Country	Key Organizations	Legislation	Regulations	Guidelines
ASIA/PACIFIC/MIDDLE EAST				
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/ 3. Universities Australia (UA): http://www.universitiesaustralia.edu.au/ 4. Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS): http://www.aiatsis.gov.au/index.html	National Health and Medical Research Council Act 1992 (2011): http://www.comlaw.gov.au/Details/C2012C00255	National Health and Medical Research Regulations (2006): http://www.comlaw.gov.au/Details/F2006L03519	NHMRC, ARC, and UA: 1. National Statement on Ethical Conduct in Human Research (2013): http://www.nhmrc.gov.au/publications/synopses/e72syn.htm 2. Australian Code for the Responsible Conduct of Research (2007): http://www.nhmrc.gov.au/publications/synopses/r39syn.htm 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/publications/synopses/e65syn.htm AIATSIS: 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 (2012): http://www.comlaw.gov.au/Details/C2012C00355	Therapeutic Goods Regulations 1990 (2012): http://www.comlaw.gov.au/Details/F2012C00455	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): http://www.tga.gov.au/pdf/clinical-trials-handbook.pdf NHMRC, ARC, and UA: 3. National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2013): http://www.nhmrc.gov.au/publications/synopses/e72syn.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
				4. 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: http://www.comlaw.gov.au/Details/C2012C00355	Therapeutic Goods (Medical Devices) Regulations 2002 (2012): http://www.comlaw.gov.au/Details/F2012C00424	Australian Regulatory Guidelines for Medical Devices (ARGMD) (2011): http://www.tga.gov.au/industry/devices-argmd.htm
Research Injury	1. Therapeutic Goods Administration (TGA): http://www.tga.gov.au/ 2. Medicines Australia http://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): http://www.tga.gov.au/pdf/euguide/ich13595.pdf Medicines Australia: Industry Standard Compensation Guidelines, Section 4 (2012): http://medicinesaustralia.com.au/issues-information/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 (2013): http://www.nhmrc.gov.au/guidelines/publications/e72
Privacy/Data Protection Note: All Australian states and territories have privacy/data protection laws: http://www.austlii.edu.au/au/other/alrc/publications/reports/108/vol_3_full.pdf	Office of the Australian Information Commissioner: http://www.privacy.gov.au/	Privacy Act 1988 (2012): http://www.comlaw.gov.au/Details/C2012C00414	Privacy (Private Sector) Regulations 2001 (2012): http://www.comlaw.gov.au/Details/F2011C00438	1. Guidelines under Section 95 of the Privacy Act 1988 (2000): http://www.nhmrc.gov.au/guidelines/publications/e26 2. Guidelines Approved under Section 95A of the Privacy Act 1988 (2001): http://www.nhmrc.gov.au/guidelines/publications/e43 3. Guidelines Approved under Section 95AA of the Privacy Act 1988 (2009): http://www.nhmrc.gov.au/guidelines/publications/e96
Human Biological Materials Note: All Australian	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Therapeutic Goods Administration:			NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research (2013): Chapters 3.2 and 3.4:

Country	Key Organizations	Legislation	Regulations	Guidelines
states and territories have laws on human biological materials.	http://www.tga.gov.au/			http://www.nhmrc.gov.au/publications/synopses/e72syn.htm TGA: Australian Regulatory Guidelines for Biologicals (2011): 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 (2011): http://www.comlaw.gov.au/Details/C2012C00172		NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research, Chapter 3.5 (2009): http://www.nhmrc.gov.au/publications/synopses/e72syn.htm
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 http://www.nhmrc.gov.au/about/committees/lc/index.htm	1. Prohibition of Human Cloning for Reproduction Act 2002 (2008): http://www.comlaw.gov.au/Details/C2008C00694 2. Research Involving Human Embryos Act 2002 (2008): http://www.comlaw.gov.au/Details/C2008C00689	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 3.6 (2013): 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
Bangladesh				
General	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			
Drugs and Devices	Bangladesh Directorate of Drug Administration: http://www.ddabd.org	1. The Drugs Act (1964) 2. Drugs (Control) Ordinance 1982, Ordinance No. VIII: http://www.ddabd.org/ordinance_1982.htm		
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. Ministry of Health National Ethics Committee on Clinical Research: www.moh.gov.mm 2. Department of Medical Research (DMR) 3. Department of Health, Ethical Review Committee		DMR: Operational Guidelines for Institutional Ethical Review Committee (2005)	

Country	Key Organizations	Legislation	Regulations	Guidelines
	4. Myanmar Academy of Medical Sciences Ethics Awareness Program			
Drugs and Devices	Ministry of Health, Food and Drug Administration	National Drug Law (1992)		
China, People's Republic of				
General	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.moh.gov.cn/zhuzhan/ 2. Ministry of Science and Technology: http://www.most.cn/eng/	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
Drugs and Devices	*Drugs*			
	China Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/	Drug Administration Law of the People's Republic of China (2001) (English): 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. Rules on the Administration of Report and Supervision of Adverse Drug Reactions (2010) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/62621.html 4. Provisions for Drug Registration (2007) (English): 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. Good Manufacturing Practice for Drugs (2010 Revision): http://eng.sfda.gov.cn/WS03/CL0768/65113.html 7. Special Review and Approval Procedure for Drug Registration	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

Country	Key Organizations	Legislation	Regulations	Guidelines
			of the State Food and Drug Administration (2005) (English): http://eng.sfda.gov.cn/WS03/CL0768/61646.html	
	Devices			
	Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/		Provisions for Clinical Trials of Medical Devices (2004): http://eng.sfda.gov.cn/WS03/CL0768/61644.html	
Privacy/Data Protection	*Hong Kong:*			
	Privacy Commissioner for Personal Data: www.pco.org.hk	Personal Data (Privacy) Ordinance (2012): http://www.pcpd.org.hk/english/review_ordinance/reviewordinance.html		
Research Injury	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.moh.gov.cn/zhuzhan/ 2. Food and Drug Administration (SFDA): 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/publicfiles/business/htmlfiles/mohkjjys/s3581/200804/18816.htm 2. Regulations on Recall of Medical Devices (Interim), Article 37 (2011) (Mandarin): http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohzcfgs/s3576/201106/51998.htm	SFDA: 1. Provisions for Clinical Trials of Medical Devices, Article 8 (2004) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/24475.html 2. Guideline on Vaccine Clinical Trials, Part 6 (2004) (Mandarin): http://www.sda.gov.cn/WS01/CL0844/10307.html 3. 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.moh.gov.cn/zhuzhan/ 2. Ministry of Science and Technology (MOST): http://www.most.cn/eng/		NHFPC and MOST: Interim Measures for the Administration of Human Genetic Resources (1998) (Mandarin): http://www.most.gov.cn/bszn/new/rlyc/wjxz/200512/t20051226_55327.htm	
Embryos, Stem Cells, and Cloning	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.moh.gov.cn/zhuzhan/ 2. Ministry of Science and Technology (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	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

Country	Key Organizations	Legislation	Regulations	Guidelines
			Application of Medical Technique (2009) http://www.moh.gov.cn/yzygj/s3589/201308/0c579ba3babf47dc8f0e811810d438a2.shtml	
	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				
General	Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			Ethical Guidelines for Biomedical Research on Human Participants (2006): http://icmr.nic.in/ethical_guidelines.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	Revised Schedule Y of the Drugs & Cosmetics Act (2005)	DCGI: 1. Good Clinical Practices for Clinical Research in India (2001): http://cdsco.nic.in/html/GCP.htm 2. Compensation: GSR 53 (E) 3. Permission for Clinical Trials: GSR 63(E) 4. Ethics Committee Registration: GSR 72(E)	ICMR: Ethical Guidelines for Biomedical Research on Human Participants: Chapter IV. Drug Trials and Vaccine Trials (2006)
	Devices			
	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			ICMR: Ethical Guidelines for Biomedical Research on Human Participants: Clinical Trials with Surgical Procedures/Medical Devices: http://www.icmr.nic.in/ethical_guidelines.pdf
Research Injury	Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			Ethical Guidelines for Biomedical Research on Human Participants: Chapter III, Section VI (2006): http://www.icmr.nic.in/ethical_guidelines.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 http://icmr.nic.in/ihd/ihd.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
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): http://dbtindia.nic.in/uniquepage.asp?id_pk=41 ICMR: Ethical Guidelines for Biomedical Research on Human Subjects: Statement 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 and Therapy (2007): http://icmr.nic.in/stem_cell/Stem_cell_guidelines.pdf
Indonesia				
General	Ministry of Health, National Institute of Health Research and Development	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	Indonesian FDA		Guidelines on Good Clinical Practice (2001)	
Human Biological Materials			National Guidelines on Use of Stored Biological Materials (2005)	
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)	
Israel				
General	Ministry of Health: http://www.health.gov.il/english/		Public Health Regulations (Medical Experiments Involving Human Subjects) (1999) (Hebrew): http://www.health.gov.il/pages/default.asp?maincat=11&catid=301&pageid=2203	
Drugs and Devices	Ministry of Health, Pharmaceutical Administration:	Public Health Order (1940)	1. Public Health Regulations (Clinical Studies in Human	Guidelines for Clinical Trials in Human Subjects (2006) (English):

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.health.gov.il/english/Pages_E/default.asp?maincat=10		Subjects) – 1980 (Hebrew): http://www.health.gov.il/download/forms/a365_si12r_81.pdf 2. 1990 Amendment (Hebrew): http://www.health.gov.il/download/forms/a1962_mr98_90.pdf 3. 1992 Amendment (Hebrew): http://www.health.gov.il/download/forms/a2117_mr23_92.pdf 4. 2005 Amendment (Hebrew): http://www.health.gov.il/download/forms/a2672_mk07_05.pdf	http://www.health.gov.il/Download/pages/GuidelinesforClinicalTrials.doc
Privacy/Data Protection	Israeli Law and Information Technologies Authority	1. Privacy Protection Act No. 5741 (1981) (Hebrew): http://www.itpolicy.gov.il/topics_security/privacy.htm 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) (Hebrew): http://www.health.gov.il/download/forms/a2658_mk01_05.pdf 2. Amendment (2007) (Hebrew): http://www.health.gov.il/download/forms/a3037_mk17_07.pdf
Embryos, Stem Cells, and Cloning		Genetic Intervention Prohibition Law (Human Cloning and Genetic Changes in Reproduction Cells) (1999)		
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 Epidemiological Research (2013) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1146_01.pdf English (2008 version): http://www.lifescience.mext.go.jp/files/pdf/n796_01.pdf MHLW: Ethical Guidelines for Clinical Research (2008) (Japanese):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.mhlw.go.jp/general/seido/kousei/i-kenkyu/rinsyo/dl/shishin.pdf English (2004 version): http://www.ncgm.go.jp/rinri/index.html
Drugs and Devices	*Drugs*			
	1. Ministry of Health, Labor, and Welfare (MHLW) 2. Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html	Pharmaceutical Affairs Law, (2013) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html	MHLW: Good Clinical Practice Guidelines for Drugs (2012) (Japanese): http://law.e-gov.go.jp/htmldata/H09/H09F03601000028.html	
	Devices			
	1. Ministry of Health, Labor, and Welfare (MHLW) 2. Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html	Pharmaceutical Affairs Law, (2013) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html	MHLW: Good Clinical Practice Guidelines for Medical Devices (2013) (Japanese): http://law.e-gov.go.jp/htmldata/H17/H17F19001000036.html	
Privacy/Data Protection	Consumer Affairs Agency: http://www.caa.go.jp/en/index.html	Act on the Protection of Personal Information (2009): http://www.japaneselawtranslation.go.jp/law/detail/?id=130&vm=04&re=01		
Research Injury	Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html		1. Good Clinical Practice Guidelines for Drugs, Chapter 1, Article 14 and 15(9) (2012) (Japanese): http://law.e-gov.go.jp/htmldata/H09/H09F03601000028.html 2. Good Clinical Practice Guidelines for Medical Devices, Chapter 1, Article 14 and 23 (2013) (Japanese): http://law.e-gov.go.jp/htmldata/H17/H17F19001000036.html	Ethical Guidelines for Clinical Research , Chapter 2, Article 1(4) and Chapter 4, Article 1(3) (2008) (Japanese): http://www.mhlw.go.jp/general/seido/kousei/i-kenkyu/rinsyo/dl/shishin.pdf English (2004 version): http://www.ncgm.go.jp/rinri/index.html
Human Biological Materials	Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html			1. 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 2. Guidelines for Quality Assurance and Safety of Medicines Manufactured from

Country	Key Organizations	Legislation	Regulations	Guidelines
				Human Cells and Tissues (2008) (Japanese): http://www.kuhp.kyoto-u.ac.jp/~ccmt/files/20080208.pdf
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) 3. Ministry of Health, Labor, and Welfare (MHLW) 4. Ministry of Economy, Trade, and Industry (METI)			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 (2013) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1115_01.pdf English (2008 version): http://www.lifescience.mext.go.jp/files/pdf/n796_00.pdf MEXT and MHLW: Guidelines for Clinical Research in Gene Therapy (2008) (Japanese): http://www.mhlw.go.jp/general/seido/kousei/i-kenkyu/idenshi/0504sisin.html
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 Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html 3. Ministry of Education, Culture, Sports, Science, and Technology (MEXT): http://www.mext.go.jp/english/	Act on Regulation of Human Cloning Techniques (2000): http://law.e-gov.go.jp/htmldata/H12/H12HO146.html	Rules for Enforcement of Act on Regulation of Human Cloning Techniques (2009) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/29_224.pdf	CSTP: Fundamental Philosophy on Handling of Human Embryo (2004) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/6_28.pdf MHLW: Guidelines for Clinical Research Using Human Stem Cells (2013) (Japanese): http://www.mhlw.go.jp/bunya/kenkou/iryousaisei06/pdf/131001_1.pdf MEXT: 1. Guidelines for Handling of a Specified Embryo (2009) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/30_226.pdf English (2001 version): http://www.lifescience.mext.go.jp/files/pdf/30_82.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
				2. Guidelines for Derivation and Distribution of Human Embryonic Stem Cells (2010): http://www.lifescience.mext.go.jp/files/pdf/n743_00.pdf 3. Guidelines for Utilization of Human Embryonic Stem Cells (2010): http://www.lifescience.mext.go.jp/files/pdf/n743_01.pdf 4. Guidelines on Research on Producing Germ Cells from Human Induced Pluripotent Stem Cells or Human Tissue Stem Cells (2013) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1146_03.pdf English (2010 version): http://www.lifescience.mext.go.jp/files/pdf/n743_02.pdf MEXT and MHLW: Ethical Guidelines for Research on Assisted Reproductive Technology to Develop Human Fertilized Embryos (2013) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1146_05.pdf English (2010 version): http://www.lifescience.mext.go.jp/files/pdf/n796_02.pdf
Jordan				
Drugs and Devices	Jordan Food and Drug Administration: http://www.jfda.jo/en/default/	1. Narcotic and Psychotropic Law No. 11 (1988) 2. Law of Clinical Studies (2001): http://www.jfda.jo/custom/law/23.doc 3. Pharmacy and Drug Law No. 80 (2001)		
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 Health, Central Bioethics Commission			Guidelines on Ethics in Health Research. (2007)
Drugs and Devices	Ministry of Health, Committee of Pharmacy (Kazakh):	Drug Law (13.01.2004 No. 522-2), Articles 19 and 20 (2004)	1. Order 14.02.2005 No. 53 Instruction on the Conduct of	Guidelines on Clinical Trials in Kazakhstan (2003)

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.mz.gov.kz/	(Kazakh): http://www.zakon.kz/	Clinical Trials in Kazakhstan (2005) 2. Order 25.06.2007 # 442 Rules on Preclinical, Medico-Biological Experiments, and Clinical Trials in Kazakhstan (2007)	
Privacy/Data protection	Ministry of Health (Kazakh): http://www.mz.gov.kz/	Law on the Health Care System (4.06.2003 # 430-II) (2003) (Kazakh): http://www.zakon.kz/		
Korea, South				
Drugs and Devices	*Drugs*			
	Ministry of Food and Drug Safety (MFDS) (2013): http://www.mfds.go.kr/eng	Pharmaceutical Affairs Act No. 11690 (2013)	1. Korean Good Clinical Practice (2013)	
	Devices			
	Ministry of Food and Drug Safety (MFDS) (2013): http://www.mfds.go.kr/eng	Medical Device Act No. 10326 (2010) : http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyCode=125&page=1&mode=view&boardSeq=66026	1. Enforcement Regulations of the Medical Device Act [Ministerial Decree Number18 of the Ministry of Health and Welfare, Effective as of September 1, 2010, and Amendment of Other Laws] http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyCode=125&page=1&mode=view&boardSeq=66026 2. Enforcement Decree of the Medical Device Act (2010): http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyCode=125&page=1&mode=view&boardSeq=66026	
Privacy/Data Protection	1. Ministry of Public Administration and Security: http://www.mopas.go.kr 2. Ministry of Health and Welfare (MOHW) : http://english.mw.go.kr/	1. Act on the Protection of Personal Information Maintained by Public Agencies No. 11690 (2012) 2. Medical Affairs Act No. 10387 (2010)	Presidential Order of Enforcement Rule of the Protection of Personal Information Maintained by Public Agencies No.23169 (2011)	Enforcement Rule of the Protection of Personal Information Maintained by Public Agencies No. 1 (2013)
Genetic Research	Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/	Bioethics and Safety Act No. 11690 (2013)	Presidential Order of Regulation for Bioethics and Safety No. 24454 (2013)	Guidelines for Bioethics and Safety Act No. 18 (2013)

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/	Bioethics and Safety Act No. 11690 (2013)	Presidential Order of Regulation for Bioethics and Safety No. 24454 (2013)	Guidelines for Bioethics and Safety Act No. 18 (2013)
Kuwait				
General	Ministry of Health, Kuwait Institute for Medical Specialization: http://www.kims.org.kw/			Ethical Guidelines for Biomedical Research (no date): http://www.kims.org.kw/Ethical%202.doc
Kyrgyzstan				
General	1. Government of the Kyrgyz Republic (Russian): http://www.gov.kg 2. Ministry of Health (Russian): http://www.med.kg	1. Constitution of Kyrgyz Republic, Chapter II, Article 22 (2010): http://www.gov.kg/?page_id=263 2. Law on Protection of Citizens Health (Sept. 1, 2005, No. 6): Articles 34 and 73 (Russian): http://www.pharm.kg/ru/legislation		
Drugs and Devices	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP) (Russian): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Drug Law of Kyrgyz Republic (30.04.2003 No. 91) Chapter VII, Articles 25-29 (2003) (Russian): http://www.pharm.kg/ru/legislation	DDMDP: 1. 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/ 2. National Standard KMC 1195:2010: Medical Devices: Rules of Preparing Clinical Testing (2010)	
Research Injury	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP) (Russian): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Drug Law of Kyrgyz Republic (30.04.2003 No. 91) Chapter VII, Article 28 (2003) (Russian): http://www.pharm.kg/ru/legislation	DDMDP: National Standard KMC 1195:2010: Medical Devices, Rules of Preparing for Clinical Testing, Paragraphs 3, 4, and 6 (2010)	
Human Biological Materials	1. Ministry of Health, Department of Drug and Medical Devices Provision (Russian): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on Protection of Citizens Health in the Kyrgyz Republic (09.01.2005 No. 6): Article 39	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) (Russian): http://www.pharm.kg 2. Ministry of Health, National	Law on Protection of Citizens Health in the Kyrgyz Republic (09.01.2005 No. 6): Article 91	1. Technical Regulations on the Safety of Medical Products for Medical Application, approved by the Governmental Order #74 from February 1, 2012:	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Bioethics Committee		http://www.pharm.kg/ru/legislation/ 2. National Standard KMC 1195:2010: Medical Devices, Rules of Preparing for Clinical Testing, Paragraphs 3, 4, and 6 (2010)	
Nepal				
General	Nepal Health Research Council: http://www.nhrc.org.np/			National Ethical Guidelines for Health Research in Nepal (2001): http://www.nhrc.org.np/guidelines/nhrc_ethical guidelines_2001.pdf
Drugs and Devices	Nepal Health Research Council: http://www.nhrc.org.np/			National Guidelines on Clinical Trials with the Use of Pharmaceutical Products (2005): https://webapps.sph.harvard.edu/live/gremap/files/np_pharmaceutical_trial_guidelines.pdf
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 at: 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. Guidelines on Pacific Health Research (2005) *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

Country	Key Organizations	Legislation	Regulations	Guidelines
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. Medicines Act 1981(2012) 2. Accident Compensation Act 2001, Section 32 (2010)	Medsafe: Medicines Regulations 1984 http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM95668.html	Medsafe: New Zealand Regulatory Guidelines for Medicines, Vol. 3: Interim Good Clinical Research Practice Guidelines (1998): http://medsafe.govt.nz/regulatory/clinicaltrials.asp RMI: Researched Medicines Industry Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial (2008): http://www.medicinesnz.co.nz/assets/Uploads/compensation-guidelines-0808-final.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
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	Standards New Zealand: New Zealand Standard 8135: 2009: Non-Therapeutic Use of Human Tissue: http://www.standards.co.nz/search/Standards+Catalogue.htm	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

Country	Key Organizations	Legislation	Regulations	Guidelines
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/ 3. Ethics Committee on Assisted Reproductive Technology (ECART): http://ecart.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 Diagnosis (2005) 3. Embryo Donation for Reproductive Purposes (2005) 4. Guidelines on Embryo Donation for Reproductive Purposes (2008) 5. 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/			Guidelines: 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): http://www.pchrd.dost.gov.ph/index.php?option=com_frontpage&Itemid=1 2. Department of Science and Technology (DOST): http://www.dost.gov.ph/ 3. Department of Health		DOST: 1. Administrative Order 001 Series 2007: Requirement for Review of All Research Involving Human Subjects/Participants 2. Administrative Order 001 Series 2008: Registration of all Ethics Review Committee at the	PHREB: National Ethical Guidelines for Health Research (2006), which includes: a. Ethical Guidelines for International Collaborative Research b. Ethical Guidelines for Herbal Research c. Ethical Guidelines for

Country	Key Organizations	Legislation	Regulations	Guidelines
	4. Commission of Higher Education (CHED)		PHREB CHED: Memo 34 Series 2007: Endorsement of DOST Administrative Order 001, Series 2007	Complementary and Alternative Medicine Research d. Ethical Guidelines for Epidemiological Research e. Ethical Guidelines for Social and Behavioral Research f. Ethical Guidelines for the Conduct of Research on Populations Traumatized in Emergencies and Disasters g. Ethical Guidelines for HIV/AIDS Research h. Ethical Guidelines for Research on Assisted Reproductive Technology *Access:* https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf
Drugs and Devices	*Drugs*			
	Food and Drug Administration: http://www.bfad.gov.ph/		Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products(Administrative Order No. 47-a) (2001)	Ethical Guidelines for Clinical Trials on Drugs, Devices, and Diagnostics (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf
	Devices			
	Food and Drug Administration: http://www.bfad.gov.ph/			Various guidelines: http://www.bfad.gov.ph/default.cfm?page_id=826&parent=633
Research Injury	1. Department of Science and Technology (DOST): http://www.dost.gov.ph/ 2. Philippine Health Research Ethics Board (PHREB): http://www.pchrd.dost.gov.ph/index.php?option=com_frontpage&Itemid=1			DOST: National Guidelines for Biomedical/Behavioral Research, page 14 (2000): www.nus.edu.sg/irb/Articles/PCHRD_DOST_NEC%20Guidelines.pdf PHREB: National Ethical Guidelines for Health Research, pages 19-20 (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf
Genetic Research	Philippine Health Research Ethics Board (PHREB)			Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	Philippine Health Research Ethics Board (PHREB)			Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf
Qatar				
General	Health Research Ethics Committee			Guidelines, Regulations, and Policies for Research Involving Human Subjects (2009): http://qatar-weill.cornell.edu/research/pdf/Ministry%20Guidelines.doc
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 4. Singapore Medical Council (SMC): http://www.smc.gov.sg	Medical Registration Act (Cap. 174) (1985): http://statutes.agc.gov.sg/	MOH: Directive of June 25, 1998: Hospital Ethics Committees	NMEC: Ethical Guidelines on Research Involving Human Subjects (1997) BAC: Research Involving Human Subjects: Guidelines for IRBs (2004) MOH: 1. Governance Framework for Human Biomedical Research (2007) 2. Operational Guidelines for IRBs (2007) 3. Code of Ethical Practice in Human Biomedical Research (2009)
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)	Medicines Act (1975): http://statutes.agc.gov.sg/	Medicines (Clinical Trials) Regulations (1998): http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/legislation.html#Medicine	HSA: 1. Singapore Guideline for Good Clinical Practice (1998) 2. Various Guidelines on Clinical Trials: http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials/guidelines.html NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)
	Devices			
	1. Health Sciences Authority of Singapore (HSA): http://www.hsa.gov.sg 2. National Environment Agency, Centre For Radiation Protection And	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.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/legislation.html#Health%20Products%20Act	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Nuclear Science		2. Radiation Protection Regulations: http://app2.nea.gov.sg/corporate-functions/about-nea/legislation	
Research Injury	1. Health Sciences Authority 2. National Environment Agency, Centre For Radiation Protection And Nuclear Science 3. Ministry of Health National Medical Ethics Committee (NMEC)	1. Medicines Act (1975): http://statutes.agc.gov.sg/ 2. Radiation Protection Act (2007): http://statutes.agc.gov.sg/	1. Medicines (Clinical Trials) Regulations (1998) http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/legislation.html#Medicine 2. Radiation Protection Regulations: http://app2.nea.gov.sg/corporate-functions/about-nea/legislation	HSA: Singapore Guideline for Good Clinical Practice (1998) NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)
Privacy/Data Protection	1. Ministry of Communications and Information (MCI) 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)
Human Biological Materials	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Health Sciences Authority 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/	Medicines (Clinical Trials) Regulations (1998): http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/legislation.html#Medicine	BAC: 1. Human Tissue Research (2002) 2. Human-Animal Combinations in Stem-Cell Research (2010)
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) BAC: Genetic Testing and Genetic Research (2005): http://www.bioethics-singapore.org/uploadfile/55211%20PMGT%20Research.pdf
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) 2. Donation of Human Eggs for Research (2008)

Country	Key Organizations	Legislation	Regulations	Guidelines
Taiwan				
General	Ministry of Health and Welfare: http://www.mohw.gov.tw/EN/Ministry/Index.aspx	1. Medical Care Act, Articles 8, 78, 79, 80, and 98 (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020021 2. Human Subjects Research Act (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020176	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) (Chinese): http://gazette.nat.gov.tw/EG_FileManager/eguploadpub/eg018127/ch08/type1/gov70/num37/Eg.htm 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) (Chinese): http://gazette.nat.gov.tw/EG_FileManager/eguploadpub/eg018127/ch08/type1/gov70/num37/Eg.htm 5. Informed Consent Exemptions for Human Research (2012) (Chinese): http://gazette.nat.gov.tw/EG_FileManager/eguploadpub/eg018127/ch08/type1/gov70/num36/Eg.htm 6. Expedited Review Categories for Human Research (2012) (Chinese): http://gazette.nat.gov.tw/EG_FileManager/eguploadpub/eg018127/ch08/type1/gov70/num37/Eg.htm	1. Ethical Guidelines for the Announcement of New Medical Knowledge or Research Report by Medical Institutes or Members (2001): 醫療機構及醫事人員發布醫學新知或研究報告倫理守則.doc 2. Healthcare Institution Institutional Review Board Organization and Operations (2003) 3. Human Research Ethics Policy Guidelines (2007)
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/	MOHW: Medical Care Act, Articles 8, 78, 79, 80, and 98 (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020021 FDA: Pharmaceutical Affairs Act (2005):	MOHW: 1. Enforcement Rules of the Medical Care Act (2006) (Chinese): http://gazette.nat.gov.tw/EG_FileManager/eguploadpub/eg018127/ch08/type1/gov70/num37/Eg.htm 2. Regulations on human trials (2009) http://law.moj.gov.tw/Eng/LawClass/	FDA: 1. Operational Guidelines for Drug Clinical Trials (2002) 2. Guidelines for Informed Consent in Clinical Trials (2007) (Chinese)

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.fda.gov.tw/EN/law.aspx?pn=2&cid=158&cchk=ed668223-c579-4bb8-b86d-1bd434ccaea5&subClassifyID=&pClass1=	LawContent.aspx?pcode=L0020162 FDA: 1. Guideline for Good Clinical Practice (2010) (Chinese): http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0030056 2.Pharmaceutical Affairs Act Enforcement Rules (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0030002 3. Regulations for Governing the Management of Medical Device (2012): http://www.fda.gov.tw/EN/law.aspx?pn=1&cid=158&cchk=ed668223-c579-4bb8-b86d-1bd434ccaea5&subClassifyID=&pClass1=	
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, Article 79 (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020021	FDA: Guideline for Good Clinical Practice, Article 22 (2010) (Chinese): http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0030056	MOHW: Human Research Ethics Policy Guidelines, Article 4 (2007)
Privacy/Data Protection	Ministry of Justice: http://www.moj.gov.tw/mp095.html	Personal Information Protection Act (2010): http://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=I0050021		
Human Biological Materials	Ministry of Health and Welfare: http://www.mohw.gov.tw/EN/Ministry/Index.aspx	1. Medical Care Act (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020021 2. Human Subjects Research Act (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020176 3. Human Biobank Management Act (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020164	Regulations on Human Trials (2009): http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0020170	1. Good Tissue Practice (2002) (Chinese): http://www.fda.gov.tw/TC/siteContent.aspx?sid=1786 2. Guidelines for Collection and Use of Human Specimens for Research (2006):

Country	Key Organizations	Legislation	Regulations	Guidelines
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. National Science Council: http://web.nsc.gov.tw/default.asp?mp=7	MOHW: Human Biobank Management Act (2010): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020164	MOHW: 1. Regulations on Commercial Benefit Feedback of Human Biobank (2010) (Chinese): http://dohlaw.doh.gov.tw/Chi/NewsContent.asp?msgid=2977&KeyWord= 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://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT0202.asp FDA: 1. Guidance for Informed Consent Forms for Pharmacogenetic Research (2005) (Chinese)
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		MOHW: Policy Instructions on the Ethics of Human Embryo and Embryonic Stem Cell Research (2007)
Tajikistan Note: For an overview of human subject protections in Tajikistan, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 9: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf				
General	1. Ministry of Public Health 2. Republic Committee on Medical Ethics		1. 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 (Russian) 2. Position of the Republic Committee on Medical Ethics, Affirmed by the Order of the Ministry of Public Health of Republic Tajikistan of March 10, 2005, No. 118 (Russian)	
Thailand				
General	1. National Research Council of Thailand (NCRT) (Thai): http://nrct.go.th/ 2. Medical Council of Thailand (MCT) (Thai): http://www.tmc.or.th	Medical Professions Act (2009), Articles 47-51: http://www.fercit.org/SIDCER-FERCAP/Handout_10/4.%20Accreditation-update_surveyor_aj.Sopit.pdf	NCRT: Regulation on the Permission of Foreign Researchers (1982) MCT: Rule of the Medical Council on the Observance of Medical Ethics (2006)	MCT: 1. National Guideline for Ethical Research on Human Subjects (2002) 2. The Ethical Guidelines for Research on Human Subject in Thailand (2007)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	*Drugs*			
	Food and Drug Administration, Drug Control Division: http://www.fda.moph.go.th/eng/index.stm	Consumer Protection Act (2007)		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		
Privacy/Data Protection	Office of the Information Commission	1. Official Information Act, B.E. 2540 (1997) 2. National Health Act, B.E. 2549 (2006)		
Embryos, Stem Cells, and Cloning		Medical Professions Act (2009), Articles 2-3		Guidelines for Genetics and Stem Cell Research in Humans and Guidelines for Material Transfer Agreements (2002)
Vietnam				
General	1. Ministry of Public Health (MOPH) (Vietnamese): http://vbqppl.moj.gov.vn/vbpq/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=26689 2. Ministry of Health (MOH) (Vietnamese): http://vbqppl.moj.gov.vn/vbpq/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=25876		MOPH: 1. Circular No. 03/2012/TT-BYT: Guidelines on Clinical Trials 2. Decision No. 458/QD-BYT, 460/QD-BYT on Promulgation of the "Procedure of Organizing and Functioning Ethical Review Committee for Bio-Medical research, Mission 2012-2017" MOH: 1. Circular No. 37/2010/TT-BYT on Management of Scientific Research and Testing Production Project at the MOH Level (2010) 2. Decision No. 2626/QD-BYT on Promulgation of the "Procedure of Organizing and Functioning Ethical Committee for Bio-Medical research, Mission 2008 – 2012" (2008)	
Drugs and Devices	Ministry of Health: http://vbqppl.moj.gov.vn/vbpq/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=25876		1. Circular No. 08/2010/TT-BYT on the Guidance to Report Data from the Research of Bioequivalence of Drug	Guidelines on Good Clinical Practice of Clinical Trials (2008)

Country	Key Organizations	Legislation	Regulations	Guidelines
			Registration (2010) 2. Regulation on Clinical Trials (2007) 3. Decision No. 799/QD-BYT of the Minister of Health on the Promulgation of the "Guidelines on Good Clinical Practice of Clinical Trials" (2008) 4. Decision No. 23 /2008/QD-BYT of the Minister of Health on the Promulgation of the "Regulations on Utilization of Vaccine and Medical Immuno-Biological Products in Prevention and Treatment" (2008)	