Country	Key Organizations	Legislation	Regulations	Guidelines
	Commissioner (HDC): http://www.hdc.org.nz/ 5. Health and Disability Ethics Committees: http://www.newhealth.govt.nz/ethicscommittees/ 6. Ministry of Science, Research, and Technology (MoRST): http://www.morst.govt.nz/	5. Injury Prevention, Rehabilitation, and Compensation Act 2001 Note: All New Zealand laws can be accessed by going to: http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes Then search alphabetically for the name of the law under Statutes of New Zealand.		(2003) 2. Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (2006) MOH: Operational Standard for Ethics Committees (2006)
Drugs	1. Health Research Council (HRC), Standing Committee on Therapeutic Trials: http://www.hrc.govt.nz/root/pages_regulatory/Standing_Committee_on_Therapeutic_Trials.html 2. New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz 3. Researched Medicines Industry (RMI): http://www.rmianz.co.nz	Medicines Act 1981(2005)		RMI: Guidelines on Clinical Trials: Compensation for Injury Resulting from Participation in an Industry Sponsored Clinical Trial (1997) Medsafe: New Zealand Regulatory Guidelines for Medicines, Vol. 3: Interim Good Clinical Research Practice Guidelines (1998)
Privacy/Data Protection	Privacy Commissioner: http://www.privacy.org.nz/	1. Official Information Act (1982) 2. Public Records Act (2005) 3. Privacy Act 1993 (2006)		
Human Biological Materials	1. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/root/Ethics/Ethics%20Overview/HRC_Ethics_Committee.html 2. Te Puni Kokiri (TPK): http://www.tpk.govt.nz/ 3. Office of the Health and Disability Commissioner (HDC): http://www.hdc.org.nz 4. Ministry of Research Science and Technology: http://www.morst.govt.nz/wayfinder/index.asp	1. Human Tissue Act 1964 (1989) 2. Health Act 1956 (2005)		Human Specimen Ethical Guidelines Committee: Ethical Guidelines for Human Specimen Collection, Storage, Use and Disposal: A Report to the New Zealand Department of Health (1992) TPK: Guidelines for the Removal, Retention, Return, and Disposal of Maori Body Parts. (1999)
Genetic Research	1. Environmental Risk Management Authority:	Hazardous Substances and New Organisms Act 1996 (2005)		

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.ermanz.govt.nz/ 2. Health Research Council (HRC), Gene Technology Advisory Committee: http://www.hrc.govt.nz/root/pages_regulatory/Gene_Technology_Advisory_Committee.html			
Embryos, Stem Cells, and Cloning	1. Advisory Committee on Assisted Reproductive Technology (ACART) http://www.acart.health.govt.nz/ 2. Ministry of Health http://www.moh.govt.nz/ 3. Ethics Committee on Assisted Reproductive Technology (ECART) http://www.ecart.health.govt.nz/ 4. Health and Disability Ethics Committees http://www.newhealth.govt.nz/ethicscommittees/	Human Assisted Reproductive Technology Act (2004)		ACART: 1. Guidelines on the Use, Storage, and Disposal of Sperm from a Deceased Man (2000) 2. Guidelines on Preimplantation Genetic Diagnosis (2005) 3. Guidelines on IVF Surrogacy (2005) 4. Guidelines on Within-Family Gamete Donation (2005) 5. Embryo Donation for Reproductive Purposes (2005) 6. Guidelines for Research on Gametes and Non-viable Embryos (Interim) MOH: Guidelines on Using Cells from Established Human Embryonic Stem Cell Lines for Research (2005)
Philippines				
General	1. Philippine Health Research Ethics Board (PHREB) 2. Philippine Council for Health Research and Development, National Ethics Committee (PCHRD) 3. Department of Science and Technology: http://www.dost.gov.ph/			PHREB: 1. National Ethical Guidelines for Health Research (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf This document includes the following: a. Ethical Guidelines for International Collaborative Research b. Ethical Guidelines for Herbal Research c. Ethical Guidelines for 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

Country	Key Organizations	Legislation	Regulations	Guidelines
				Research on Populations Traumatized in Emergencies and Disasters g. Ethical Guidelines for HIV/AIDS Research h. Ethical Guidelines for Research on Assisted Reproductive Technology
Drugs	Bureau of Food and Drugs: 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
Genetic Research	Philippine Council for Health Research and Development, National Ethics Committee (PCHRD)			PCHRD: 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
Embryos, Stem Cells, and Cloning	Philippine Council for Health Research and Development, National Ethics Committee (PCHRD): http://www.pchrd.dost.gov.ph/pchrd/			PCHRD: 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
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)
Drugs	1. Ministry of Health National Medical Ethics Committee (NMEC) 2. Health Sciences Authority of Singapore (HSA): http://www.hsa.gov.sg	1. Medicines Act Section 74 (Cap. 176) (1975): http://statutes.agc.gov.sg/ 2. Medicines (Clinical Trials) Regulations (2000)	Singapore Guideline for Good Clinical Practice (1998)	NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://statutes.agc.gov.sg/ 3. Health Products Act (2007): http://statutes.agc.gov.sg/		
Privacy/Data Protection	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	Computer Misuse Act (Cap. 50A) (1993): http://statutes.agc.gov.sg/		MOH: Advisory on Data Protection Standards for Electronic Medical Records (EMR) Systems (2002) BAC: Personal Information in Biomedical Research (2007)
Human Biological Materials	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	Medical (Therapy, Education, and Research) Act (1973): http://statutes.agc.gov.sg/		BAC: Human Tissue Research (2002)
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)
Embryos, Stem Cells, and Cloning	1. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org/ 2. Ministry of Health (MOH): http://www.moh.gov.sg/	Human Cloning and Other Prohibited Practices Act (2005): http://statutes.agc.gov.sg/	Directives for Private Healthcare Institutions Providing Assisted Reproduction Services: Regulation 4 of the Private Hospitals and Medical Clinics Act (2006)	BAC: Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning (2002)
Taiwan				
General	1. Department of Health (DOH): http://www.doh.gov.tw/EN2006/index_EN.aspx 2. Forum for Independent Review System in Taiwan: http://www.jirb.org.tw/English_Version/eng-index.asp	Medical Care Act, Articles 8, 70, 78, 79, 80, and 98 (2004): http://www.doh.gov.tw/ufile/doc/200408_Medical%20Care%20Act.pdf		DOH: 1. Ethical Guidelines for the Announcement of New Medical Knowledge or Research Report by Medical Institutes or Members (2001) 2. Standards for the Organization of Human Trial Committees in Medical Care Institutions and their Operation (2003): http://www.doh.gov.tw/EN2006/DM/DM2_p01.aspx?class_no=386&now_fod_list_no=9064&level_no=1&doc_no=43274 3. Categories of Research that may be Reviewed by the Institutional Review Board (IRB) through an Expedited Review

Country	Key Organizations	Legislation	Regulations	Guidelines
				(2006) 4. Announcement of Human Research Ethics Policy Guidelines (2007): http://www.doh.gov.tw/EN2006/DM/DM1_p01.aspx?class_no=246&now_fod_list_no=246&level_no=1&doc_no=50681
Drugs	1. Department of Health: http://www.doh.gov.tw/EN2006/index_EN.aspx 2. Center for Drug Evaluation: http://www.cde.org.tw		DOH: Guideline for Good Clinical Practice (2005)	DOH: 1. Operational Guideline for Drug Clinical Trials (2002) 2. Structure and Content of Clinical Study Reports (2003) 3. The Criteria for IRB review (2004) 4. Guidelines for Informed Consent Form of Pharmacogenetic Study (2005)
Privacy/Data Protection	Ministry of Justice	Computer-Processed Personal Data Protection Law (1995): http://www.privacyexchange.org/legal/nat/omni/taiwan.html		
Human Biological Materials				1. Good Tissue Practice (2002) 2. Guidelines for Collection and Use of Human Specimens for Research (2006): http://www.doh.gov.tw/EN2006/DM/DM1_p01.aspx?class_no=246&now_fod_list_no=246&level_no=1&doc_no=46850
Genetic Research	1. Department of Health: http://www.doh.gov.tw/EN2006/index_EN.aspx 2. National Science Council: http://web.nsc.gov.tw/default.asp?mp=7			Guidance for Informed Consent Form for Pharmacogenetic Research (2005)
Embryos, Stem Cells, and Cloning	Department of Health: http://www.doh.gov.tw/EN2006/index_EN.aspx			Policy Instructions on the Ethics of Human Embryo and Embryonic Stem Cell Research (2007): http://www.doh.gov.tw/ufile/doc/Policy%20Instructions%20on%20the%20Ethics%20of%20Human%20Embryos.pdf
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.ru/files/docs/shs/2007/publications/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	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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): http://www.nrct.net/eng 2. Medical Council of Thailand (MCT) (Thai): http://www.tmc.or.th		NCRT: Regulation on the Permission of Foreign Researchers (1982) MCT: Rule of the Medical Council on the Observance of Medical Ethics (2006)	MCT: National Guideline for Ethical Research on Human Subjects (2002)
Drugs	Food and Drug Administration, Drug Control Division: http://www.fda.moph.go.th/eng/index.stm/			Thailand Good Clinical Practice Guidelines (2002)
Privacy/Data Protection		1. Official Information Act, B.E. 2540 (1997) 2. National Health Act, B.E. 2549 (2006)		

Country	Key Organizations	Legislation	Regulations	Guidelines
LATIN AMERICA/CARIBBEAN				
Pan American Health Organization				
Drugs				Good Clinical Practice: Document for the Americas (2006) (Spanish): http://www.paho.org/spanish/ad/ths/ev/BPC-doct-esp.doc
Argentina				
General	Ministry of Health: http://www.msal.gov.ar		MOH: Ministerial Resolution 1490/2007 Approving the Good Clinical Practice Guideline for Clinical Research with Human Beings	
Drugs	*National:*			
	1. National Administration of Medications, Foods, and Medical Technology (ANMAT) (Spanish): http://www.anmat.gov.ar/index.asp		ANMAT: Provision 5330/97 on General Guidelines for the Conduct of Clinical Trials (1997) (Spanish): http://infoleg.mecon.gov.ar/infolegInternet/anexos/45000-49999/46745/norma.htm	
	Buenos Aires Province:			
		Requirements for Health Research, Law 11.044 (1991)		
Privacy/Data Protection		Personal Data Protection Act No. 25.326 (2000)		
Bolivia				
General	Ministry of Health and Sport: http://www.sns.gov.bo/			Research Ethics and Guidelines for Clinical Trials (2003)
Brazil				
General	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Commission on Research Ethics (CONEP) (Portuguese): http://www.conselho.saude.gov.br/comissao/eticapesq.htm	CNS: Decree 98 830: Collection by Foreigners of Data and Scientific Materials in Brazil (1990) (Portuguese): http://ibama2.ibama.gov.br/cnia2/renima/cnia/lema/lema_texto/HTM-ANTIGOS/98830-90.HTM	CONEP: 1. Resolution 196/96: Rules on Research Involving Human Subjects (1996): http://www.conselho.saude.gov.br/docs/Resolucoes/reso_196_english.doc 2. Resolution 304/2000: On Complimentary Rules for Research Involving Indigenous People (2000) 3. Internal CONEP Regulation (2001)	

Country	Key Organizations	Legislation	Regulations	Guidelines
			4. Regulation of Resolution CNS 292/99 on Research with Foreign Cooperation (2002) (Portuguese): http://www.conselho.saude.gov.br/docs/Resolucoes/Reso292.doc 5. Resolution 346/2005: On Multicenter Research (2005) (Portuguese): http://www.conselho.saude.gov.br/docs/Resolucoes/Reso346.doc	
Drugs	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Healthcare Surveillance Agency (Portuguese): http://www.anvisa.gov.br		CNS: Resolution 251/1997: On Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests (Portuguese) (1997): http://conselho.saude.gov.br/docs/Resolucoes/CNS_Reso251_English.doc	
Human Biological Materials	National Commission on Research Ethics (CONEP) (Portuguese): http://www.conselho.saude.gov.br/comissao/eticapesq.htm		CONEP: CNS Resolution 347/05 Approval Guidelines for Ethical Analysis of Research Projects Involving Storage of Materials or Use of Materials Stored by Previous Research: http://conselho.saude.gov.br/docs/Reso347.doc	CONEP: Approval Guidelines for Ethical Analysis of Research Projects Involving Storage of Materials or Use of Materials Stored by Previous Research: Resolution 347/05 (2005)
Genetic Research	1. National Commission on Research Ethics (CONEP) (Portuguese): http://www.conselho.saude.gov.br/comissao/eticapesq.htm 2. National Biosafety Technical Commission (CTNBio) (Portuguese): http://www.ctnbio.gov.br	Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/3671.html	CONEP: Resolution 304/2004 : On Research on Human Genetics (2004) (Portuguese): http://www.conselho.saude.gov.br/docs/Reso%20340.doc CTNBio: Decree No. 5,591, of November 22, 2005: http://www.ctnbio.gov.br/index.php/content/view/3670.html	CONEP: Approval Guidelines for Ethical Analysis and Conduct of Research Projects in the Special Thematic Area of Human Genetics: Resolution 340/04 (2004)
Embryos, Stem Cells, and Cloning	National Biosafety Technical Commission (Portuguese):	Biosafety Law 11.105/05 (2005):	CTNBio: Decree No. 5,591, of November	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.ctnbio.gov.br	http://www.ctnbio.gov.br/index.php/content/view/3671.html	22, 2005: http://www.ctnbio.gov.br/index.php/content/view/3670.html	
Chile				
General	Ministry of Health (Spanish): http://www.minsal.cl	Law No. 26.027 (2005)	1. Supreme Decree No. 42 (1986) 2. Supreme Decree No. 1.935 (1993) 3. General Technical Rule No. 2 of the Ministry of Health (1993) 4. Exemption Resolution No. 134 (1994) 5. Supreme Decree No. 494 (1999) 6. Exemption Resolution No. 1.856 (1999) 7. Resolution No. 2.085 of the Ministry of Health (2001)	
Drugs	Ministry of Health (Spanish): http://www.minsal.cl		Technical Rule No. 57: Regulation of the Conduct of Clinical Trials that Use Pharmaceutical Products in Human Beings (2001)	Ethical Guidelines for Clinical Trials with Pharmaceutical and Biological Products (2001)
Privacy/Data Protection		Law for the Protection of Private Life No. 19.628 (1999)		
Genetic Research		Law No. 26.027 (2005)		
Colombia				
General	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430 (1993)	
Drugs	National Institute of Drug and Food Surveillance (Spanish): http://www.invima.gov.co/			
Privacy/Data Protection		Constitution, Article 15 (2003)		
Human Biological Materials	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter VI (1993)	
Genetic Research	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No.	

Country	Key Organizations	Legislation	Regulations	Guidelines
			008430, Title III, Chapter II (1993)	
Costa Rica				
General	1. National Council on Health Research (CONIS) Network of Scientific Ethics Committees 2. Social Security Fund (CCSS), Research and Bioethics Subarea 3. Ministry of Health: http://www.ministeriodesalud.go.cr/	Law 5395, General Health Law, Articles 64-68 (1973) (Spanish): http://www.ministeriodesalud.go.cr/leyes/leygeneraldesalud.pdf	CONIS: Executive Decree No. 31078-S (2003): http://www.ministeriodesalud.go.cr/reglamentos/31078-s.pdf CCSS: Regulation of Clinical Investigation in the Assistance Services of the Social Security Fund (2005)	CONIS: 1. Ethical and Legal Principles 2. Duties and Responsibilities of the National Council on Health Research, of Investigators, and of the Sponsor 3. Structure and Functioning of the Committee Network 4. Design of the Research Protocol 5. Requirements for the Submission of a Research Protocol 6. Informed Consent 7. Approval and Follow-up of a Research Project 8. Sanctions
Drugs	1. National Council on Health Research (CONIS) Network of Scientific Ethics Committees (Spanish): http://www.ministeriodesalud.go.cr/comconis.htm 2. Ministry of Health (Spanish): www.ministeriodesalud.go.cr			CONIS: 1. Guidelines for Good Clinical Practice (1996) 2. Protocol for Clinical Trials
Human Biological Materials	National Council on Health Research Network (CONIS) of Scientific Ethics Committees (Spanish): http://www.ministeriodesalud.go.cr/comconis.htm			Informed Consent, Research that Requires Biobanks
Jamaica				
General	Ministry of Health: http://www.moh.gov.jm			Ministry of Health Guidelines for the Conduct of Research on Human Subjects (2002)
Mexico				
General	Secretariat of Health (Spanish): http://www.salud.gob.mx/	General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2005)	Regulation of the General Health Law in the Area of Health Research (1986)	
Drugs	General Directorship of Medicines and Health Technologies		Regulation of the General Health Law in the Area of Health Research, Title Three (1986)	
Privacy/Data Protection		See listing at (Spanish): http://profesor.uia.mx/aveleyra/c		

Country	Key Organizations	Legislation	Regulations	Guidelines
		omunica/privacidad/leyes2.htm		
Human Biological Materials	Secretariat of Health (Spanish): http://www.salud.gob.mx/	General Health Law, Title XIV, Articles 313-350 (2005)	Regulation of the General Health Law in the Area of Health Research, Title II, Chapter VI (1986)	
Genetic Research	Secretariat of Health (Spanish): http://www.salud.gob.mx/		Regulation of the General Health Law in the Area of Health Research, Title III, Chapter II (1986)	
Panama				
General	National Research Bioethics Committee (Spanish): http://www.gorgas.gob.pa/index.php?option=com_content&task=view&id=15&Itemid=43		Ministry of Health Resolution No. 390 Adopting the Operational Guide for Research Bioethics, Official Gazette 24,938 (2003) (Spanish): http://www.gorgas.gob.pa/images/Gaceta%20N°%2024%20938%20%20Resolucion390.doc	Informed Consent (2006) (Spanish): http://www.gorgas.gob.pa/images/bioetica/Elementos%20del%20Consentimiento%20Informado.pdf
Human Biological Materials		Law 52 of 1995, Official Gazette 22,929		
Embryos, Stem Cells, and Cloning		Law 3 of 2004, Official Gazette 24,969		
Peru				
General	1. National Institute of Health (Spanish): http://www.ins.gob.pe/ 2. National Network of Research Ethics Committees: http://www.ins.gob.pe/gxpsites/hgxpp001.aspx?2,13,59,O,S,0,MNU;C;1;14;20;5;MNU;,	General Health Law No. 26842, Article 28 (1997) (Spanish)		
Drugs	National Institute of Health (Spanish): http://www.ins.gob.pe/gxpsites/hgxpp001.aspx?2,13,326,O,S,0,MNU;E;1;14;20;10;MNU;,		1. Supreme Decree No. 017-2006-SA: Regulation on Clinical Trials in Peru (2006) 2. Supreme Decree No. 006-2007-SA: Modification of the Regulation on Clinical Trials in Peru (2007)	
Uruguay				
Human Biological Materials	Ministry of Public Health (Spanish): http://www.msp.gub.uy/index_1.html		Circular No. 40/95 Establishing Rules Regarding the Donation of Organs and Tissues for Scientific and Therapeutic Purposes (1995)	

Country	Key Organizations	Legislation	Regulations	Guidelines
Venezuela				
General	1. National Fund on Science and Technology, Commission on Bioethics and Biosecurity (FONACIT) (Spanish): http://www.fonacit.gov.ve/bioetica.asp 2. Venezuelan Institute of Scientific Research, Bioethics Commission (IVIC) (Spanish): http://www.ivic.ve/bioetica/	Constitution, Article 46 (Spanish)	Resolution No. 48 (1998)	FONACIT: Code on Bioethics and Biosecurity (2002) IVIC: 1. Annex 1: General Ethical Issues in Research Involving Living Persons 2. Annex 2: Necessity of Establishing a Clear and Precise Study Protocol Before Starting Research 3. Informed Consent
Drugs	National Institute of Hygiene "Rafael Rangel" (Spanish): http://www.inhrr.gov.ve	Medicines Act, Articles 72 and 73		
Genetic Research	Venezuelan Institute of Scientific Research, Bioethics Commission (Spanish): http://www.ivic.ve/bioetica/			1. Contract for Accessing Genetic Resources (2003) (Spanish): http://www.ivic.ve/bioetica/contrato.pdf 2. Revised Outline of the International Declaration of Human Genetic Data (2003): http://www.ivic.ve/bioetica/chapter3.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
AFRICA				
Botswana				
General	Ministry of Health, Research and Development Committee: http://www.moh.gov.bw/	Anthropological Research Act 45 (1967)		1. Guide – Consent Form (2005): https://webapps.sph.harvard.edu/live/gremap/files/bw_consent_form.pdf 2. Guidelines for the Review of Research Proposals (2005)
Drugs	Ministry of Health, Drug Regulatory Unit: http://www.moh.gov.bw/		Drugs and Related Substances Regulations (1993)	
Ethiopia				
General	Ethiopian Science and Technology Commission, Health Department: http://www.estc.gov.et/	Proclamation 60/1999, Section 21		National Health Research Ethics Review Guideline, Fourth Edition (2005): http://www.estc.gov.et/Ethics%20Guideline.pdf
Human Biological Materials	Ethiopian Science and Technology Commission, Health Department: http://www.estc.gov.et/			National Health Research Ethics Review Guideline, Fourth Edition, Section 8 (2005)
Kenya				
General	1. National Council for Science and Technology (NCST) 2. Ministry of Health (MOH): http://www.health.go.ke/index.html	Science and Technology Act (2001)	NCST: Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (2004): https://webapps.sph.harvard.edu/live/gremap/files/ke_NCST_guidelines.pdf MOH: Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005): https://webapps.sph.harvard.edu/live/gremap/files/ke_HIV_vaccine_guidelines.pdf	
Drugs	Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/	Pharmacy and Poisons Act, Chapter 244 (2001)		
Human Biological Materials	Ministry of Health (MOH): http://www.health.go.ke/index.html		Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, page 44 (2005)	

Country	Key Organizations	Legislation	Regulations	Guidelines
Malawi				
General	1. National Research Council of Malawi (NRCM) 2. National Health Sciences Research Committee (NHSRC) 3. College of Medicine Research and Ethics Committee (COMREC) 4. Ministry of Health	1. Presidential Decree on 30th March 1974 2. Malawi Government Gazette, June 11, 1976, General Notice No. 398	NRCM: Procedures and Guidelines for the Conduct of Research in Malawi (2002)	NHSRC: 1. Operational Guidelines (2001) 2. Summary Guidelines for Writing Research Proposals (2001) COMREC: Research Guidelines (2004): http://www.medcol.mw/comrec/res.guidelines.php
Drugs	Pharmacy, Medicines, and Poisons Board of Malawi	Pharmacy, Medicines, and Poisons Act, Act 15 of 1988)		
Genetic Research	National Research Council of Malawi (NRCM)		Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002)	
Nigeria				
General	National Health Research Ethics Committee: http://nhrec.net/	National Health Bill 2004		National Code of Health Research Ethics (2006)
Drugs	National Agency for Food, Drug Administration and Control (NAFDAC): http://www.nafdacnigeria.org/	Decree No. 15 of 1993		Guidelines, Procedures, and Protocols for Clinical Trials (1993)
South Africa				
General	1. Department of Health (DH): http://www.doh.gov.za 2. Medical Research Council of South Africa (MRC): http://www.mrc.ac.za 3. National Health Research Ethics Council	National Health Act No. 61, Chapter 9 (2003): http://www.doh.gov.za/docs/legislation-f.html		DH: Ethics in Health Research: Principles, Structures, and Processes (2004): http://www.doh.gov.za/docs/policy-f.html MRC: http://www.sahealthinfo.org/ethics/index.htm 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	Medicines Control Council: http://www.mccza.com		Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2000): http://www.doh.gov.za/docs/policy/trials/trials_contents.html	

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za			MRC: 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			MRC: Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.sahealthinfo.org/ethics/book2.htm
Tanzania				
General	1. Ministry of Health (MOH) 2. National Institute for Medical Research (NIMR), National Health Research Ethics Committee (NHREC): http://www.nimr.or.tz/index.php?option=com_content&task=view&id=26&Itemid=34 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 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. Guidelines on Ethics for Health Research in Tanzania (2001): https://webapps.sph.harvard.edu/live/gremap/files/tz_health_research_ethics.pdf 2. Brochure for Health Researchers in Tanzania (2006) COSTECH: COSTECH Guidelines on Research Permits and Clearance (2006)
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/tfdaact.pdf		
Uganda				
General	Uganda National Council on Science and Technology (UNCST): http://www.uncst.go.ug/			National Guidelines for Research Involving Humans as Research Participants (2007)
Drugs	National Drug Authority: http://www.nda.or.ug/	National Drug Authority Statute (1993)		
Zimbabwe				
General	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw	1. Government Notice Act (1974) 2. Research Act (1986)		1. Guidelines for Researchers and Ethics Review Committees in Zimbabwe (2004): http://www.mrcz.org.zw/docs/MRCZ%20guidelines%20for%20researchers%202004.pdf 2. Conducting Health Research in Zimbabwe: What Researchers Need to Know (2004): http://www.mrcz.org.zw/docs/conducting_health_research_in_zim.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs	Medicines Control Authority of Zimbabwe	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	Guidelines for Good Clinical Practice
Human Biological Materials	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw			Ethical Guidelines on the Collection of Blood Samples for Research (1999): http://www.mrcz.org.zw/docs/blood%20collection%20guidelines%201999.pdf

各国の臨床研究に関する法制の形態について（追加情報　暫定版）

1．臨床研究を一律に規制する法制がある国

(1)　医薬品を用いたもの及びその他の臨床研究の要件（ＩＣ、倫理審査等）を規定する法律

（例）

フランス(Public Health Code)：拘束力あり、刑事罰適用あり

※ 事前の国の計画審査、倫理委員会、インフォームド・コンセント等の実施要件。

オランダ(Medical Research Involving Human Subject Act)

スウェーデン (Law on the Ethical Review of Research Involving Humans)

デンマーク (Act on the Biomedical Research Ethics Committee System)

※ 倫理委員会、インフォームド・コンセント等の実施要件。

アイスランド (Act on the Rights of Patients, Regulation no. 552/1999 on Scientific Research in the Health Sector)

台湾(Medical Care Act)

※ 計画の当局への届出及び倫理審査委員会設置。non-teaching hospitals への研究の限定。

2．臨床研究を一律に規制する法制はないが、臨床研究に関連する法制のある国

(1)　臨床研究費の交付条件等に関する規定を有する法律（倫理的確保に関する指導権限、交付先研究機関の倫理審査委員会設置等）

（例）

米国 (Public Health Service Act)

※ 臨床研究の要件（ＩＣ、倫理審査等）である連邦規則 45CFR46（コモンルール）自体が法律ではない。PHS Act は、倫理審査委員会の設置を研究費交付の条件としている。

豪州 (National Health & Medical Research Council Act)

※ NHMRC 発行の臨床研究のガイドラインは存在する。

(2)　企業治験以外の医薬品の臨床研究を薬事法制で規制

（例）

米国 (Food, Drug & Cosmetics Act)

英国 (Medicines Act)

ドイツ (Medicinal Products Act)

その他欧州連合加盟国

韓国 (Pharmaceutical Affairs Law)

出典：　米国厚生省「International Compilation of Human research Protections」(2008) 等より