelines Approved under Section 95A of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr2 4. Guidelines Approved under Section 95AA of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr3 5. Privacy Regulation 2013 (2016): https://www.legislation.gov.au/Details/F2016C00599	3. Guidelines Approved under Section 95A of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr2 4. Guidelines Approved under Section 95AA of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr3
Human Biological Materials Note: All Australian states and territories have laws on human biological materials.	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Therapeutic Goods Administration (TGA): http://www.tga.gov.au/			NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research (2015): Chapters 3.2 and 3.4: http://www.nhmrc.gov.au/guidelines/publications/e72 TGA: Australian Regulatory Guidelines for Biologicals (2014): http://www.tga.gov.au/industry/biologicals-argb.htm
Genetic Research	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Office of the Gene Technology Regulator: http://www.ogtr.gov.au/	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, ARC, and UA: National Statement on Ethical Conduct in Human Research, Chapter 3.5 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72
Embryos, Stem Cells, and Cloning	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. National Health and Medical Research Council: Embryo Research Licensing Committee https://www.nhmrc.gov.au/about/nhmrc-committees/embryo-research-licensing-committee	1. Prohibition of Human Cloning for Reproduction Act 2002 (2008): http://www.comlaw.gov.au/Details/C2008C00694 2. Research Involving Human Embryos Act 2002 (2014): http://www.comlaw.gov.au/Details/C2014C00605	Research Involving Human Embryos Regulations (2008): http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/all/search/53B9DAE14F396A2CCA25744E0005E313	NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research, Chapter 3.4 (2015): http://www.nhmrc.gov.au/publications/synopses/e72syn.htm NHMRC: Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2007): http://www.nhmrc.gov.au/publications/synopses/e78syn.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
Bangladesh				
General	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			
Drugs and Devices	Bangladesh Directorate of Drug Administration: http://www.dgda.gov.bd/	1. The Drugs Act (1964) 2. Drugs (Control) Ordinance 1982, Ordinance No. VIII: http://bdlaws.minlaw.gov.bd/pdf_part.php?id=623		
Human Biological Materials	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			Guidelines for Transfer of Human Biological Materials Abroad for Research Purposes (2004)
Burma (Myanmar)				
General	1. Department of Medical Research (DMR): http://www.dmrlm.gov.mm/ 2. Ministry of Health National Ethics Committee on Clinical Research: www.moh.gov.mm			DMR: Operational Guidelines for Institutional Ethical Review Committee (2005)
Drugs and Devices	Ministry of Health, Food and Drug Administration: http://www.fdamyanmar.gov.mm/index.php/en/	National Drug Law (1992)		
Human Biological Materials		1. Blood and Blood Products Law (2003) (Burmese): http://www.moh.gov.mm/file/Law/Blood%20and%20Blood%20Product%20Law%20(2003).pdf 2. Body Organ Donation Law (2004)		
China, People's Republic of For an overview of clinical research regulations in China, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=44				
General	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC): http://en.nhfpc.gov.cn 2. Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/	Law on Practicing Doctors (June 26, 1998), Articles 26 and 37 (Mandarin): http://www.gov.cn/banshi/2005-08/01/content_18970.htm		NHFPC: Interim Measures for Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2007) (Mandarin): http://www.moh.gov.cn/qjjys/s3581/200804/b9f1bfee4ab344ec892e68097296e2a8.shtml NHFPC, CFDA, and State Administration of TCM: Management Guidelines for Conducting Clinical Research at Medical/Health Institutions (Mandarin) (2014):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.nhfpc.gov.cn/yzygj/s3593g/201410/9bd03858c3aa41ed8aed17467645fb68.shtml
Drugs and Devices	*Drugs*			
	Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/	Drug Administration Law of the People's Republic of China (2001): http://eng.sfda.gov.cn/WS03/CL0766/61638.html	1. Regulations for Implementation of the Drug Administration Law of the People's Republic of China (2002): http://eng.sfda.gov.cn/WS03/CL0767/61640.html 2. Chinese Good Clinical Practice (2003) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/24473.html 3. Special Review and Approval Procedure for Drug Registration of the State Food and Drug Administration (2005): http://eng.sfda.gov.cn/WS03/CL0768/61646.html 4. Provisions for Drug Registration (2007): http://eng.sfda.gov.cn/WS03/CL0768/61645.html 5. Qualification and Evaluation of Clinical Trial Sites (2008) (Mandarin): http://www.sfda.gov.cn/WS01/CL0121/29571.html 6. Rules on the Administration of Report and Supervision of Adverse Drug Reactions (2010) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/62621.html	1. Guideline for HIV Vaccine Research Technology (2003) (Mandarin): http://www.sfda.gov.cn/WS01/CL0237/15705.html 2. Guideline for Vaccine Research Technology (2004) (Mandarin): http://www.sfda.gov.cn/WS01/CL0055/10307.html 3. Guidelines on Ethical Review of Drug Clinical Trials (2010) (Mandarin): http://www.sfda.gov.cn/WS01/CL0058/55613.html
	Devices			
	Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/		CFDA and NHFPC: Good Clinical Practice on Medical Device Clinical Trials (2016) (Mandarin): http://www.sda.gov.cn/WS01/CL0053/148101.html	CFDA: Guiding Principles of the Clinical Trail Technology on In Vitro Diagnostic (IVD) Reagents (2014) (Mandarin): http://www.sda.gov.cn/WS01/CL0087/106241.html Templates for Medical Device Clinical Trials (Mandarin): 1. Ethical Review Application And

Country	Key Organizations	Legislation	Regulations	Guidelines
				Review Form 2. Informed Consent Form 3. CRF Template 4. Protocol Template 5. Report Template 6. Required Documents List Access: http://www.sda.gov.cn/WS01/CL0087/148126.html
Clinical Trials Registry	Chinese Clinical Trial Registry: http://www.chictr.org.cn/index.aspx			FAQs: http://www.chictr.org.cn/question.aspx
Privacy/Data Protection	*Hong Kong:*			
	Office of the Privacy Commissioner for Personal Data: http://www.pcpd.org.hk	Personal Data (Privacy) Ordinance (2013): http://www.legislation.gov.hk/blis_pdf.nsf/6799165D2FEE3FA94825755E0033E532/B4DF8B4125C4214D482575EF000EC5FF/$FILE/CAP_486_e_b5.pdf		
Research Injury	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Chinese Food and Drug Administration (CFDA): http://eng.sfda.gov.cn/WS03/CL0755/	Chinese Good Clinical Practice, Article 43 (2003) (Mandarin): http://www.sda.gov.cn/WS01/CL0053/24473.html	NHFPC: 1. Interim Measures for Guidelines on Ethical Review of Biomedical Research Involving Human Subjects, Article 20 (2007) (Mandarin): http://www.moh.gov.cn/qjjys/s3581/200804/b9f1bfee4ab344ec892e68097296e2a8.shtml 2. Regulations on Recall of Medical Devices (Interim), Article 37 (2011) (Mandarin): http://www.gov.cn/flfg/2011-06/13/content_1882686.htm CFDA and NHFPC: Good Clinical Practice on Medical Device Clinical Trials (2016), Articles 10, 22, 33, and 48; (Mandarin): http://www.sda.gov.cn/WS01/CL0053/148101.html	SFDA: 1. Guideline on Vaccine Clinical Trials, Part 6 (2004) (Mandarin): http://www.sda.gov.cn/WS01/CL0844/10307.html 2. Guideline on Ethical Review of Drug Clinical Trials, Appendix 1, Section 6.10 (2010) (Mandarin): http://www.sda.gov.cn/WS01/CL0058/55613.html
Genetic Research	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/		NHFPC and MOST: 1. Interim Measures for the Administration of Human Genetic Resources (1998) (Mandarin): http://www.most.gov.cn/bszn/new/rly	MOST: Service Guidelines for the Collection, Selling, Export and Admission Application of Human Genetic Resources

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of Science and Technology of the People's Republic of China (MOST): http://www.most.cn/eng/		c/wjxz/200512/t20051226_55327.htm 2. Regulations for the Administration of Human Genetic Resources (2012) (Mandarin): http://www.gov.cn/gzdt/2012-10/31/content_2254379.htm	(2015) (Mandarin): http://www.most.gov.cn/tztg/201507/t20150703_120547.htm
Embryos, Stem Cells, and Cloning	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Ministry of Science and Technology of the People's Republic of China (MOST): http://www.most.cn/eng/		NHFPC: 1. Ethical Principles and Conduct Norms for Human Assisted Reproductive Technologies. (2003) (Mandarin): http://www.moh.gov.cn/qjjys/s3581/200805/f69a925d55b44be2a9b4ada7fcdec835.shtml 2. Regulation on the Clinical Application of Medical Technique (2009) http://www.moh.gov.cn/yzygj/s3589/201308/0c579ba3babf47dc8f0e811810d438a2.shtml NHFPC and CFDA Interim Measures for the Management of Stem Cell Clinical Research (2015) (Mandarin): http://www.nhfpc.gov.cn/qjjys/s3581/201508/28635ef99c5743e294f45e8b29c72309.shtml	NHFPC and MOST: Ethical Guidelines for Research on Human Embryo Stem Cells (2003) (Mandarin): http://www.most.gov.cn/fggw/zfwj/zfwj2003/200512/t20051214_54948.htm
	Hong Kong:			
	Legislative Council of the Hong Kong Special Administrative Region of the People's Republic of China: http://www.legco.gov.hk/index.html		Human Reproductive Technology Ordinance, Chapter 561 (2007): http://www.legislation.gov.hk/blis_pdf.nsf/6799165D2FEE3FA94825755E0033E532/795C7496522C8237482575EF001B5A45?OpenDocument&bt=0	
India 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	Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			1. Ethical Guidelines for Biomedical Research on Human Participants (2006): http://icmr.nic.in/ethical_guidelines.pdf 2. Guidelines for Preparing Standard Operating Procedures (SOP) for IECs for Human Research (no date):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.icmr.nic.in/ethics_SOP.pdf
Drugs and Devices	*Drugs*			
	1. Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): http://cdsco.nic.in 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Schedule Y of the Drugs and Cosmetics Act (2005): http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf	DCGI: 1. Good Clinical Practices for Clinical Research in India (2001): http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf 2. Permission for Clinical Trials: General Statutory Rules 63(E) 3. Ethics Committee Registration: General Statutory Rules 72(E) 4. A/V Consent – General Statutory Rules 611 (E) (2015) 5. Phytopharmaceutical Drug: General Statutory Rules 918(E) 6. Exemption for Academic Research and Animal Toxicity: General Statutory Rules 313(E) (2016)	ICMR: Ethical Guidelines for Biomedical Research on Human Participants: Chapter IV. Drug Trials and Vaccine Trials (2006)
	Devices			
	1. Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): http://cdsco.nic.in 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Drugs & Cosmetics Act, 1940 (2005): http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf	1. Rules: Schedule D & K (2014): http://www.cdsco.nic.in/writereaddata/GSR%20690(E),%2025th%20Sep,%202014.pdf 2. Rules: Schedule MIII (2016): http://www.cdsco.nic.in/writereaddata/GSR%20640%20(E)%20dated%2029_06_2016%20-%20Copy.pdf	ICMR: Ethical Guidelines for Biomedical Research on Human Participants: Clinical Trials with Surgical Procedures/Medical Devices: http://www.icmr.nic.in/ethical_guidelines.pdf
Clinical Trials Registry	Clinical Trials Registry – India: http://ctri.nic.in/			Clinical Trials Registry – India: FAQs: http://ctri.nic.in/Clinicaltrials/faq.php Office of Drugs Controller General: Registration of Clinical Trial in ICMR Clinical Trial Registry: http://www.cdsco.nic.in/writereaddata/CTRegistration.doc
Research Injury	1. Central Drugs Standard Control Organization (CDSCO): http://www.cdsco.nic.in/ 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Drugs & Cosmetics Act, 1940 (2005): http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf	DCGI: Compensation: General Statutory Rules 53 (E): http://www.manupatra.com/manufeed/contents/PDF/634969625902580076.pdf	ICMR: Ethical Guidelines for Biomedical Research on Human Participants: Chapter III, Section VI (2006): http://www.icmr.nic.in/ethical_guidelines.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			CDSCO: 1. Compensation and Reporting of SAE timelines GSR 889 (E) 2014 (scroll down to see English version): http://www.cdsco.nic.in/writereaddata/Notificatiohn%20on%20Compensation%20on%20clincial%20trial%20(1).pdf 2. Compensation in Case of Injury or Death During Clinical Trial, Schedule Y, Appendix XII (2013) (Scroll down to see English version): http://www.pharmamedtechbi.com/~/media/Supporting%20Documents/Pharmasia%20News/2013/February/Clinical%20Trials%20Compensation%20Guidelines.pdf 3. Compensation Formula for Clinical Trial Injury Other than Death (2014) : http://www.cdsco.nic.in/writereaddata/ORDER%20and%20Formula%20to%20Determine%20the%20quantum%20of%20compensation%20in%20the%20cases%20of%20Clinical%20Trial%20related%20serious%20Adverse%20Events(SAEs)%20of%20Injury%20other%20than%20Death.pdf	
Human Biological Materials	Ministry of Health and Family Welfare: http://mohfw.nic.in/		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	Guidance on Transfer of Human Biological Material for Commercial Purposes and /or Research for Development of Commercial Products (1997): http://icmr.nic.in/ihd/ihd.htm
Genetic Research	1. Department of Biotechnology (DBT): http://dbtindia.nic.in/ 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Environmental Protection Act (1986)		DBT: 1. Recombinant DNA Safety Guidelines (1990) 2. Ethical Policies on the Human Genome, Genetic Research, and Services (2002) ICMR: Ethical Guidelines for Biomedical Research on Human Subjects: Statement

Country	Key Organizations	Legislation	Regulations	Guidelines
				of Specific Principles for Human Genetics and Genomics Research (2006): http://www.icmr.nic.in/ethical_guidelines.pdf
Embryos, Stem Cells, and Cloning	1. Department of Biotechnology (DBT): http://dbtindia.nic.in/ 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			DBT and ICMR: Guidelines for Stem Cell Research, Revised (2013): http://www.icmr.nic.in/guidelines/NGSCR%202013.pdf
Indonesia				
General	Ministry of Health, National Institute of Health Research and Development: http://indonesia.go.id/en	Indonesian Health Act No. 23/1992 Section on Health Research, Article 69	Regulation No. 39/1995 on Health Research & Development	National Guidelines on Ethics in Health Research (2003)
Drugs and Devices	National Agency of Drug and Food Control: http://www.pom.go.id/index.php/home/en		Guidelines on Good Clinical Practice (2001)	
Human Biological Materials			National Guidelines on Use of Stored Biological Materials (2005)	
Japan				
General	1. Ministry of Education, Culture, Sports, Science, and Technology (MEXT): http://www.mext.go.jp/english/ 2. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html			MEXT and MHLW: Ethics Guidelines for Medical and Health Research Involving Human Subjects (2014): http://www.lifescience.mext.go.jp/files/pdf/n1500_01.pdf
Drugs and Devices	*Drugs*			
	1. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html 2. Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html	Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (Revised Pharmaceutical Affairs Law, (2015) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html	MHLW: Ministerial Ordinance on Good Clinical Practice for Drugs (2014) (Japanese): http://law.e-gov.go.jp/htmldata/H09/H09F03601000028.html	MHLW: Guidance for the Ministerial Ordinance on Good Clinical Practice for Drugs (2013) (Japanese): http://www.jmacct.med.or.jp/plan/files/gcp130404.pdf
	Devices			
	1. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html 2. Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html	Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (Revised Pharmaceutical Affairs Law, (2015) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.	MHLW: Ministerial Ordinance on Good Clinical Practice for Medical Devices (2014) (Japanese): http://law.e-gov.go.jp/htmldata/H17/H17F19001000036.html	MHLW: Guidance for the Ministerial Ordinance on Good Clinical Practice for Medical Devices (2013) (Japanese): http://www.jmacct.med.or.jp/plan/files/gcp_130404_1.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
		html	English (2009 version): https://www.pmda.go.jp/files/000153732.pdf	
Clinical Trials Registry	Japan Primary Registries Network:* http://rctportal.niph.go.jp/			FAQs (Japanese): http://rctportal.niph.go.jp/qa
Privacy/Data Protection	Personal Information Protection Commission: http://www.ppc.go.jp/en/	Amended Act on the Protection of Personal Information (2015): http://www.ppc.go.jp/files/pdf/280222_amendedlaw.pdf		
Research Injury	Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html	Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (2015) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html	1. Ministerial Ordinance on Good Clinical Practice for Drugs, Article 14 (2014): http://www.pmda.go.jp/files/000152996.pdf 2. Ministerial Ordinance on Good Clinical Practice for Medical Devices, Article 14 and 23 (2014)	Ethics Guidelines for Medical and Health Research Involving Human Subjects, Chapter 2, No. 5, 1-(3) and No. 6, 2-(2) (2014): http://www.lifescience.mext.go.jp/files/pdf/n1500_01.pdf
Human Biological Materials	Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html			On Research and Development Utilizing Human Tissues Removed by Surgery and Other Procedures (1998) (Japanese) http://www1.mhlw.go.jp/shingi/s9812/s1216-2_10.html
Genetic Research	1. Council for Science and Technology Policy (CSTP): http://www8.cao.go.jp/cstp/english/index.html 2. Ministry of Education, Culture, Sports, Science, and Technology (MEXT): http://www.mext.go.jp/english/ 3. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html 4. Ministry of Economy, Trade, and Industry (METI): http://www.meti.go.jp/english/			CSTP: Fundamental Principles of Research on the Human Genome (2000): http://www.lifescience.mext.go.jp/files/pdf/43_137.pdf MEXT, MHLW, and METI: Ethics Guidelines for Human Genome/Gene Analysis Research (2014) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1432_01_01.pdf English (2008 version): http://www.lifescience.mext.go.jp/files/pdf/n796_00.pdf MHLW: Guidelines for Clinical Research in Gene Therapy and Others (2015) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/150812_rinrisisin.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	1. Council for Science and Technology Policy (CSTP): http://www8.cao.go.jp/cstp/english/index.html 2. Ministry of Education, Culture, Sports, Science, and Technology (MEXT): http://www.mext.go.jp/english/	1. Act on Regulation of Human Cloning Techniques (2014) (Japanese): http://law.e-gov.go.jp/htmldata/H12/H12HO146.html English (2000 version): http://www.cas.go.jp/jp/seisaku/hourei/data/htc.pdf 2. Act on Safety of Regenerative Medicine (2013) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000030847.pdf	1. Ordinance for Enforcement of Act on Regulation of Human Cloning Techniques (2009): http://www.lifescience.mext.go.jp/files/pdf/n1564_01.pdf 2. Ordinance for Enforcement of Act on Safety of Regenerative Medicine (2014) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000065532.pdf	CSTP: Fundamental Philosophy on Handling of Human Embryo (2004) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/6_28.pdf MEXT: 1. Guidelines on the Handling of a Specified Embryo (2009): http://www.lifescience.mext.go.jp/files/pdf/n1564_02.pdf 2. Guidelines on the Derivation of Human Embryonic Stem Cells (2014): http://www.lifescience.mext.go.jp/files/pdf/n1553_01.pdf 3. Guidelines on the Distribution and Utilization of Human Embryonic Stem Cells (2014): http://www.lifescience.mext.go.jp/files/pdf/n1553_02.pdf 4. Guidelines on Research on Producing Germ Cells from Human Induced Pluripotent Stem Cells or Human Tissue Stem Cells (2015) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1492_01.pdf English (2010 version): http://www.lifescience.mext.go.jp/files/pdf/n1567_02.pdf MEXT and MHLW: Ethical Guidelines for Research on Assisted Reproductive Technology to Develop Human Fertilized Embryos (2015) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1492_03.pdf English (2010 version): http://www.lifescience.mext.go.jp/files/pdf/n1567_01.pdf
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	Ministry of Healthcare and Social Development, Central Commission on Research Ethics:			1. Guidelines on Ethics in Health Research. (2007) 2. Local Ethics Committees: Policy, Rules

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.mzsr.gov.kz/en			and Procedures (2014) 3. Guidelines on Ethics in Biomedical Research (2015)
Drugs and Devices	Ministry of Healthcare and Social Development, Control Committee of Medical and Pharmacy Activity: https://www.mzsr.gov.kz/en/taxonomy/term/674	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	1. 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 2. 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 3. 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	Ministry of Healthcare and Social Development: http://www.mzsr.gov.kz/en	Code of the Republic of Kazakhstan "On People's Health and the Health Care System" (18.09.2009 No.193-IV), Article 24 (2015): http://online.zakon.kz/Document/?doc_id=30479065#pos=1;-8		
Korea Note: All documents are in Korean.				
General	Ministry of Health and Welfare: http://english.mw.go.kr/	Bioethics and Safety Act No. 12844 (2014): http://www.law.go.kr/lsInfoP.do?lsiSeq=162503#0000)	1. Enforcement Decree of Bioethics and Safety Act No. 25840 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=164877#0000 2. Enforcement Rule of Bioethics and Safety Act No. 283 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=166794#0000	

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	*Drugs*			
	1. Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/ 2. Ministry of Food and Drug Safety (MFDS) (2013): http://www.mfds.go.kr/eng	Pharmaceutical Affairs Act No. 13320 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=170970#0000	MOHW: 1. Enforcement Decree of Pharmaceutical Affairs Act No. 26544 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=175075#0000 2. Enforcement Rule of Pharmaceutical Affairs Act No. 337 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=173445#0000 MFDS: Enforcement Rule of Medicinal Product Safety No. 1194 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=175272#0000	MFDS: 1. Guidelines on Human Research Protection Program (2014): http://www.mfds.go.kr/index.do?x=0&searchkey=title:contents&mid=1161&searchDivision=&searchClass=&searchword=hrpp&y=0&searchSubDivision=&pageNo=1&seq=7877&cmd=v 2. IND regulations No 2015-22 (2015): http://www.law.go.kr/admRulLsInfoP.do?admRulSeq=2100000018982
	Devices			
	Ministry of Food and Drug Safety: http://www.mfds.go.kr/eng	Medical Device Act No. 13320 (2015): http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyCode=125&page=1&mode=view&boardSeq=67030	1. Enforcement Decree of the Medical Device Act (2015): http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyCode=125&page=1&mode=view&boardSeq=66026 2. Enforcement Regulations of the Medical Device Act (2105): http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyCode=125&page=1&mode=view&boardSeq=66026	
Clinical Trials Registry	Clinical Research Information Service: https://cris.nih.go.kr/cris/en/use_guide/cris_introduce.jsp			
Research Injury	Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng		Enforcement Rule of Medicinal Product Safety No. 1194 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=175272#0000	Guidelines for Clinical Trial Indemnity and Its Process (2013): http://www.mfds.go.kr/index.do?x=0&searchkey=title:contents&mid=1161&searchDivision=&searchClass=&searchword=임상시험 피해자&y=0&searchSubDivision=&pageNo=1&seq=7205&cmd=v
Privacy/Data Protection	1. Ministry of the Interior (MOI): http://www.moi.go.kr/eng/a01/engMain.do	MOI: Personal Information Protection Act No.13423 (2015):	MOI: 1. Enforcement Rules to Personal Information Protection Act No. 1	MOI: Guidelines on Standard Personal Information Protection (2011):

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/	http://www.law.go.kr/lsInfoP.do?lsiSeq=173223#0000 MOHW: Bioethics and Safety Act No. 12844 (2014): http://www.law.go.kr/lsInfoP.do?lsiSeq=162503#0000)	(2014): http://www.law.go.kr/lsInfoP.do?lsiSeq=163788#0000 2. Enforcement Decrees to Personal Information Protection Act No. 26140 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=169145#0000 MOHW: Enforcement Rule of Bioethics and Safety Act No. 283 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=166794#0000	http://www.law.go.kr/admRulLsInfoP.do?admRulSeq=2000000064994
Human Biological Materials	1. Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/ 2. Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng	MOHW: Bioethics and Safety Act No. 12844 (2014): http://www.law.go.kr/lsInfoP.do?lsiSeq=162503#0000)	1. Enforcement Decree of Bioethics and Safety Act No. 25840 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=164877#0000 2. Enforcement Rule of Bioethics and Safety Act No. 283 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=166794#0000	MFDS: Guideline for human tissue management (2014): http://www.mfds.go.kr/index.do?searchkey=title:contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=인체&x=0&mid=1161&pageNo=1&seq=8094&cmd=v
Genetic Research	1. Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/ 2. Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng	MOHW: MOHW: Bioethics and Safety Act No. 12844 (2014): http://www.law.go.kr/lsInfoP.do?lsiSeq=162503#0000)	MOHW: MOHW: 1. Enforcement Decree of Bioethics and Safety Act No. 25840 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=164877#0000 2. Enforcement Rule of Bioethics and Safety Act No. 283 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=166794#0000	MFDS: Guideline on the Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (2005): http://www.mfds.go.kr/index.do?searchkey=title:contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=유전자&x=0&mid=1161&pageNo=2&seq=4662&cmd=v
Embryos, Stem Cells, and Cloning	1. Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/ 2. Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng	Bioethics and Safety Act No. 12447 (2014)	MOHW: 1. Enforcement Decree of Bioethics and Safety Act No. 25840 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=164877#0000 2. Enforcement Rule of Bioethics and Safety Act No. 283 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=166794#0000	MFDS: Guideline on Sponsor-Investigator Trials of Cell Therapy Products for Academic Purpose (2014): http://www.mfds.go.kr/index.do?searchkey=title:contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=세포&x=0&mid=1161&pageNo=1&seq=8730&cmd=v

Country	Key Organizations	Legislation	Regulations	Guidelines
Kyrgyzstan Note: All websites and documents are in Russian.				
General	1. Government of the Kyrgyz Republic: http://www.gov.kg 2. Ministry of Health: http://www.med.kg 3. Ministry of Justice of the Kyrgyz Republic: http://cbd.minjust.gov.kg	1. Constitution of Kyrgyz Republic, Chapter II, Article 22 (2010): http://www.gov.kg/?page_id=263 2. Law on Health Protection of the Kyrgyz Republic (Sept. 1, 2005, No. 6): Articles 34 and 73: http://www.pharm.kg/ru/legislation	1. Code of Professional Ethics of Medical Worker of the Kyrgyz Republic (2004): http://www.med.kg/index.php/dokumenty-2/kodex-prof-etiki-2.html 2. 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: http://www.pharm.kg/ru/legislation/	
Drugs and Devices	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee 3. Pharmaceutical Union of Kyrgyzstan, Ethics Committee: http://farmunion.kg/o-nas/eticheskij-komitet/	Law on Drugs of the Kyrgyz Republic (30.04.2003 No. 91) Chapter VII, Articles 25-29 (2003): http://www.pharm.kg/ru/legislation	DDMDP: 1. National Standard KMC 1195:2010: Medical Devices: Rules for Clinical Trials (2010): http://www.pharm.kg/ru/legislation/ 2. 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	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on Drugs of the Kyrgyz Republic (30.04.2003 No. 91) Chapter VII, Article 28 (2003): http://www.pharm.kg/ru/legislation	DDMDP: 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	1. Ministry of Health, Department of Drug and Medical Devices Provision: http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	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/	
Privacy/Data Protection	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on Health Protection of the Kyrgyz Republic (09.01.2005 No. 6): Article 91: http://www.pharm.kg/ru/legislation	DDMDP: 1. National Standard KMC 1195:2010: Medical Devices, Rules for Clinical Trials, Paragraphs 3, 4, and 6 (2010): http://www.pharm.kg/ru/legislation/ 2. Technical Regulations on the Safety of Medical Products for	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Medical Application, Approved by the Governmental Order #74 from February 1, 2012: http://www.pharm.kg/ru/legislation/	
Malaysia				
Drugs and Devices	National Committee for Clinical Research: http://www.nccr.gov.my/			1. Guidelines for Ethical Review of Clinical Research or Research Involving Human Subjects (2006): http://www.nccr.gov.my/view_file.cfm?fileid=16 2. Malaysian Guidelines of Good Clinical Practice (2011): http://www.nih.gov.my/mrec/documents/Malaysian%20GCP.pdf
Privacy/Data Protection		Act 709: Personal Data Protection Act 2010: http://www.pdp.gov.my/images/LAWS_OF_MALAYSIA_PDPA.pdf		
Human Biological Materials	National Committee for Clinical Research: http://www.nccr.gov.my/	1. Act 130: Human Tissues Act (1974): http://www.agc.gov.my/Akta/Vol.%203/Act%20130.pdf 2. Act 699: DNA Identification Act 2009. Malaysian Government Gazette of 3 September 2009	DNA Identification Regulations 2012. Malaysian Government Gazette of 30 Aug 2012.	Guideline on the Use of Human Biological Tissues for Research (2006): http://www.nccr.gov.my/index.cfm?menuid=25&parentid=17
Genetic Research	Malaysian Medical Council: http://www.mmc.gov.my/v1/			Medical Genetics and Genetic Services. MMC Guidelines 010/2006: http://www.mmc.gov.my/v1/docs/Medical%20Genetics%20&%20Genetic%20Services.pdf
Embryos, Stem Cells and Cloning	Ministry of Health, Medical Research and Ethics Committee			Checklist for Research on Stem Cell and Cell-Based Therapies: http://www.nih.gov.my/mrec/documents/Research_On_Stem_cell_and_Cell_based_Therapies.pdf
Nepal				
General	Nepal Health Research Council, Ethical Review Board: http://www.nhrc.org.np/	Nepal Health Research Council Act, 1991, Section 3(1): http://www.lawcommission.gov.np/en/documents/2015/08/nepal-health-research-council-act-2047-1991.pdf		1. National Ethical Guidelines for Health Research in Nepal and Standard Operating Procedure (2011): http://nhrc.org.np/guidelines 2. Guidelines for Institutional Review Committees (IRCs) for Health Research in Nepal (2016): http://nhrc.org.np/guidelines
Drugs and Devices	Nepal Health Research Council: http://www.nhrc.org.np/			National Guidelines on Clinical Trials with the Use of Pharmaceutical Products (2005): http://nhrc.org.np/guidelines

Country	Key Organizations	Legislation	Regulations	Guidelines
New Zealand				
General	1. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ 2. National Ethics Advisory Committee (NEAC): http://www.neac.health.govt.nz/ 3. Ministry of Health (MOH): http://www.moh.govt.nz/ 4. Health and Disability Commissioner (HDC): http://www.hdc.org.nz/ 5. Health and Disability Ethics Committees: http://www.ethics.health.govt.nz/ 6. Ministry of Business, Innovation and Employment: http://www.mbie.govt.nz/	1. Health Research Council Act 1990, Sections 24 and 25 2. New Zealand Bill of Rights Act, Article 10 (1990) 3. Health and Disability Commissioner Act 1994 4. New Zealand Public Health and Disability Act 2000, Section 16 5. Accident Compensation Act 2001 Access: All New Zealand acts, bills, and regulations can be found here: http://www.legislation.govt.nz/	HDC: The Code of Health and Disability Services Consumers' Rights (the Code of Rights) (2004): http://www.hdc.org.nz/the-act--code/the-code-of-rights	HRC: 1. Guidelines for Researchers on Health Research Involving Māori (2010) 2. HRC Guidance Notes on Research Ethics (2014) 3. Pacific Health Research Guidelines (2014) Access*:* http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval NEAC: 1. Goals, Objectives, and Desired Outcomes of an Ethical Review System (2003) 2. Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (2012) 3. Ethical Guidelines for Intervention Studies (2012) Access*:* http://www.neac.health.govt.nz/moh.nsf/indexcm/neac-resources-publications MOH: Standard Operating Procedures for Health and Disability Ethics Committees (2012): http://www.ethics.health.govt.nz/operating-procedures
Drugs and Devices	*Drugs*			
	1. New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz 2. Medicines New Zealand: http://www.medicinesnz.co.nz/ 3. Health Research Council (HRC), Standing Committee on Therapeutic Trials: http://www.hrc.govt.nz/about-us/committees/standing-committee-therapeutic-trials-scott	1. Accident Compensation Act 2001, Section 32 (2010) 2. 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): https://ethics.health.govt.nz/system/files/documents/pages/2015-medicines-new-zealand-

Country	Key Organizations	Legislation	Regulations	Guidelines
				compensation-guidelines.pdf
	Devices			
	New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz		Medicines (Database of Medical Devices) Regulations (2003): http://www.legislation.govt.nz/regulation/public/2003/0325/latest/DLM224223.html	1. Standard Operating Procedures for Health and Disability Ethics Committees (2012): http://www.ethics.health.govt.nz/operating-procedures 2. Various: http://medsafe.govt.nz/regulatory/DevicesNew/13ConductingClinicalTrials.asp
Clinical Trials Registry	Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/			FAQs: http://www.anzctr.org.au/Faq.aspx
Privacy/Data Protection	Privacy Commissioner: http://www.privacy.org.nz/	1. Official Information Act 1982 (2012) 2. Public Records Act (2005) 3. 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	1. Ministry of Health (MOH): http://www.moh.govt.nz/ 2. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval 3. Te Puni Kokiri (TPK): http://www.tpk.govt.nz/ 4. Office of the Health and Disability Commissioner (HDC): http://www.hdc.org.nz 5. Ministry of Business, Innovation and Employment: http://www.mbie.govt.nz/	1. Health Act 1956 (2012) 2. 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	1. Environmental Protection Authority: http://www.epa.govt.nz/ 2. Health Research Council (HRC), Gene Technology Advisory Committee: http://www.hrc.govt.nz/about-us/committees/gene-technology-advisory-committee-gtac	Hazardous Substances and New Organisms Act 1996 (2012)		
Embryos, Stem Cells, and Cloning	1. Ministry of Health: http://www.moh.govt.nz/ 2. Advisory Committee on Assisted Reproductive Technology (ACART): http://acart.health.govt.nz/	Human Assisted Reproductive Technology Act 2004 (2009)		ACART: 1. Guidelines on the Use, Storage, and Disposal of Sperm from a Deceased Man (2000) 2. Guidelines on Preimplantation Genetic

Country	Key Organizations	Legislation	Regulations	Guidelines
	3. Ethics Committee on Assisted Reproductive Technology (ECART): http://ecart.health.govt.nz/			Diagnosis (2005) 3. Guidelines on Embryo Donation for Reproductive Purposes (2008) 4. Guidelines on Donation of Eggs or Sperm between Certain Family Members (2010) Access: http://acart.health.govt.nz/publications-and-resources
Pakistan				
General	Pakistan Medical Research Council, National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Various: http://nbcpakistan.org.pk/?page_id=61
Drugs and Devices	Pakistan Medical Research Council, National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Guidelines For Healthcare Professionals Interaction with Pharmaceutical Trade and Industry (PPI Guidelines): http://nbcpakistan.org.pk/?page_id=61
Embryos, Stem Cells, and Cloning	Pakistan Medical Research Council, National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Protocol/Guidelines for Stem Cell Research/Regulation in Pakistan: http://nbcpakistan.org.pk/?page_id=61
Philippines				
General	1. Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph 2. Department of Science and Technology (DOST): http://www.dost.gov.ph/ 3. Department of Health (DOH): http://www.doh.gov.ph/ 4. Commission of Higher Education (CHED): www.ched.gov.ph/	Republic Act No. 10532: An Act Institutionalizing the Philippine National Health Research System (2013): http://www.gov.ph/2013/05/07/republic-act-no-10532/	PHREB: Memorandum: Registration and Accreditation of all Ethics Review Committees in the Philippines (2015): http://www.ethics.healthresearch.ph/index.php/orders-and-memorandums/10-orders-and-memos/226-phreb-memo DOST: 1. Administrative Order 001 Series 2007: Requirement for Review of All Research Involving Human Subjects/Participants (2007): http://ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/112-ao-001-2007 2. Administrative Order 001 Series 2008: Registration of All Ethics Review Committee at the PHREB (2008):	PHREB: National Ethical Guidelines for Health Research (2011): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/111-ao-001 3. PCHRD Special Order No. 146 Series of 2013: Reactivation and Amendment of Functions of the National Ethics Committee http://nec.pchrd.dost.gov.ph/components/com_ethics/pdf_files/nec_so.pdf DOH: Department Circular No. 2015-0059: Research Ethics Review Committees Registration and Accreditation: http://www.ethics.healthresearch.ph/index.php/orders-and-memorandums/10-orders-and-memos/217-doh-circular CHED: 1. Memo 34 Series 2007: Policy Requirement in the Conduct of Health Research involving Human Subjects: http://www.ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/130-ched-memorandum 2. Memorandum from the CHED Chairperson: Philippine Health Research Ethics Board – Registration and Accreditation of All Ethics Review Committees: http://www.ethics.healthresearch.ph/index.php/orders-and-memorandums/10-orders-and-memos/225-ched-memo	
Drugs and Devices	*Drugs*			
	Food and Drug Administration (FDA): http://www.fda.gov.ph/		FDA: 1. 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	Ethical Guidelines for Clinical Trials on Drugs, Devices, and Diagnostics (2006): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
			Order No. 47-a) (2001) 2. FDA Circular 2015-026: Adoption of the ICH Harmonised Tripartite Guideline, Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products Q5C: http://www.fda.gov.ph/attachments/article/118205/FC2013-026.pdf DOST, DOH, CHED, and UPM: Joint Memorandum Order 001 Series of 2012: http://www.ethics.healthresearch.ph/index.php/component/content/article/10-orders-and-memos/215-joint-memo-01 DOST, DOH, CHED, and UPM-NIH: Joint Administrative Order No. 001: The Implementing Rules and Regulations of Republic Act 10532 Otherwise Known as "The Philippine National Health Research System Act of 2013:" http://www.ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/214-implementing-rules-of-pnhrs	
	Devices			
	Food and Drug Administration: http://www.fda.gov.ph/			FDA Guidelines: Regulation of Clinical Trials in the Philippines http://www.pcrp.org.ph/pdf/GuidelinesversionLR.PDF
Clinical Trials Registry	Philippine Health Research Registry: http://registry.healthresearch.ph/			FAQs: http://registry.healthresearch.ph/index.php?option=com_content&view=article&id=7&Itemid=185
Research Injury	1. Department of Science and Technology (DOST): http://www.dost.gov.ph/ 2. Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph			PHREB: National Ethical Guidelines for Health Research, pages 19-20 (2011): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph			Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research (2006): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011
Singapore				
General	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Ministry of Health, National Medical Ethics Committee (NMEC) 3. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	1. Medical Registration Act (Cap. 174) (1985): http://statutes.agc.gov.sg/ 2. Human Biomedical Research Bill No. 25/2015: http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A1f615627-01d3-4250-a720-de776cd4f794;rec=0	MOH: Directive of June 25, 1998: Hospital Ethics Committees	MOH: 1. Governance Framework for Human Biomedical Research (2007): https://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Human%20Biomedical%20Research/2007/Governance%20Frwk%20for%20HBR_14-12-07_formatted.pdf 2. Operational Guidelines for IRBs (2007): https://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Human%20Biomedical%20Research/2007/IRB%20Operational%20Guidelines_14-12-07_formatted.pdf 3. Code of Ethical Practice in Human Biomedical Research (2009): https://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Human%20Biomedical%20Research/2009/Code%20of%20Ethical%20Practice%20in%20Human%20Biomedical%20Research_Apr%2009_final.pdf NMEC: Ethical Guidelines on Research Involving Human Subjects (1997): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines/1997/nmec_ethical_guidelines_on_research_involving_human_subjects.html BAC: 1. Research Involving Human Subjects: Guidelines for IRBs (2004): http://www.bioethics-singapore.org/index/publications/reports/172-research-involving-human-subjects-guidelines-for-irbs.html 2. Ethics Guidelines for Human Biomedical Research (2015):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.bioethics-singapore.org/index/publications/reports/86-reports/ethics-guidelines-for-human-biomedical-research.html
Drugs and Devices	*Drugs*			
	1. Health Sciences Authority of Singapore (HSA): http://www.hsa.gov.sg 2. Ministry of Health, National Medical Ethics Committee (NMEC): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines.html	Medicines Act (1975): http://statutes.agc.gov.sg/	Medicines (Clinical Trials) Regulations (2000): http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A7e3c748b-8089-4699-a4b2-9f66af6f7820;rec=0	HSA: Singapore Guideline for Good Clinical Practice (1990): http://www.pacra.org/dev-pacra/images/pdf-files/singapore/sg-gcp.pdf NMEC: Recommendations on Clinical Trials: Update Focusing On Phase I Trials (2007): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines/2007.html
	Devices			
	1. Health Sciences Authority (HSA): http://www.hsa.gov.sg 2. National Environment Agency, Centre For Radiation Protection And Nuclear Science: http://www.nea.gov.sg/anti-pollution-radiation-protection/radiation-protection	1. Health Products Act (2007): http://statutes.agc.gov.sg/ 2. Radiation Protection Act (2007): http://statutes.agc.gov.sg/	1. Health Products (Medical Device) Regulations (2010): http://www.emergogroup.com/sites/default/files/file/singapore-health-products-medical-devices-regulations-2010.pdf 2. Radiation Protection Regulations (2014): http://www.nea.gov.sg/anti-pollution-radiation-protection/radiation-protection/regulatory/summary-of-radiation-protection-(amendment)-act-2014	
Research Injury	1. Health Sciences Authority: http://www.hsa.gov.sg 2. Ministry of Health, National Medical Ethics Committee (NMEC): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines.html	1. Medicines Act (1975): http://statutes.agc.gov.sg/ 2. Radiation Protection Act (2007): http://statutes.agc.gov.sg/	Medicines (Clinical Trials) Regulations (2000): http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A7e3c748b-8089-4699-a4b2-9f66af6f7820;rec=0	HSA: Singapore Guideline for Good Clinical Practice (1999): http://www.pacra.org/dev-pacra/images/pdf-files/singapore/sg-gcp.pdf NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)
Privacy/Data Protection	1. Ministry of Communications and Information (MCI): http://www.mci.gov.sg/web 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	1. Computer Misuse Act (Cap. 50A) (1993): http://statutes.agc.gov.sg/ 2. Personal Data Protection Act (2012): http://statutes.agc.gov.sg/		BAC: Personal Information in Biomedical Research (2007): http://www.bioethics-singapore.org/index/publications/reports/170-personal-information-in-biomedical-research.html

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Health Sciences Authority: http://www.hsa.gov.sg 3. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	1. Medical (Therapy, Education, and Research) Act (1973): http://statutes.agc.gov.sg/ 2. Medicines Act (1975): http://statutes.agc.gov.sg/ 3. Human Biomedical Research Bill No. 25/2015, Part 6: http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A1f615627-01d3-4250-a720-de776cd4f794;rec=0	Medicines (Clinical Trials) Regulations (2000): http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev,loadTime;page=0;query=Id%3A7e3c748b-8089-4699-a4b2-9f66af6f7820;rec=0	BAC: Human Tissue Research (2002): http://www.bioethics-singapore.org/index/publications/reports/173-human-tissue-research.html
Genetic Research	1. Ministry of Health, National Medical Ethics Committee (NMEC) 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org			NMEC: Ethical Guidelines for Gene Technology (2001): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines/2001.html BAC: Genetic Testing and Genetic Research (2005): http://www.bioethics-singapore.org/index/publications/reports/171-genetic-testing-and-genetic-research.html
Embryos, Stem Cells, and Cloning	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org/	Human Cloning and Other Prohibited Practices Act (2004): http://statutes.agc.gov.sg/	Licensing Terms and Conditions on Assisted Reproduction Services (2011): http://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Private%20healthcare%20institutions/2011/AR_LTCs_260411.pdf	BAC: 1. Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning (2002): http://www.bioethics-singapore.org/index/publications/reports/86-reports/174-stem-cell-research.html 2. Donation of Human Eggs for Research (2008): http://www.bioethics-singapore.org/index/publications/reports/86-reports/168-donation-of-human-eggs-for-research.html 3. Human-Animal Combinations in Stem-Cell Research (2010): http://www.bioethics-singapore.org/index/publications/reports/86-reports/167-human-animal-combinations-in-stem-cell-research.html
Sri Lanka				
Drugs and Devices	Cosmetics, Devices, and Drugs Regulatory Authority, Subcommittee on Clinical Trials:	National Medicines Regulatory Authority Act of 2015: http://www.cdda.gov.lk/images/stori		Guidelines for the Conduct of Clinical Trials in Sri Lanka (2014): http://www.cdda.gov.lk/images/pdf/clinical%2

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.cdda.gov.lk/index.php?option=com_content&view=article&id=78&Itemid=115&lang=en	es/new/pdf/legislations/5e_nmdra.pdf		0trials%20guidelines_oct2014.pdf
Clinical Trials Registry	Sri Lanka Clinical Trials Registry: http://www.slctr.lk/			FAQs: http://slctr.lk/faq
Taiwan				
General	Ministry of Health and Welfare: http://www.mohw.gov.tw/EN/Ministry/Index.aspx	1. Human Subjects Research Act (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020176 2. Medical Care Act (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020021	1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162 2. Enforcement Rules of the Medical Care Act (2010): http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0020023 3. Regulations Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020179 4. Exempt Review Categories for Human Research (2012): http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp 5. Informed Consent Exemptions for Human Research (2012): http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp 6. Expedited Review Categories for Human Research (2012): http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp 7. Partial Amended Articles of Enforcement Rules of Medical Care Act (2016) http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp	Regulations Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research (2012): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020179
Drugs and Devices	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Taiwan Food and Drug Administration (FDA): http://www.fda.gov.tw/EN/index.aspx	MOHW: Medical Care Act (2014): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020021 FDA: Pharmaceutical Affairs Act	MOHW: 1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162 2. Pharmaceutical Affairs Act Enforcement Rules (2012): http://law.moj.gov.tw/Eng//LawClass	

Country	Key Organizations	Legislation	Regulations	Guidelines
		(2015): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0030001	/LawContent.aspx?pcode=L0030002 3. Regulations for Drug Safety Monitoring (2013) http://mohwlaw.mohw.gov.tw/Chi/EngContent.asp?msgid=516&KeyWord= 4. Guideline for Good Clinical Practice (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0030056 5. Regulations for Governing the Management of Medical Devices (2014): http://mohwlaw.mohw.gov.tw/Chi/EngContent.asp?msgid=528&KeyWord= 6. Regulations for Bioavailability and Bioequivalence Studies (2015): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0030065	
Research Injury	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Food and Drug Administration (FDA), MOHW: http://www.fda.gov.tw/EN/index.aspx	Medical Care Act (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020021	FDA: Guideline for Good Clinical Practice (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0030056	
Privacy/Data Protection	Ministry of Justice: http://www.moj.gov.tw/mp095.html	Personal Information Protection Act (2015): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=I0050021		
Human Biological Materials	Ministry of Health and Welfare: http://www.mohw.gov.tw/EN/Ministry/Index.aspx	1. Human Subjects Research Act (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020176 2. Human Biobank Management Act (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020164	1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162 2. Administrative Regulations on the Establishment of Human Biobanks (2011) http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020173	1. 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 2. Guidelines for 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

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Medical Care Act (2015): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020021		
Genetic Research	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Food and Drug Administration (FDA): http://www.fda.gov.tw/EN/index.aspx 3. Ministry of Science and Technology: https://www.most.gov.tw/en/public	MOHW: Human Biobank Management Act (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020164	MOHW: 1. Regulations on Commercial Benefit Feedback of Human Biobanks (2010) (Chinese): http://law.moj.gov.tw/LawClass/LawContentIf.aspx?PCODE=L0020170 2. Administrative Regulations on the Establishment of Human Biobanks (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020173	MOHW: Guidance for Information Safety of Human Biobank (2010) (Chinese): http://mohwlaw.mohw.gov.tw/Chi/FLAW/FLAWDAT0202.asp
Embryos, Stem Cells, and Cloning	Health Promotion Administration, MOHW: http://www.hpa.gov.tw/BHPNet/English/Index.aspx	Artificial Reproduction Act (2007): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0070024		
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 Note: All websites and documents are in Russian.				
General	Ministry of Public Health: http://www.health.tj/		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	
Thailand For an overview of the clinical research regulations in Thailand, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=213				
General	1. National Research Council of Thailand (NCRT): http://en.nrct.go.th/en/home.aspx 2. Medical Council of Thailand (MCT): http://www.tmc.or.th/en_home.php 3. Forum for Ethical Review Committees in Thailand (FERCIT) (Thai): http://www.fercit.org/	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): http://www.dnp.go.th/otec/eng_laws_regs/NRCT_Reg2525E.pdf 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

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	*Drugs*			
	1. Food and Drug Administration, Drug Control Division: http://www.fda.moph.go.th/eng/index.stm 2. Medical Council of Thailand (MCT): http://www.tmc.or.th/en_home.php	Consumer Protection Act (2007)		MCT: Thailand Good Clinical Practice Guidelines (2002)
	Devices			
	Food and Drug Administration, Medical Device Control Division: http://www.fda.moph.go.th/eng/medical/pre.stm	1988 Medical Device Act: http://www2.fda.moph.go.th/Exporters/law/Document/Mdc/36-MEDICAL%20DEVICE%20ACT.htm		
Clinical Trials Registry	Thai Clinical Trials Registry: http://www.clinicaltrials.in.th/			FAQs: http://www.clinicaltrials.in.th/index.php?meun=home&smenu=4&task=home&task1=openpage&task2=view&topid=4
Privacy/Data Protection	Office of the Information Commission: http://www.oic.go.th/content_eng/default_eng.asp	Official Information Act, B.E. 2540 (1997): http://www.oic.go.th/content_eng/act.htm		
Uzbekistan Note: All websites and documents are in Uzbek and Russian.				
General	1. Government of the Republic of Uzbekistan: http://www.gov.uz 2. Ministry of Health: http://www.minzdrav.uz	1. Constitution of Republic of Uzbekistan, Articles 24, 26, 40, 44 (1992): http://www.gov.uz 2. Law on Protection of Citizens' Health (1997): http://www.minzdrav.uz		
Drugs and Devices	1. Ministry of Health, Pharmacological Committee of the Central Department for Quality Control of Pharmaceuticals and Medical Equipment: http://www.minzdrav.uz 2. Ministry of Health, National Ethics Committee 3. Scientific Boards of Medical Institutes	1. Law on Protection of Citizens' Health (1997): http://www.minzdrav.uz 2. Law on Drugs and Pharmaceutical Activity (1997) 3. Law on Narcotic and Psychoactive Drugs (2000)	1. Guidelines on Conducting Clinical Trials and Determining Clinical Sites (2001) 2. National Standard of Uzbekistan: Good Clinical Practice (2013)	
Human Biological Materials	1. Ministry of Health, Pharmacological Committee of the Central Department for Quality Control of Pharmaceuticals and Medical Equipment: http://www.minzdrav.uz		1. Guidelines on Conducting Clinical Trials and Determining Clinical Sites (2001) 2. National Standard of Uzbekistan: Good Clinical Practice (2013)	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of Health, National Ethics Committee 3. Scientific Boards of Medical Institutes			
Vietnam 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	1. Ministry of Health (MOH): http://www.moh.gov.vn/homebyt/en/portal/index.jsp 2. Ministry of Health, Independent Ethics Committee (MOH) (Vietnamese): http://iecmoh.vn	MOH: 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	MOH: 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	
Drugs and Devices	Ministry of Health: http://www.moh.gov.vn/homebyt/en/portal/index.jsp	1. 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 2. 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	1. 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 2. 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

Country	Key Organizations	Legislation	Regulations	Guidelines
MIDDLE EAST				
Egypt				
General	Medical Professionals Union	Constitution of the Arab Republic of Egypt, Article 43: http://www.sis.gov.eg/Newvr/Dustor-en001.pdf	Professional Ethics Regulations: Conducting Medical Research on Human Beings, Articles 52-61 (2003)	
Drugs and Devices	Egyptian Drug Authority: http://www.eda.mohp.gov.eg/			
Iran				
General	Ministry of Health and Medical Education, Office for the Study of Humanistic and Islamic Science in Medicine and Medical Ethics: http://www.mohme.gov.ir/		Protection Code for Human Subjects in Medical Research (1999)	
Clinical Trials Registry	Iranian Registry of Clinical Trials: http://www.irct.ir/			FAQs: http://www.irct.ir/faq.php
Israel				
General	Ministry of Health: http://www.health.gov.il/english/		Public Health Regulations (Medical Experiments Involving Human Subjects) (1999) (Hebrew)	
Drugs and Devices	Ministry of Health, Pharmaceutical Administration: http://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/Drugs/Pages/default.aspx	Public Health Order (1940)	1. Public Health Regulations (Clinical Studies in Human Subjects) – 1980 2. 1990 Amendment 3. 1992 Amendment 4. 2005 Amendment	Guidelines for Clinical Trials in Human Subjects (2006): https://firstclinical.com/regdocs/doc/?db=INT_Israel_Clinical_Trials
Privacy/Data Protection	Israeli Law, Information, and Technology Authority: http://www.justice.gov.il/MOJEng/ILITA/	1. Privacy Protection Act No. 5741 (1981): http://www.justice.gov.il/NR/rdonlyres/6A5EC09A-BDBC-419F-8007-5FD6A6B8E0A5/18334/ProtectionofPrivacyLaw57411981unofficialtranslatio.pdf 2. Protection of Privacy Law No. 5741, as Amended by Law No. 5745 (1985)		
Genetic Research	Ministry of Health: http://www.health.gov.il/english/	Genetic Information Law (2000) (Hebrew): http://www.moital.gov.il/NR/exeres/66F4DD4E-FA4A-4B76-94BC-DC29543471DE.htm		1. The Instruction of the Supreme Committee for Clinical Studies on Humans Regarding Establishment and Usage of Genetic Samples Reservoir (2005)

Country	Key Organizations	Legislation	Regulations	Guidelines
				2. Amendment (2007)
Embryos, Stem Cells, and Cloning		Genetic Intervention Prohibition Law (Human Cloning and Genetic Changes in Reproduction Cells) (1999)		
Jordan				
Drugs and Devices	1. Ministry of Health: http://www.moh.gov.jo/en/Pages/default.aspx 2. Jordan Food and Drug Administration: http://www.jfda.jo/Default.aspx	1. Law of Clinical Studies, Law No. 2 (2011) 2. Drug and Pharmacy Law No. 12 (2013) 3. Narcotic and Psychotropic Law No. 23 (2016)		
Research Injury			Regulations for Insurance on Research-Related Injury (2013) (Arabic): http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/22_252.pdf	
Embryos, Stem Cells, and Cloning		Stem Cell By-law No. 10 (2014)		
Kuwait				
General	Ministry of Health, Kuwait Institute for Medical Specialization: http://www.kims.org.kw/			Ethical Guidelines for Biomedical Research: http://www.kims.org.kw/Ethical%202.doc
Qatar				
General	Supreme Council of Health: https://www.sch.gov.qa/home-en			Various: https://www.sch.gov.qa/about-sch/departments/research
Saudi Arabia				
General	National Committee of BioEthics: http://bioethics.kacst.edu.sa/?lang=en-US	Law of Ethics of Research on Living Creatures (Arabic): http://bioethics.kacst.edu.sa/getattachment/4bd0d4e2-1b93-4c32-b483-57902227fae2/Bioethic-Rgl-fin-bks.aspx	Implementing Regulations of the Law of Ethics of Research on Living Creatures, Royal Decree No. M/59: http://www.kacst.edu.sa/ar/depts/bioethics/Documents/The%20final%20draft%20of%20the%20translation%20Law%20and%20Regulations2.pdf	
Turkey For an overview of human subject protections in Turkey, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Turkey%20definitive%20Updated.pdf				
General	Ministry of Health (Turkish): http://www.saglik.gov.tr/	1. Turkish Constitution, Article 17 2. Health Services Basic Law No. 3359 (1987) 3. Oviedo Convention on	1. Regulation on Medical Deontology, Article 11 (1960) 2. Bylaw on Patient Rights No. 23420 (1998)	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Human Rights and Biomedicine (2004) 4. Update on the Law of the Support of Research and Development Activities (2016). Official Gazette (Turkish): http://www.resmigazete.gov.tr/eskiler/2016/02/20160226.htm		
Drugs and Devices	*Drugs*			
	1. Turkey Pharmaceuticals and Medical Devices Agency (Turkish) (TITCK): http://www.titck.gov.tr 2. Clinical Research Association (CRA): http://www.klinikarastirmalar.org.tr/en/	Turkish Penal Law, Article 90 (2005)	1. Fundamental Law #3359 on Health Services, Supplemental Article 10 (2011) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=1&thelawId=347 2. Regulation on Clinical Trials with Drugs and Biological Products (2015): An Update of 2014 Clinical Trials Regulation (Turkish): http://www.klinikarastirmalar.org.tr/doc/file_345.docx 3. Regulation on Efficacy, Safety, and Clinical Trials of Cosmetic Products (2015) (Turkish): http://www.klinikarastirmalar.org.tr/doc/file_346.pdf 4. Update on the Regulation of the Management and Inspection of the Support of Research and Development Activities (2016). Official Gazette (Turkish): http://www.resmigazete.gov.tr/eskiler/2016/08/20160810-7.htm	CRA: Various: http://www.klinikarastirmalar.org.tr/en/documents.php?dok_cat=0
	Devices			
	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr		Regulation on Research on Medical Devices (2014) (Turkish): http://www.klinikarastirmalar.org.tr/doc/file_318.pdf	
Research Injury	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr	Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2004)		Guidance on Insuring Volunteers in a Clinical Trial (2011)
Human Biological		1. Law on Procurement,	Regulation on Blood and Blood	1. Convention on Human Rights and

Country	Key Organizations	Legislation	Regulations	Guidelines
Materials		Preservation, Grafting, and Transplantation of Organs and Tissues, No. 2238 (1979) 2. Law on Blood and Blood Products, No. 2857 (1983)	Products, No. 7314 (1983)	Biomedicine (Convention of Oviedo), Articles 21-22 (1999) 2. Good Clinical Practice Guidelines for Advanced Therapy Medicinal Products (2011)
Genetic Research			Regulation on Centers for Diagnosis and Genetic Diseases, No. 23368 (1998)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14 (1999)
Embryos, Stem Cells, and Cloning			1. Regulation on Centers for Medically Assisted Procreation, No. 19551 (1987) 2. Regulation on Organ and Tissue Transplantation Services (2005) 3. Regulation on Cordon Blood Banks (2005)	1. Circular on Research of Embryonic Stem Cells (2005) 2. Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)
United Arab Emirates				
General	Health Authority - Abu Dhabi: http://www.haad.ae/haad/			Standard Operating Procedures for Research Ethics Committees (2012): http://www.haad.ae/HAAD/LinkClick.aspx?fileticket=UL7o8f5mukc%3D&tabid=820

Country	Key Organizations	Legislation	Regulations	Guidelines
LATIN AMERICA and the CARIBBEAN				
Regionwide				
General	Caribbean Public Health Agency: http://carpha.org/What-We-Do/Research-Training-and-Policy-Development			
Drugs and Devices	*Drugs*			
	Pan American Health Organization: http://www.paho.org/			Good Clinical Practices: Document for the Americas (2004): http://www.paho.org/english/ad/ths/ev/GCP-Eng-doct.pdf
	Devices			
	Pan American Health Organization: http://www.paho.org/			A Model Regulatory Program for Medical Devices: An International Guide (2001): http://www.paho.org/English/HSP/HSE/medical_devices.pdf
Argentina Notes: Several provinces have their own regulations pertaining to human subjects research. All websites and documents are in Spanish.				
General	Ministry of Health: http://www.msal.gov.ar	Civil and Commercial Code, Articles 26, 58, and 59 (2015): http://servicios.infoleg.gob.ar/infolegInternet/anexos/235000-239999/235975/norma.htm	Ministerial Resolution 1480/2011 Approving the Guidelines for Human Health Research and Creating the National Register for Human Health Research: http://www.anmat.gov.ar/webanmat/legislacion/medicamentos/Resolucion_1480-2011.pdf	Resolution 1480/2011: Guidelines for Investigators Working with Human Beings: http://www.fecicla.org/archivos/regulaciones/Resolucion1480-11.pdf
Drugs and Devices	*Drugs*			
	National Administration of Medications, Foods, and Medical Technology (ANMAT): http://www.anmat.gov.ar/index.asp		1. Provision 2247/09: Guide for the Study of Clinical Trials of Type II Diabetes (2009): http://www.anmat.gov.ar/webanmat/Legislacion/Medicamentos/Disposicion_ANMAT_2247-2009.pdf 2. Provision ANMAT 6677/10 on Good Research Practices in Clinical Pharmaceutical Studies (2010): http://www.anmat.gov.ar/Comunicados/Dispo_6677-10.pdf	
	Devices			
	National Administration of Medications, Foods, and Medical Technology (ANMAT): http://www.anmat.gov.ar/index.asp		1. Provision 969/97 on the Regulation of Good Clinical Practice with Medical Technology Products (1997)	

Country	Key Organizations	Legislation	Regulations	Guidelines
			2. Disposition Nº 969/97(Including Modifications of Disposition ANMAT Nº 6550/2008)	
Privacy/Data Protection	National Directorate for the Protection of Personal Data (Spanish): http://www.jus.gob.ar/datos-personales.aspx	Personal Data Protection Act No. 25.326 (2000): http://www.protecciondedatos.com.ar/law25326.htm		
Barbados				
	University of the West Indies – Cave Hill / Ministry of Health: http://www.cavehill.uwi.edu/researchethics/home.aspx			Research Ethics Policy and Guidelines
Bermuda				
General	Department of Health: https://www.gov.bm/department/health			Research Governance Framework (2008): http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.592.8671&rep=rep1&type=pdf
Bolivia				
General	1. Ministry of Health and Sport (MHS): http://www.sns.gob.bo 2. National Bioethics Committee (NBC)	1. Legal Decree No. 15.629 of July 18, 1978, Articles 147 and 148. 2. New Political Constitution of the State, Article 44 (2009): https://www.constituteproject.org/constitution/Bolivia_2009.pdf	1. Regulations on Public Health Research, Chapter V (1978) 2. Rules and Regulations of the National Bioethics Committee	MHS: Guidelines for the Development of Health Research and Ethical Norms (2002) NBC: 1. Requirements for the Evaluation of Research Projects 2. Code of Ethics and Medical Deontology
Drugs and Devices	1. Ministry of Health and Sport, National Pharmacological Commission (MHS): http://www.sns.gob.bo 2. National Bioethics Committee (NBC)			MHS: Rule on Clinical Studies with Medicines or Products in the Clinical Investigation Stage (2005) NBC: Projects that Involve Drugs or Therapeutic Products
Brazil For an overview of clinical research regulations in Brazil, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=30				
General	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html	CNS: Decree 98 830: Collection by Foreigners of Data and Scientific Materials in Brazil (1990) (Portuguese): http://www.planalto.gov.br/ccivil_03/decreto/1990-1994/D98830.htm	CNS/CONEP: 1. Resolution CNS No. 240/97 - Defining "Participating User" According to IRB (Portuguese): http://conselho.saude.gov.br/resolucoes/1997/reso240.doc 2. Regulation of Resolution CNS No. 292/99 on Research with	CNS/CONEP: Operational Standard Nº 001/2013: http://conselho.saude.gov.br/arquivos/NO_01-12_english.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			Foreign Cooperation: http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/regulation_res_292_english.doc 3. Resolution CNS No. 304/2000: http://conselho.saude.gov.br/resolucoes/2000/Res304_en.pdf 4. Internal CONEP Regulation (2001) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/aquivos/conep/regimento.doc 5. Resolution CNS No. 301, 16th March 2002: http://conselho.saude.gov.br/resolucoes/2000/Res301_en.pdf 6. Resolution CNS No. 346/2005 on Multicenter Research: http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf 7. Resolution CNS No. 370/07 on Registration and Accreditation or Renewal of Registration and Accreditation of CEP (Portuguese): http://conselho.saude.gov.br/resolucoes/2007/Reso370.doc 8. Resolution CNS No. 421/09 (Portuguese): http://conselho.saude.gov.br/resolucoes/2009/Reso421.doc 9. Resolution CNS No. 446/2011on Composition of the National Commission on Research Ethics: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf 10. Resolution CNS No. 466/2012 on Guidelines and Rules for Research Involving humans Subjects: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf	
Drugs and Devices	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/	Law Nº 9782/99 Defining the National Health Surveillance System (Portuguese):	CNS: 1. Resolution CNS No. 251/1997: On Complimentary Rules for	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Brazilian Health Surveillance Agency: http://portal.anvisa.gov.br/wps/portal/anvisa-ingles 3. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 4. National Secretary on Science, Technology and Innovation (Portuguese): http:www.saude.gov.br/sctie/	http://www.planalto.gov.br/ccivil_03/leis/L9782.htm	Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests: http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf 2. Resolution CFM Nº 1.885, 2008 (Portuguese): http://www.portalmedico.org.br/resolucoes/cfm/2008/1885_2008.htm 3. Resolution ANVISA 09/15 - Regulations for Clinical Trials with Drugs (Portuguese): http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=03/03/2015&jornal=1&pagina=69&totalArquivos=140 4. Resolution ANVISA 10/15 - Regulations for Clinical Trials with Drugs (Portuguese): http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=03/03/2015&jornal=1&pagina=73&totalArquivos=140 5. Resolution RDC No. 9 of 20 February 2015: https://clinregs.niaid.nih.gov/documents/brazil/ResolutionNo9-English.pdf	
Clinical Trials Registry	Brazilian Clinical Trials Registry: http://www.ensaiosclinicos.gov.br/			FAQs: http://www.ensaiosclinicos.gov.br/assistance/faq/
Research Injury	1. Brazilian Health Surveillance Agency: http://portal.anvisa.gov.br/wps/portal/anvisa-ingles 2. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 3. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html	ANVISA: Law Nº 6360/76 (Portuguese): http://www.planalto.gov.br/ccivil_03/leis/l6360.htm	CNS/CONEP: 1. Standards Survey of New Drugs, Medicines, Vaccines, and Diagnostic Tests Involving Human Beings - Resolution CNS No. 251/97 (Portuguese): http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf 2. Resolution CNS No. 346/2005 on Multicenter Research (Portuguese): http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf 3. Resolution MS/CNS No. 466/2012 - Guidelines and Rules	CNS/CONEP: Orientation of Adverse Event Reporting in Clinical Trials (2011) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/carta_circular/Informacoes_sobre_o_formulario_para_submissao_de_Eventos_Adversos_Serios_a_CONEP.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			for Research Involving Human Subjects: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf	
Privacy/Data Protection	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 3. Federal Council of Medicine: http://portal.cfm.org.br		Resolution CFM Nº 1.821, 23 November 2007 (Portuguese): http://www.portalmedico.org.br/resolucoes/cfm/2007/1821_2007.htm	
Human Biological Materials	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html	Ordinance No. 2.201/11: Establishing the National Guidelines for Biobanks of Human Biological Material for Research Purposes (2011) (Portuguese): http://www2.inca.gov.br/wps/wcm/connect/8b19d5804eb688ee9cb39ef11fae00ee/portaria_2201_de_14_de_set_2011.pdf?MOD=AJPERES&CACHEID=8b19d5804eb688ee9cb39ef11fae00ee	CONEP: 1. Resolution No. 347, 13th January 2005 (Portuguese): http://conselho.saude.gov.br/resolucoes/2005/Res347_en.pdf 2. Resolution CNS No. 441 of 12 May 2011: http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/Resolution441_English_contribuicao_pesquisadora.doc 3. Resolution – RDC No. 20 of 10 April 2014 (Portuguese): http://www.saude.pr.gov.br/arquivos/File/RDC_20_de_10_de_abril_2014_Transporte_de_material_Biologico.pdf	
Genetic Research	1. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 2. National Biosafety Technical Commission (CTNBio) (Portuguese): http://www.ctnbio.gov.br 3. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/	1. Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/12847.html 2. Decree No. 5,591, of November 22, 2005 (Portuguese): http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/Decreto/D5591.htm	CTNBio: 1. Instruction CTNBio No. 8 of 9 July 1997 (Portuguese): http://www.ctnbio.gov.br/index.php/content/view/11971.html 2. Instruction CTNBio No. 9 of 10 October 1997 (Portuguese): http://www.ctnbio.gov.br/index.php/content/view/11972.html 3. Resolution CNS No. 340/2004: On Research on Human Genetics (2004): http://conselho.saude.gov.br/resolucoes/2004/Res340_en.pdf	1. Guidance to Researchers and Ethics Committees about the Item V.1.a of CNS Resolution 340 2004 (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/aquivos/documentos/Carta_Circular_041_Orientacoes_pesquisadores_comites.pdf 2. Statement on Pharmacogenetic Studies in Brazil N/° 011/2012/CONEP, 12 January 2012: http://www.fcm.unicamp.br/fcm/sites/default/files/11_-_Comunicado_sobre_estudos_farmacogeneticos_no_Brasil.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	1. National Biosafety Technical Commission (Portuguese): http://www.ctnbio.gov.br 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 3. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/	1. Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/12847.html 2. Decree No. 5,591, of November 22, 2005 (Portuguese): http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/Decreto/D5591.htm	Resolution RDC No. 9, 14 March 2011 (Portuguese): http://portal.anvisa.gov.br/wps/wcm/connect/623ecb0047458efe9836dc3fbc4c6735/RDC_09_2011.pdf?MOD=AJPERES	
Chile Note: All websites and documents are in Spanish.				
General	1. Ministry of Health: http://www.minsal.cl 2. Institute of Public Health: http://www.ispch.cl	1. Law No. 20.120 Regarding Scientific Research in Human Beings, their Genome, and the Prohibition of Human Cloning (2006): http://www.leychile.cl/Navegar?idNorma=253478 2. Law No. 20584. Regulating the Rights and Duties Incumbent upon Persons in Connection with Actions Linked to their Health Care (2012): http://www.leychile.cl/Navegar?idNorma=1039348 3. Law No. 20.724 Modifying the Health Code in the Area of the Regulation of Pharmacies and Medications (2014): http://www.leychile.cl/Navegar?idNorma=1058373	1. Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: http://www.leychile.cl/Navegar?idNorma=1032919 2. Supreme Decree Nº 30/2013 Regulation on Law Nº20.120 Modifying Supreme decree Nº114/2010, Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning Official Diary January 14, 2013: http://www.leychile.cl/Navegar?idNorma=1048008&	
Drugs and Devices	1. Ministry of Health : http://www.minsal.cl 2. Institute of Public Health: http://www.ispch.cl	Law No. 20.724 Modifying the Health Code in the Area of the Regulation of Pharmacies and Medications (2014): http://www.leychile.cl/Navegar?idNorma=1058373	1. Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: http://www.leychile.cl/Navegar?idNorma=1032919 2. Supreme Decree No. 3 of 2010. Regulation of the National Control System of Pharmaceutical Products for Human Use. Official	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Diary of June 25, 2011: http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/ds_minsal_3_2010.pdf 3. Exempt Resolution 2263, July 30th 2015 Modifying Resolution Nº 403 Ex. February 5, 2015 that Approves the Guidelines for Use Control of Pharmaceuticals Products in Scientific Research: http://www.leychile.cl/Navegar?idNorma=1080011	
Research Injury	1. Ministry of Health: http://www.minsal.cl 2. Institute of Public Health: http://www.ispch.cl	Law No. 20.120 Regarding Scientific Research in Human Beings, their Genome, and the Prohibition of Human Cloning (2006): http://www.leychile.cl/Navegar?idNorma=253478	1. Supreme Decree No. 3 of 2010. Regulation of the National Control System of Pharmaceutical Products for Human Use. Official Diary of Jun 25, 2011: http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/ds_minsal_3_2010.pdf 2. General Technical Rule No. 140 Regarding the National System of Pharmacovigilance of Pharmaceutical Products for Human Use. June 20, 2012: http://web.minsal.cl/portal/url/item/c4a31ad6db50e085e040010165017a39.pdf 3. Resolution No. 441, Notification of Adverse events in Clinical Research in Chile, February13, 2012: http://www.ispch.cl/sites/default/files/res_441.pdf	
Privacy/Data Protection	1. Ministry of Health: http://www.minsal.cl 2. Ministry of the Secretary General of the Government: http://www.msgg.gob.cl	1. Law for the Protection of Private Life No. 19.628 (1999): http://www.bcn.cl/leyes/141599 2. Law No. 20584. Regulating the Rights and Duties Incumbent upon Persons in Connection with Actions Linked to their Health Care (2012): http://www.leychile.cl/Navegar?idNorma=1039348	Supreme Decree No. 41 of 2012: Regulation Regarding Clinical Records of December 15, 2012: http://www.leychile.cl/Navegar?idNorma=1046753	

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research	Ministry of Health: http://www.minsal.cl	Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2006): http://www.leychile.cl./Navegar?idNorma=253478	Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: http://www.leychile.cl/Navegar?idNorma=1032919	
Embryos, Stem Cells, and Cloning	Ministry of Health: http://www.minsal.cl	Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2006): http://www.leychile.cl./Navegar?idNorma=253478	Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: http://www.leychile.cl/Navegar?idNorma=1032919	
Colombia Note: All websites and documents are in Spanish.				
General	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 8430 (1993): https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF	1. Guide for Research Ethics Committees. Code: ASS-RSA-GU040 Version: 00 (2015): https://www.invima.gov.co/images/stories/formatotramite/ASS-RSA-GU040.pdf 2. Guide for Assessing and Monitoring of Research Protocols. Code: ASS-RSA-GU039 Version: 00 (2016): https://www.invima.gov.co/images/stories/formatotramite/ASS-RSA-GU039.pdf
Drugs and Devices	*Drugs*			
	National Institute of Drug and Food Surveillance: http://www.invima.gov.co/		1. Resolution No. 2378 of 2008, Adapting Good Clinical Practices for Institutions that Conduct Research with Medicines in Human Beings: http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=31169 2. Resolution No. 2011020764 of June 10th, 2011: Regulation Related to the Content and Frequency of Adverse Event Reports in Clinical Investigation in Humans: https://www.invima.gov.co/index.php	1. ABC Good Clinical Practice (2009) https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/ABCBPCultima_version.pdf 2. Circular No 600-5776-14: Processes of Good Clinical Practice (2014): https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/normatividad/CIRCULAR_600-5776-14-2.pdf 3. Guide of Medications and Supplies for Clinical Research (2015): https://www.invima.gov.co/images/stories/formatotramite/ASS-RSA-GU045.pdf 4. Guide for the Evaluation and Follow-up

Country	Key Organizations	Legislation	Regulations	Guidelines
			?option=com_content&view=article&id=725:resolucion-no-2011020764-del-10-de-junio-de-2011&catid=58:2011&Itemid=105	of Research Protocols (2016): https://www.invima.gov.co/images/stories/formatotramite/ASS-RSA-GU039.pdf 5. External Circular No. 600-2006-16: National Reporting Serious Adverse Events (2016): https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/normatividad/Circular-600-1081-16-Reporte-de-Eventos-adversos-serios-Nacionales-Febrero2016.pdf 6. External Circular No. 600-1414-16: Notification of Deviations (2016): https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/normatividad/Circular_600-2006-16_Alcance-Circular-600-1081-16_Abril2016.pdf
	Devices			
	National Institute of Drug and Food Surveillance: http://www.invima.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapters I and III (1993): https://www.unisabana.edu.co/fileadmin/Documentos/Investigacion/comite_de_etica/Res__8430_1993_-_Salud.pdf	
Research Injury	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Art. 13 (1993): https://www.unisabana.edu.co/fileadmin/Documentos/Investigacion/comite_de_etica/Res__8430_1993_-_Salud.pdf	
Privacy/Data Protection	Ministry of Health and Social Protection: http://www.minsalud.gov.co	Constitution of Colombia, Article 15 (2003): http://www.corteconstitucional.gov.co/inicio/Constitucion%20politica%20de%20Colombia%20-%202015.pdf	Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Article 8 (1993)	
Human Biological Materials	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter VI (1993):	

Country	Key Organizations	Legislation	Regulations	Guidelines
			https://www.unisabana.edu.co/fileadmin/Documentos/Investigacion/comite_de_etica/Res__8430_1993_-_Salud.pdf	
Genetic Research	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapter II (1993): https://www.unisabana.edu.co/fileadmin/Documentos/Investigacion/comite_de_etica/Res__8430_1993_-_Salud.pdf	
Costa Rica Note: All websites and documents are in Spanish.				
Drugs and Devices	National Health Research Council: http://www.ministeriodesalud.go.cr/index.php/consejos/conis	Regulatory Law of Biomedical Research No. 9234 (2014): http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=77070&nValor3=96424&strTipM=TC	1. Regulatory Decree N° 39061-S (2016) on the Regulatory Law of Biomedical Research N° 39533-S: http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC 2. Reforms to the Regulatory Decree No. 39533-S (2016) Regulatory Law of Biomedical Research No. 9234: http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC	Various: http://www.ministeriodesalud.go.cr/index.php/consejos/conis
Clinical Trials Registry	National Health Research Council (Spanish): http://www.ministeriodesalud.go.cr/index.php/consejos/conis (scroll to bottom of page to Investigaciones Registradas)			
Cuba Note: All websites and documents are in Spanish.				
Drugs and Devices	Center for State Control of Medications: http://www.cecmed.cu/			Various: http://www.cecmed.cu/ensayos-clinicos/autorizos
Clinical Trials Registry	Public Cuban Registry of Clinical Trials: http://registroclinico.sld.cu/en/home			

Country	Key Organizations	Legislation	Regulations	Guidelines
Dominica				
General	Ministry of Health: http://www.dominica.gov.dm/cms/index.php?q=node/21			Guidelines for the Conduct of Research on Human Subjects (2005)
Dominican Republic				
General	National Council on Health Bioethics: http://conabios.gob.do/	National Health Law 42-01, Chapter VI: https://www.dol.gov/ilab/submissions/pdf/20100408-10.pdf	Regulation for Evaluation Request for a Clinical Investigation Project: http://conabios.gob.do/index.php/reglamentos	
Biological Materials		National Health Law 42-01, Book Five: https://www.dol.gov/ilab/submissions/pdf/20100408-10.pdf		
Ecuador Note: All websites and documents are in Spanish.				
General	Ministry of Public Health : http://www.salud.gob.ec/	1. National Constitution of the Republic: http://www.asambleanacional.gob.ec/sites/default/files/documents/old/constitucion_de_bolsillo.pdf 2. Organic Health Law of 22 December 2006, Articles 207-208 (2011): http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf		National Policy on Scientific Research. Ministerial Agreement 209, Public Registry No. 87 of August 23, 2005
Drugs and Devices	1. Ministry of Public Health: http://www.salud.gob.ec/ 2. National Health Agency for Regulation, Control, and Oversight: http://www.controlsanitario.gob.ec/ensayos-clinicos/		1. Regulation on Research, Ministerial Agreement No. 0066, Public Registry No. 292, March 11, 2008. 2. Regulation for the Approval of Ethics Committees (2014): http://www.bioetica.org.ec/registro_comites.pdf	
Biological Materials	National Institute on Donation and Transplantation of Organs, Tissues, and Cells: http://www.donaciontrasplante.gob.ec/indot/	1. Organic Health Law of December 22, 2006, Articles 81-86 (2006): http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf 2. Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells (2011):	Regulation for the Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells. Executive Order 1205, July 13, 2012: http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_de_donacion_y_trasplantes.pdf	de_donacion_y_trasplantes.pdf	
Genetic Research	Ministry of Public Health: http://www.salud.gob.ec/	Organic Health Law, December 22, 2006, Articles 209-210 (2011): http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf		
Embryos, Stem Cells, and Cloning	1. Ministry of Public Health: http://www.salud.gob.ec/ 2. National Institute of Donation and Transplantation of Organs, Tissues, and Cells: http://www.donaciontrasplante.gob.ec/indot/	Organic Health Law of 22 December 2006, Article 214 (2011): http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf	Regulation for the Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells. Executive Order 1205, July 13, 2012: http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_de_donacion_y_trasplantes.pdf	
Grenada				
General	St. George's University/Windward Islands Research and Education Foundation: http://www.sgu.edu/school-of-medicine/institutional-review-board.html			45 CFR 46: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
Guyana				
			Medical Research Involving Human Subjects Regulations (2007)	
Guatemala Note: All websites and documents are in Spanish.				
Drugs and Devices	Ministry of Public Health and Social Assistance: http://www.mspas.gob.gt/		Rules for the Regulation of Human Clinical Trials. Ministerial Accord SP-M-466-2007: http://medicamentos.com.gt/index.php/legislacion-vigente/acuerdos	
Haiti				
General	Ministry of Public Health and Population (French): http://mspp.gouv.ht/newsite/			Internal Regulations (2010) (French)

Country	Key Organizations	Legislation	Regulations	Guidelines
Honduras Note: All websites and documents are in Spanish.				
General	Secretariat of Health: http://www.salud.gob.hn/		Health Code, Decree No. 65-91, Articles 175 and 176	
Jamaica				
General	Ministry of Health, Ethics and Medico-Legal Affairs Panel: http://moh.gov.jm/			Ministry of Health Guidelines for the Conduct of Research on Human Subjects (2010): http://moh.gov.jm/guidelines/guidelines-for-the-conduct-of-research-on-human-subjects/
Drugs and Devices	Ministry of Health, Standards and Regulation Division: http://moh.gov.jm/divisions-agencies/divisions/standards-and-regulation-division/	Food and Drugs Act (1975): http://www.moj.gov.jm/sites/default/files/laws/Food%20and%20Drugs%20Act%20LN%2065%20of%2075.pdf	Food and Drugs Regulations (1975): http://www.moj.gov.jm/sites/default/files/laws/Food%20and%20Drugs%20Act%20LN%2065%20of%2075.pdf	
México Note: All websites and documents are in Spanish.				
General	1. Secretariat of Health: http://www.salud.gob.mx/ 2. General Health Council: www.csg.salud.gob.mx/ 3. National Bioethics Commission (CNB): http://www.conbioetica-mexico.salud.gob.mx/ 4. Federal Commission for Protection Against Health Risks: http://www.cofepris.gob.mx/Paginas/Inicio.aspx	General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2014)	1. Rule NOM-012-SSA3-2012 Establishing Criteria for the Conduct of Health Research Projects (2013): http://dof.gob.mx/nota_detalle.php?codigo=5284148&fecha=04/01/2013 2. Regulation on the General Health Law in the Matter of Health Research (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf	CNB: 1. Agreement by Which General Provisions are Issued for the Integration and Operation of Research Ethics Committees and Their Hospital Units, In Accordance with Criteria Established by the National Bioethics Commission (2016): http://www.dof.gob.mx/nota_detalle.php?codigo=5422410&fecha=11/01/2016 2. National Guidelines for the Integration and Operation of Research Ethics Committees (2016): http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/registrocomites/Guia_CEI_paginada_con_forros.pdf
Drugs and Devices	Federal Commission for Protection Against Health Risks (COFEPRIS): http://www.cofepris.gob.mx/Paginas/Inicio.aspx	General Health Law, Title V, Chapter I, Articles 96-103: Health Research (2014)	Regulation on the General Health Law in the Matter of Health Research (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf	1. Guidelines to Fulfill Good Clinical Practice in Health Research 2. Technical Rule No. 314 for Registration and Follow-up in the Area of Health Research 3. Technical Rule 315 for the Operation of Research Commissions in Healthcare Institutions: http://www.cofepris.gob.mx/AS/Documents/M

Country	Key Organizations	Legislation	Regulations	Guidelines
				oléculas%20Nuevas/Formatos/CONFIDENCIALIDAD%20CMN%20CAS-CAS-P-02-F-02.pdf
Privacy/Data Protection	Federal Institute on Access to Public Information (Spanish): www.ifai.org.mx/	1. Federal Law for the Protection of Personal Data in the Possession of Private Individuals (2010): http://www.diputados.gob.mx/LeyesBiblio/pdf/LFPDPPP.pdf 2. Federal Law on Transparency and Access to Public Governmental Information (2014): http://www.diputados.gob.mx/LeyesBiblio/pdf/244_140714.pdf		
Human Biological Materials	Secretariat of Health: http://www.salud.gob.mx/	General Health Law, Title XIV, Articles 313-342 (2005): http://www.diputados.gob.mx/LeyesBiblio/pdf/142_040615.pdf	Regulation of the General Law of Health in Matter of Transplants (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MT.pdf	
Genetic Research	National Institute of Genomic Medicine: http://www.inmegen.gob.mx/es/	1. Biosafety Law on Genetically Modified Organisms (2005): http://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM.pdf 2. Regulation of the Biosafety Law on Genetically Modified Organisms (2008) http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LBOGM.pdf 3. Modifications to the General Health Law to Protect Genomic Sovereignty (2008) 4. Modifications to the General Health Law to Protect Genomic Sovereignty (2008)	Regulation on the General Health Law in the Matter of Health Research, Title Four, Chapter Two (1984): www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html	
Panamá				
General	1. Ministry of Health (MINSA) (Spanish): http://www.minsa.gob.pa/ 2. ICGES Bioethics Research Committee (CBI): http://www.gorgas.gob.pa/index.php?option=com_content&view=article&id=54&Itemid=103&lang=es		MINSA: 1. Resolution No. 390 Adopting the Operational Guide for Research Bioethics, Official Gazette 24,938 (2003) 2. Executive Decree N°1843 on the National Research Ethics Committee of Panama (2014) (Spanish):	CBI : Various (Spanish): http://www.gorgas.gob.pa/index.php?option=com_content&view=article&id=54&Itemid=103&lang=es

Country	Key Organizations	Legislation	Regulations	Guidelines
			https://www.gacetaoficial.gob.pa/.../GacetaNo_27716_20150206.pdf 3. Executive Decree N° 6 on the National Research Ethics Committee of Panama (2015) (Spanish): https://www.gacetaoficial.gob.pa/pdfTemp/27716/GacetaNo_27716_20150206.pdf	
Drugs and Devices		Law 1 of 2001, Official Gazette 24,218 (Spanish): http://www.perezcarrera.com/leyes/ley-registro-sanitario-panama.pdf		
Privacy/Data Protection		Law 68 of 2003, Official Gazette 24,935		
Human Biological Materials		Law 3 of 2010, Official Gazette 26,468-B on Transplant of Organs and Tissues: https://www.gacetaoficial.gob.pa/pdfTemp/26468_B/GacetaNo_26468b_20100210.pdf		
Embryos, Stem Cells, and Cloning			Executive Decree No. 2 on Stem Cells (2013) (Spanish): http://www.gacetaoficial.gob.pa/pdfTemp/27207/40367.pdf	
Perú For an overview of clinical research regulations in Peru, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=170				
General	1. National Institute of Health (Spanish): http://www.ins.gob.pe/ 2. National Network of Research Ethics Committees	General Health Law No. 26842, Article 28 (1997) (Spanish): http://www.wipo.int/wipolex/en/text.jsp?file_id=203140		
Drugs and Devices	1. National Institute of Health (Spanish): http://www.ins.gob.pe/portal/jerarquia/1/251/drug-quality-control/jer.251 2. National Directorate of Drugs and Medical Devices: www.digemid.minsa.gob.pe		1. Supreme Decree No. 017-2006-SA: Regulation on Clinical Trials in Peru (2006) (Spanish): 2. Supreme Decree No. 006-2007-SA: Modification of the Regulation on Clinical Trials in Peru (2007) (Spanish): http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990	
Clinical Trials Registry	Peruvian Registry of Clinical Trials: http://www.ins.gob.pe/ensayosclinicos/			
Research Injury	National Institute of Health (Spanish): http://www.ins.gob.pe/portal/jerarquia/1/2		Regulation on Clinical Trials in Peru: Articles 26, 27 and 28	

Country	Key Organizations	Legislation	Regulations	Guidelines
	51/drug-quality-control/jer.251		(Spanish): http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990	
Privacy/Data Protection	National Directorate of Drugs and Medical Devices: www.digemid.minsa.gob.pe	1. Law 29733 for the Protection of Personal Information: http://www.minjus.gob.pe/legislacion/ 2. Law for Electronic Medical Charts (2013): http://elperuanolegal.blogspot.com/2013/05/ley-30024-ley-que-crea-el-registro.html		
Trinidad and Tobago				
	1. Ministry of Health http://www.health.gov.tt/ 2. University of the West Indies (UWI), St. Augustine: http://sta.uwi.edu/fms/research/ethics.asp			UWI: 1. UWI Policy on Research Ethics 2. Application Guidelines 3. Ethics Committee Protocols Access: http://sta.uwi.edu/fms/research/ethics.asp
Uruguay Note: All websites and documents are in Spanish.				
General	Ministry of Public Health: http://www.msp.gub.uy/	1. Decree 189/998 http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF 2. Decree 379/008: http://www.elderechodigital.com.uy/smu/legisla/D0800379.html	Decree No. 370/2008: Regulation Concerning Research with Humans	
Drugs and Devices	Ministry of Public Health: http://www.msp.gub.uy/	Decree 189/998: http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF		
Research Injury	Ministry of Public Health: http://www.msp.gub.uy/	1. Decree 189/998 http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF 2. Decree 379/008:		

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.elderechodigital.com.uy/smu/legisla/D0800379.html		
Privacy/Data Protection	Ministry of Public Health: http://www.msp.gub.uy/	1. Law 18.331: http://www0.parlamento.gub.uy/leyes/AccesoTextoLey.asp?Ley=18331 2. Decree 379/008: http://www.elderechodigital.com.uy/smu/legisla/D0800379.html		
Human Biological Materials	1. Ministry of Public Health: http://www.msp.gub.uy/ 2. National Institute on Donation and Transplantation: www.indt.edu.uy	Decree 160/006: http://www.indt.edu.uy/documentos/documentacion_legal/decreto_160-006.pdf		
Venezuela Note: All websites and documents are in Spanish.				
General	1. National Fund on Science and Technology, Commission on Bioethics and Biosecurity (FONACIT): www.fonacit.gov.ve/ 2. Venezuelan Institute of Scientific Research, Bioethics Commission (IVIC): http://www.ivic.gob.ve/bioetica/?mod=home.php	Constitution, Article 46 (3): http://www.venezuelaemb.or.kr/english/ConstitutionoftheBolivarianingles.pdf	Resolution No. 48 (1998): http://www.ivic.gob.ve/bioetica/?mod=bioeticahome.php	FONACIT: Code on Bioethics and Biosecurity (2002) IVIC: 1. Annex 1: General Ethical Issues in Research Involving Living Persons: http://www.ivic.gob.ve/bioetica/?mod=Anexo.php 2. Annex 2: Necessity of Establishing a Clear and Precise Study Protocol Before Starting Research: http://www.ivic.gob.ve/bioetica/?mod=Anexo.php 3. Informed Consent: http://www.ivic.gob.ve/bioetica/?mod=manual.php
Drugs and Devices	National Institute of Hygiene "Rafael Rangel": http://www.inhrr.gob.ve/	Medicines Act, Title III, Chapter II: http://www.ginecoweb.com/PDF/Ley-del-Ejercicio-de-la-Medicina.pdf		
Genetic Research	Venezuelan Institute of Scientific Research, Bioethics Commission: http://www.ivic.gob.ve/bioetica/?mod=home.php			1. Contract for Accessing Genetic Resources (2003): http://www.ivic.gob.ve/bioetica/contrato.pdf 2. Revised Outline of the International Declaration of Human Genetic Data (2003): http://www.ivic.gob.ve/bioetica/chapter3.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
AFRICA				
Regionwide				
Clinical Trials Registry	Pan African Clinical Trials Registry: http://www.pactr.org/			FAQs: http://www.pactr.org/ATMWeb/appmanager/atm/atmregistry?_nfpb=true&_pageLabel=atmportal_page_FAQ
Benin				
General		Law No. 2010-40 of 8 December, 2010 Regarding the Ethical Code and Duties in Health Research in the Republic of Benin (French): http://ethique-sante.org/pdf/loi-portant-code-ethique.pdf		
Botswana				
General	Ministry of Health, Research and Development Committee: http://www.moh.gov.bw/	Anthropological Research Act 45 (1967): http://www.elaws.gov.bw/docs/statutes/Botswana%20Statute%20Law%201967.pdf		1. Guidelines for Application for Research Permit (2004): http://www.gov.bw/Global/OP%20Ministry/RESEARCH%20PERMIT%20GUIDELINES.pdf Guide for a Consent Form (2005) 2. Guidelines for the Review of Research Proposals (2005)
Drugs and Devices	Ministry of Health, Drug Regulatory Unit: http://www.moh.gov.bw/		Drugs and Related Substances Regulations (1993)	SADC Guidelines for Regulating Clinical Trials in Human Subjects (2006)
Burkina Faso Note: All websites and documents are in French.				
General	Ethics Committee for Health Research		Joint Order 2004-147 / MS / MESSE of 11 May 2004 on the Organization and Functioning of the Ethics Committee for Health Research in Burkina Faso	
Drugs and Devices			Order No. 2010-292 / MS / CAB of 1 October 2010 on the Conditions for Granting Authorizations for Clinical Trials: http://elearning.trree.org/pluginfile.php/34806/mod_folder/content/0/19_Arrete_autorisations_essais_cliniques.pdf?forcedownload=1	

Country	Key Organizations	Legislation	Regulations	Guidelines
Cameroon For an overview of human subject protections in Cameroon, see: http://elearning.trree.org/mod/nationalsupplement/view.php?id=227				
General	Cameroon Bioethics Initiative: www.cambin.org		Ministerial Order No. 079/A/MSP/DS of MINSANTE (1987) (French): http://elearning.trree.org/pluginfile.php/34735/mod_folder/content/0/cm-arrete-079-MSP-CreationComiteEthique-1987.pdf?forcedownload=1	Operational Guidelines for Ethics Committees in Charge of the Evaluation of Biomedical Research
Congo, Democratic Republic of				
General		National Policy on Health Systems Research (2004) (French)		
Côte-d'Ivoire For an overview of human subject protections in Côte-d'Ivoire, see: http://elearning.trree.org/course/view.php?id=19 Note: All websites and documents are in French.				
Drugs and Devices	National Committee on Ethics and Research		Decree No 317 / SP / DSPH of 14 July 1987 on the Regulation of Drugs Before and After Marketing in Ivory Coast: http://elearning.trree.org/pluginfile.php/34816/mod_folder/content/0/20_Arrete_Regl_exp_clinique_des_substances_med.pdf?forcedownload=1	
Ethiopia				
General	Ethiopian Science and Technology Commission, Health Department: http://www.most.gov.et/	Proclamation 60/1999, Section 21		National Health Research Ethics Review Guideline, Fourth Edition (2014): http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf
Drugs and Devices	Food, Medicine, and Health Administration and Control Authority: www.fmhaca.gov.et		Drug Administration and Control Proclamation No. 176/1999, Article 21	
Human Biological Materials	Ethiopian Science and Technology Commission, Health Department: http://www.most.gov.et/			National Health Research Ethics Review Guideline, Fourth Edition, Chapter 9 (2005): http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf
Gambia				
Genetic Research	MRC: Gambia Unit: http://www.mrc.gm/			Guidelines of the National DNA Bank (2001)

Country	Key Organizations	Legislation	Regulations	Guidelines
Ghana				
Drugs and Devices	Food and Drugs Authority: http://www.fdaghana.gov.gh	Public Health Act, 2012: ACT 851	Act 851 Section 150-166	1. Conduct of Clinical Trials Document No. FDA/SMC/CTD/GL-CCT/2013/0, Version No. 02 2. Good Clinical Practice Document No. FDA/SMC/CTD/GL-GCP/2013/02, Version No. 01
Guinea For an overview of the clinical research regulations in Guinea, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=90 Note: All websites and documents are in French.				
General	National Ethics Committee on Health Research (CNERS): http://cners-guinee.org/	Public Health Code, Articles 237-316 (1997): http://www.vertic.org/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf	Decree No. D/218/PRG/SGG: On the Establishment, Functions and Organization of the National Ethics Committee for Research in Health (CNERS), Chapters I and II (1998): http://cners-guinee.org/wp-content/uploads/2014/02/Decret-.pdf	CNERS: Frequently Asked Questions: http://cners-guinee.org/faq/
Research Injury	National Ethics Committee on Health Research: http://cners-guinee.org/	Public Health Code, Articles 301-302 (1997): http://www.vertic.org/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf		
Kenya For an overview of the clinical research regulations in Kenya, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=111				
General	1. National Council for Science and Technology (NCST): http://www.nacosti.go.ke/ 2. Ministry of Health (MOH): www.health.go.ke/	1. Science and Technology Act (2001) 2. HIV and AIDS Prevention and Control Act, Chapter 14 (2006)		MOH: National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): https://healthresearchweb.org/?action=download&file=Final%20national%20ethical%20guidelines-last%20draft.pdf
Drugs and Devices	Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/	Pharmacy and Poisons Act, Chapter 244 (2009): http://apps.who.int/medicinedocs/documents/s18245en/s18245en.pdf	MOH: Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005)	Guidelines for Applications to Conduct Clinical Trials in Kenya (2014): http://pharmacyboardkenya.org/downloads/?file=Clinical%20Trial%20Guidelines%202014.pdf
Human Biological Materials	Ministry of Health (MOH): www.health.go.ke/		Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, page 44 (2005)	

Country	Key Organizations	Legislation	Regulations	Guidelines
Liberia For an overview of the clinical research regulations in Liberia, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=122				
General	Ministry of Health and Social Welfare: http://www.mohsw.gov.lr/		1. Institutional Review Board (IRB) Policies and Procedures Handbook (2008): http://www.ul-acre.org/wp-content/uploads/2013/03/UL-IRB-Policy-Handbook.pdf 2. Ethics Committee Guidelines: Procedures for Researchers, Section 1 (2011): http://clinregs.niaid.nih.gov/documents/liberia/G-LIBR-NHSREC.pdf	
Drugs and Devices	Liberia Medicines and Health Products Regulatory Authority			Guideline for Application to Conduct Clinical Trials in Liberia (2014): https://clinregs.niaid.nih.gov/documents/liberia/G-LibClinTrial.pdf
Malawi For an overview of the clinical research regulations in Malawi, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=129				
General	1. National Commission for Science and Technology (NCST): http://www.ncst.mw/ 2. National Health Sciences Research Committee (NHSRC): http://www.ncst.mw/national-health-science-research-committee-nhsrc/ 3. College of Medicine Research and Ethics Committee (COMREC): http://www.medcol.mw/ 4. Ministry of Health: www.malawi.gov.mw	1. Presidential Decree on 30th March 1974 2. Malawi Government Gazette, June 11, 1976, General Notice No. 398 3. Constitution of Malawi, Article 19(5) (1994)		NCST: 1. The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011) 2. Policy Requirements, Procedures and Guidelines for the Conduct and Review of Research (2012) 3. National Policy Measures and Requirements for the Improvement of Health Research Co-ordination in Malawi (2012) 4. National Policy Requirements and Guidance for the Provision of Insurance Cover for Research Participants in Clinical Trials in Malawi (2012) NHSRC: 1. Operational Guidelines (2001) 2. Summary Guidelines for Writing Research Proposals (2001) COMREC: General Guidelines on Health Research (2014): http://www.medcol.mw/comrec/wp-content/uploads/2014/07/comrec_guidelines.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	Pharmacy, Medicines, and Poisons Board of Malawi	1. Pharmacy, Medicines, and Poisons Act, Act 15 of 1988: http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CB0QFjAAahUKEwi3qf2P2vLIAhUEqh4KHfyNBvw&url=http%3A%2F%2Fwww.malawilii.org%2Ffiles%2Fmw%2Flegislation%2Fconsolidated-act%2F35%3A01%2Fpharmacy_medicines_poisons_act_pdf_19885.pdf&usg=AFQjCNFJR-Y4F7y3eoC6DV0H7Jr77s5Msg 2. Section 42(1) of PMPB Act, 2003 Supplement		
Genetic Research	National Research Council of Malawi (NRCM): www.sdnp.org.mw/nrcm/		Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002)	
Mozambique For an overview of human subject protections in Mozambique, see: http://elearning.trree.org/course/view.php?id=14&lang=en				
General				Science and Technology Ethics Code (2007) (Portugese): http://elearning.trree.org/pluginfile.php/34764/mod_folder/content/0/02-CodigoDeEtica.pdf?forcedownload=1
Nigeria For an overview of human subject protections in Nigeria, see: http://elearning.trree.org/mod/page/view.php?id=142				
General	National Health Research Ethics Committee: http://nhrec.net/	National Health Act 2014		Nigerian Code of Health Research Ethics (2007): http://www.nhrec.net/nhrec/NCHRE_10.pdf Various: http://nhrec.net/download-guides-and-forms/
Drugs and Devices	National Agency for Food, Drug Administration and Control (NAFDAC): http://www.nafdac.gov.ng/	Decree No. 15 of 1993	Good Clinical Practice Regulations (2009): http://apps.who.int/medicinedocs/documents/s17103e/s17103e.pdf	
Clinical Trial Registries	National Health Research Ethics Committee: http://nhrec.net/			Frequently Asked Questions: http://nhrec.net/nctr/FAQ.php
Human Biological Materials	National Health Research Ethics Committee: http://nhrec.net/			Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria (2013): http://nhrec.net/nhrec/NHREC_Policy_Statement_on_Biobanks_FINAL.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Rwanda				
General	Ministry of Health, National Ethics Committee: http://www.moh.gov.rw/index.php?id=2			Standard Operating Procedures (2009): http://www.moh.gov.rw/index.php?option=com_docman&task=doc_download&gid=126&Itemid=81
Senegal				
General	National Committee on Health Research Ethics	Law Supporting the Code of Ethics for Health Research (2009) (French): http://www.sante.gouv.sn/document/1432205899.pdf		
Sierra Leone For an overview of the clinical research regulations in Sierra Leone, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=193				
General	Sierra Leone Ethics and Scientific Review Committee			1. Application Guidelines http://health.gov.sl/wp-content/uploads/2015/01/Guidelines-and-Checklist-for-Ethical-Clearance-2016.pdf 2. Application Form: https://www.healthresearchweb.org/?action=download&file=SierraLeoneEthicsandScientificReviewCommittee.docx
Drugs and Devices	1. Ministry of Health (French): http://www.sante.gov.bf/ 2. Pharmacy Board of Sierra Leone: http://pharmacyboard.gov.sl/		1. Guidelines for Conducting Clinical Trials of Medicines, Food Supplements, Vaccines, and Medical Devices in Sierra Leone, Sections: 3.1.7 and 3.2 (2014): http://pharmacyboard.gov.sl/site/LinkClick.aspx?fileticket=9jeTGC2WIZ8%3d&tabid=316&portalid=1&mid=934 2. Guideline for Good Clinical Practice (GCP) in Sierra Leone, Sections 3.2 and 3.3 (2014): http://pharmacyboard.gov.sl/site/LinkClick.aspx?fileticket=9jeTGC2WIZ8%3d&tabid=316&portalid=1&mid=934 3. Guideline for Conducting Clinical Trials: http://pharmacyboard.gov.sl/site/LinkClick.aspx?fileticket=YrGQkXzfLP8%3d&tabid=316&portalid=1&mid=934&forcedownload=true	Forms: http://pharmacyboard.gov.sl/site/Downloads/Forms.aspx

Country	Key Organizations	Legislation	Regulations	Guidelines
South Africa For an overview of human subject protections in South Africa, see: http://elearning.trree.org/course/view.php?id=9&lang=en For an overview of the clinical research regulations, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=199				
General	1. Department of Health (DH): http://www.doh.gov.za 2. National Health Research Ethics Council: http://www.nhrec.org.za/ 3. Medical Research Council of South Africa (MRC): http://www.mrc.ac.za 4. Human Sciences Research Council (HSRC): http://www.hsrc.ac.za/index.phtml	1. Constitution of South Africa, Section 12 (2) (1996) 2. National Health Act No. 61, Chapter 9 (2003): http://www.saflii.org/za/legis/consol_act/nha2003147.pdf	Regulations Relating to Research with Human Participants No. R719 (2014): http://www.google.co.za/url?url=http://www.lawsofsouthafrica.up.ac.za/index.php/browse/medical-and-health/national-health-act-61-of-2003/regulations-and-notices/61-of-2003-national-health-act-regs-gnr-719-19-sept-2014-to-date-pdf/download&rct=j&frm=1&q=&esrc=s&sa=U&ei=W6UtVOOvLa6S7Aa34YDwAg&ved=0CBUQFjAA&usg=AFQjCNFpKA9W0jNyeWhk0n0l0Q-WxazBtg	DH: Ethics in Health Research: Principles, Structures, and Processes (2015): http://www.nhrec.org.za/docs/Documents/EthicsHealthResearchFinalAused.pdf MRC: 1. Guidelines on Ethics in Medical Research: General Principles (2002) 2. Guidelines on Ethics in the Use of Biohazards and Radiation (2003) 3. Guidelines on Ethics in HIV Vaccine Trials (2003)
Drugs and Devices	1. Department of Health (DH): http://www.doh.gov.za 2. Medicines Control Council: http://www.mccza.com	Medicines and Related Substances Control Act, 101 of 1965 http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/legislations/acts/medicines_and_related_sub_act_101_of_1965.pdf	General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (2003): http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/legislations/acts/medicines_and_related_sub_act_101_of_1965.pdf	DH: Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006): http://www.nhrec.org.za/docs/trainingrequirements/gcp.pdf
Clinical Trials Registry	South African National Clinical Trials Register: http://www.sanctr.gov.za/			FAQs: http://www.sanctr.gov.za/InvestigatorbrnbspInformation/FAQ/tabid/200/Default.aspx
Human Biological Materials	Department of Health (DH): http://www.doh.gov.za	National Health Act No. 61, Chapter 8, Sections 53-68 (2003): http://www0.sun.ac.za/ruralhealth/ukwandahome/rudasaresources2009/DOH/ethics/app5.pdf	1. Regulations Relating to the Use of Human Biological Material, 2 March 2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf 2. Regulations Regarding General Control of Human Bodies, Tissues, Blood Products and Gametes, 2 March 2012 3. Regulations Relating to Blood and Blood Products, 2 March 2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf 4. Regulations Relating to Artificial Insemination of Persons, 2 March 2012:	

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.sashg.org/documents/GovGazette2Mar2012.pdf	
Genetic Research	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za			Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.sahealthinfo.org/ethics/book2.htm
Embryos, Stem Cells, and Cloning	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za	National Health Act No. 61, Chapter 8, Section 57 (2003): http://www0.sun.ac.za/ruralhealth/ukwandahome/rudasaresources2009/DOH/ethics/app5.pdf	Regulations relating to Stem Cell Banks, 2 March 2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf	Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.kznhealth.gov.za/research/ethics2.pdf
Sudan				
General	Federal Ministry of Health: http://www.fmoh.gov.sd/			National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): http://sites.google.com/site/healthresearchlibrary/national-guidelines
Drugs and Devices	National Medicines and Poisons Board: http://www.nmpb.gov.sd/en/	Act on Pharmaceuticals and Poisons (2009) (Arabic): http://www.nmpb.gov.sd/index.php/2015-08-05-11-05-04/regulations/113-laws2009		
Human Biological Materials	Federal Ministry of Health: http://www.fmoh.gov.sd/	Human Organs and Tissues Transplant Legislation, Chapter 2, Articles 3 and 4 (1978)		
Genetic Research	University of Khartoum, Institute of Endemic Diseases: http://iend.uofk.edu/index.php?lang=en			Guidelines for Genetics Research on Sudanese Subjects (2005)
Tanzania For an overview of human subject protections in Tanzania, see: http://elearning.trree.org/mod/resource/view.php?id=41&lang=en For an overview of the clinical research regulations in Tanzania, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=212				
General	1. Ministry of Health (MOH) 2. National Institute for Medical Research (NIMR), National Health Research Ethics Committee (NHREC): http://www.nimr.or.tz/ 3. Tanzania Commission for Science and Technology (COSTECH): www.costech.or.tz	1. National Institute for Medical Research, Act of Parliament No. 23, of 1979: http://www.parliament.go.tz/Polis/PAMS/Docs/23-1979.pdf 2. Tanzania Commission for Science and Technology, Act No. 7 of 1986 3. Amendment of NIMR Act 1997, Tanzania Government Gazette, No. 675	NIMR: 1. Coordination of Health Research in Tanzania 2. Coordination of Formation of Institutional Health Research Committees to Formally Approve for Local Health Research 3. Coordination of Research in Tanzania	NHREC: 1. Brochure for Health Researchers in Tanzania (2006) 2. Guidelines on Ethics for Health Research in Tanzania (2009): https://clinregs.niaid.nih.gov/documents/tanzania/G-EthicsHR.pdf COSTECH: COSTECH Guidelines on Research Permits and Clearance (2006)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	*Drugs*			
	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003): http://www.tfda.or.tz/index.php?option=com_phocadownload&view=category&download=44:tfdc-acts-2003&id=52:tfdc-acts-2003&Itemid=417		
	Devices			
	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Medical Device Act (1988)		
Tunisia				
Drugs and Devices	Ministry of Public Health, Institut Pasteur: www.pasteur.tn		Conditions of Contract and Specifications Related to Medical or Scientific Experimentation of Medicines Intended for Humans	Disposals and Director's Principles Related to Good Practices in Clinical Trials
Clinical Trials Registry	Tanzania Clinical Trial Registry: http://www.tzctr.or.tz/			FAQs: http://www.tzctr.or.tz/faq.php
Uganda For an overview of the clinical research regulations in Uganda, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=223				
General	Uganda National Council for Science and Technology (UNCST): http://www.uncst.go.ug/	Uganda National Council for Science and Technology Act (CAP 209)		National Guidelines for Research Involving Humans as Research Participants (2014): http://www.uncst.go.ug/dmdocuments/Human%20Subjects%20Protection%20Guidelines%20July%202014.pdf
Drugs and Devices	National Drug Authority: http://www.nda.or.ug/	National Drug Policy and Authority Act (CAP 206) (1993)		
Zambia				
General	Ministry of Health: http://www.moh.gov.zm/	National Health Research Act (2013)		
Zimbabwe				
General	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw	1. Medical Research Government Notice Act (1974) 2. Research Act (1986)		Various: http://www.mrcz.org.zw/faqs/
Drugs and Devices	*Drugs*			
	Medicines Control Authority of Zimbabwe: http://www.mcaz.co.zw/	Medicines and Allied Substances Control Act, Chapter 15:03 (1997)	1. Medicines and Allied Substances Control Act, General Regulations (1991) 2. Statutory Instrument 150 of 1991	1. Guidelines for Good Clinical Practice (2012): http://www.medbox.org/guidelines-for-good-clinical-trial-practice-in-zimbabwe-2012/download.pdf 2. Pharmacy Guidelines for Investigational Drugs (2016):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.mcaz.co.zw/index.php/downloads/file/114-pharmacy-guidelines-for-investigational-drugs-draft-1
	Devices			
	Medicines Control Authority of Zimbabwe: http://www.mcaz.co.zw/devices.html	Medicines and Allied Substances Control Act, Chapter 15:03 (1997): https://www.unodc.org/res/cld/document/zwe/medicines-and-allied-substances-control-act_html/Zimbabwe_Medicines_and_Allied_Substances_Control_Act.pdf	Medicines and Allied Substances Control (Condom) Regulations (2005): http://www.mcaz.co.zw/index.php/downloads/category/15-regulations-and-guidelines?download=29:condom-regulations	
Human Biological Materials	Research Council of Zimbabwe: www.rcz.ac.zw	Research Act (2001): http://faolex.fao.org/docs/pdf/zim93551.pdf		Various: http://www.rcz.ac.zw/research-registration/
Genetic Research	National Biotechnology Authority of Zimbabwe: http://www.nba.ac.zw/	National Biotechnology Authority Act, Chapter 14:31 (2006): http://www.nba.ac.zw/index.php/our-resources/finish/1-national-biotechnology-association/2-national-biotechnolgy-authority-act		

ACKNOWLEDGEMENTS

The DHHS Office for Human Research Protections thanks the following individuals for providing updates or confirmations of accuracy for the 2017 Edition of the International Compilation of Human Research Standards. We particularly thank Carla Saenz of the Pan American Health Organization, Washington DC; Dragana Zaharieva of Comac Medical, Sofia, Bulgaria; and Pamela Wernett of the National Institutes of Health, Office of Science Policy for their assistance.

North America:
Canada: Hanan Abdel-Akher
United States:

- *Consumer Product and Safety Commission: Alice Thaler*
- *Department of Commerce: Anne Andrews*
- *Department of Defense: Stephanie Bruce*
- *DHHS Food and Drug Administration: Kevin Prohaska*
- *DHHS Health Resources and Services Administration: Lydie A. Lebrun-Harris*
- *DHHS National Institutes of Health: Jon Kagan and Pamela Wernett*
- *Department of Homeland Security: Ryan Gearheart*
- *Department of Housing and Urban Development: Warren Friedman*
- *Social Security Administration: Leola Brooks*
- *United States Department of Agriculture: David Klurfeld*

Europe:
European Commission: Caroline Attard and Miguel González-Sancho
European Medicines Agency: Sophia Mylona and Fergus Sweeney
Belgium: Monique Bosson
Bosnia: Dragana Zaharieva
Bulgaria: Dragana Zaharieva
Czech Republic: Alice Němcová
Croatia: Dragana Zaharieva
Cyprus: Dragana Zaharieva
Denmark: Ann-Sofie Lydiksen Nygaard
Estonia: Dragana Zaharieva and Kristi Louk
Finland: Outi Konttinen
France: Emmanuelle Rial-Sebbag
Georgia: Dragana Zaharieva
Greece: Dragana Zaharieva
Hungary: Ernö Bácsy
Iceland: Thorunn Oddný Steinsdóttir
Ireland:
Kyrgyzstan: Tamara Kudaibergenova
Latvia: Dragana Zaharieva
Lithuania: Dragana Zaharieva
Luxembourg: *Malika Pailhes*
Macedonia: Dragana Zaharieva
Moldova: Dragana Zaharieva and Svetlana Nichita
Montenegro: Dragana Zaharieva
Netherlands: Jim Terwiel
Poland: Dragana Zaharieva
Romania: Dragana Zaharieva
Russia: Sergey Tabakov
Serbia: Dragana Zaharieva and Jelena Rakobradovic
Slovenia: Dragana Zaharieva
Spain: Iñigo de Miguel Beriain and Mª Concepción Martín Arribas
Sweden: Stefan Eriksson
Switzerland: Brigitte Meier, Sue le Roux, Dominique Sprumont, Sarah Desailly, and Songül Yavavli
Turkey: Hamdi Akan
Ukraine: Zoryana Chernenko
United Kingdom: Clive Collett and Fiona Law

Asia/Pacific/Middle East:
Australia: Colin Thomson and Alana Lucas
China, People's Republic of: Yali Cong, Haihong Zhang, and Feng Hong
India: Nandini Kumar
Japan: Shimon Tashiro
Jordan: Amal Al Omari
Korea: B.I. Choe
Kyrgyzstan: Tamara Kudaibergenova
Nepal: Khem Bahadur Karki
New Zealand: Lana Lon and Chris James
Saudi Arabia: Henry Silverman
Singapore: Charmaine Chan
Taiwan: Benjamin Kuo
Thailand: NIAID ClinRegs
United Arab Emirates: Henry Silverman

Uzebekistan: Dilfuza Aniyozova
Vietnam: NIAID ClinRegs

Latin America and the Caribbean:
Caribbean Public Health Agency: Derrick Aarons
Pan American Health Organization: Carla Saenz
Antigua: Colin O'Keiffe
Argentina: María del Carmen Díaz
Bermuda: Derrick Aarons
Brazil: NIAID ClinRegs
Chile: María Ximena Luengo Charath, Isabel Margarita Pacheco, and Guillermo Olivares
Colombia: Maria Consuelo Miranda, Claudia Ayala Leal, Francisco Javier Sierra Esteban, and Carlos Alberto Marín
Costa Rica: Esteban Cerdas Quirós and Yohana Díaz de Valle
Dominica: Sean Reid
Dominican Republic: Julio Arturo Canario and David Hernandez Martich
Ecuador: Karina Castro
Grenada: Cheryl Macpherson
Guyana: Derrick Aarons
México: M en C Ma. de los Dolores, Delgado Ochoa, and María de la Luz
Panama: Claude Vergès
Perú: Roxana Lescano
Trinidad and Tobago: Allana Roach, Shivananda Nayak, and Evelyn Rose Ferreira

Africa:
Egypt: Henry Silverman
Kenya: NIAID ClinRegs
Malawi: Lucinda Manda-Taylor
Nigeria: Aminu Yakubu
Sierra Leone: Eddie Foday and Hector Morgan
South Africa: Douglas Wassenaar
Sudan: Lamis Beshir
Tanzania: NIAID ClinRegs
Zimbabwe: Paul Ndebele