

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

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	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				
<i>General</i>	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)	
<i>Drugs</i>	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)
<i>Privacy/Data Protection</i>		Law for the Protection of Private Life No. 19.628 (1999)		
<i>Genetic Research</i>		Law No. 26.027 (2005)		
Colombia				
<i>General</i>	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)	
<i>Drugs</i>	National Institute of Drug and Food Surveillance (Spanish): http://www.invima.gov.co/			
<i>Privacy/Data Protection</i>		Constitution, Article 15 (2003)		
<i>Human Biological Materials</i>	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)	
<i>Genetic Research</i>	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No.	

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			008430, Title III, Chapter II (1993)	
Costa Rica				
<i>General</i>	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
<i>Drugs</i>	1. National Council on Health Research (CONIS) Network of Scientific Ethics Committees (Spanish): http://www.ministeriodesalud.go.cr/c/omconis.htm 2. Ministry of Health (Spanish): www.ministeriodesalud.go.cr			CONIS: 1. Guidelines for Good Clinical Practice (1996) 2. Protocol for Clinical Trials
<i>Human Biological Materials</i>	National Council on Health Research Network (CONIS) of Scientific Ethics Committees (Spanish): http://www.ministeriodesalud.go.cr/c/omconis.htm			Informed Consent, Research that Requires Biobanks
Jamaica				
<i>General</i>	Ministry of Health: http://www.moh.gov.jm			Ministry of Health Guidelines for the Conduct of Research on Human Subjects (2002)
Mexico				
<i>General</i>	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)	
<i>Drugs</i>	General Directorship of Medicines and Health Technologies		Regulation of the General Health Law in the Area of Health Research, Title Three (1986)	
<i>Privacy/Data Protection</i>		See listing at (Spanish): http://profesor.uia.mx/aveleyra/c		

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		omunica/privacidad/leyes2.htm		
<i>Human Biological Materials</i>	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)	
<i>Genetic Research</i>	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				
<i>General</i>	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
<i>Human Biological Materials</i>		Law 52 of 1995, Official Gazette 22,929		
<i>Embryos, Stem Cells, and Cloning</i>		Law 3 of 2004, Official Gazette 24,969		
Peru				
<i>General</i>	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)		
<i>Drugs</i>	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				
<i>Human Biological Materials</i>	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)	

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Venezuela				
<i>General</i>	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
<i>Drugs</i>	National Institute of Hygiene “Rafael Rangel” (Spanish): http://www.inhrr.gov.ve	Medicines Act, Articles 72 and 73		
<i>Genetic Research</i>	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

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AFRICA				
Botswana				
<i>General</i>	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)
<i>Drugs</i>	Ministry of Health, Drug Regulatory Unit: http://www.moh.gov.bw/		Drugs and Related Substances Regulations (1993)	
Ethiopia				
<i>General</i>	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
<i>Human Biological Materials</i>	Ethiopian Science and Technology Commission, Health Department: http://www.estc.gov.et/			National Health Research Ethics Review Guideline, Fourth Edition, Section 8 (2005)
Kenya				
<i>General</i>	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	
<i>Drugs</i>	Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/	Pharmacy and Poisons Act, Chapter 244 (2001)		
<i>Human Biological Materials</i>	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)	

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Malawi				
<i>General</i>	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 30 th 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
<i>Drugs</i>	Pharmacy, Medicines, and Poisons Board of Malawi	Pharmacy, Medicines, and Poisons Act, Act 15 of 1988)		
<i>Genetic Research</i>	National Research Council of Malawi (NRCM)		Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002)	
Nigeria				
<i>General</i>	National Health Research Ethics Committee: http://nhrec.net/	National Health Bill 2004		National Code of Health Research Ethics (2006)
<i>Drugs</i>	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				
<i>General</i>	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)
<i>Drugs</i>	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	

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<i>Genetic Research</i>	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
<i>Embryos, Stem Cells, and Cloning</i>	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				
<i>General</i>	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)
<i>Drugs</i>	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				
<i>General</i>	Uganda National Council on Science and Technology (UNCST): http://www.uncst.go.ug/			National Guidelines for Research Involving Humans as Research Participants (2007)
<i>Drugs</i>	National Drug Authority: http://www.nda.or.ug/	National Drug Authority Statute (1993)		
Zimbabwe				
<i>General</i>	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

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<i>Drugs</i>	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
<i>Human Biological Materials</i>	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