

Country	Key Organizations	Legislation	Regulations	Guidelines
<b>LATIN AMERICA and the CARIBBEAN</b>				
<b>Pan American Health Organization</b>				
<i>Drugs and Devices</i>	<i>Drugs</i>	Pan American Health Organization: <a href="http://www.paho.org/">http://www.paho.org/</a>		Good Clinical Practices: Document for the Americas (2004): <a href="http://www.paho.org/english/ad/thse/ev/GCP-Eng-doct.pdf">http://www.paho.org/english/ad/thse/ev/GCP-Eng-doct.pdf</a>
	<i>Devices</i>	Pan American Health Organization: <a href="http://www.paho.org/">http://www.paho.org/</a>		A Model Regulatory Program for Medical Devices: An International Guide (2001): <a href="http://www.paho.org/English/HSP/HSE/medical_devices.pdf">http://www.paho.org/English/HSP/HSE/medical_devices.pdf</a>
<b>Argentina</b>				
<i>General</i>	Ministry of Health: <a href="http://www.msal.gov.ar">http://www.msal.gov.ar</a>		1. Ministerial Resolution 1480/2011 Approving the Guidelines for Human Health Research and Creating the National Register for Human Health Research: <a href="http://www.anmat.gov.ar/webanmat/legislacion/medicamentos/Resolucion_1480-2011.pdf">http://www.anmat.gov.ar/webanmat/legislacion/medicamentos/Resolucion_1480-2011.pdf</a> 2. Ministerial Resolution 102/09: National Register for Clinical Trials	Resolution 1480/2011: Guidelines for Investigators Working with Human Beings: <a href="http://www.fecicla.org/archivos/regulaciones/Resolucion1480-11.pdf">http://www.fecicla.org/archivos/regulaciones/Resolucion1480-11.pdf</a>
<i>Drugs and Devices</i>	<i>Drugs</i>	National Administration of Medications, Foods, and Medical Technology (ANMAT) (Spanish): <a href="http://www.anmat.gov.ar/index.asp">http://www.anmat.gov.ar/index.asp</a>	1. Provision 2247/09: Guide for the Study of Clinical Trials of Type II Diabetes (2009) (Spanish): <a href="http://www.anmat.gov.ar/webanmat/Legislacion/Medicamentos/Disposicion_ANMAT_2247-2009.pdf">http://www.anmat.gov.ar/webanmat/Legislacion/Medicamentos/Disposicion_ANMAT_2247-2009.pdf</a> 2. Provision ANMAT 6677/10 on Good Research Practices in Clinical Pharmaceutical Studies (2010) (Spanish): <a href="http://www.anmat.gov.ar/Comunicados/Dispo_6677-10.pdf">http://www.anmat.gov.ar/Comunicados/Dispo_6677-10.pdf</a>	
	<i>Devices</i>	National Administration of Medications, Foods, and Medical Technology (ANMAT) (Spanish):	Provision 969/97 on the Regulation of Good Clinical Practice with Medical	

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	<a href="http://www.anmat.gov.ar/index.asp">http://www.anmat.gov.ar/index.asp</a>		Technology Products (1997) (Spanish): <a href="http://www.anmat.gov.ar/Legislacion/ProductosMedicos/Disposicion_AN_MAT_969-1997.pdf">http://www.anmat.gov.ar/Legislacion/ProductosMedicos/Disposicion_AN_MAT_969-1997.pdf</a>	
<i>Privacy/Data Protection</i>	National Personal Data Protection Authority (Spanish): <a href="http://www.jus.gov.ar/datospersonales/index.html">http://www.jus.gov.ar/datospersonales/index.html</a>	Personal Data Protection Act No. 25.326 (2000): <a href="http://www.protecciondedatos.com.ar/law25326.htm">http://www.protecciondedatos.com.ar/law25326.htm</a>		
<b>Barbados</b>				
	University of the West Indies – Cave Hill / Ministry of Health: <a href="http://www.cavehill.uwi.edu/researchethics/home.aspx">http://www.cavehill.uwi.edu/researchethics/home.aspx</a>			Research Ethics Policy and Guidelines
<b>Bolivia</b>				
<i>General</i>	1. Ministry of Health and Sport (MHS): <a href="http://www.sns.gov.bo/">http://www.sns.gov.bo/</a> 2. National Bioethics Committee (NBC)	1. Legal Decree No. 15.629 of July 18, 1978, Articles 147 and 148. 2. New Political Constitution of the State, Article 44 (2009): <a href="http://www.repac.org.bo/documentos/NUEVA%20CPE.pdf">http://www.repac.org.bo/documentos/NUEVA%20CPE.pdf</a>	1. Regulations on Public Health Research, Chapter V (1978) 2. Rules and Regulations of the National Bioethics Committee (Spanish)	MHS: Guidelines for the Development of Health Research and Ethical Norms (2002)  NBC: 1. Requirements for the Evaluation of Research Projects 2. Code of Ethics and Medical Deontology
<i>Drugs and Devices</i>	1. Ministry of Health and Sport, National Pharmacological Commission (MHS): <a href="http://www.sns.gov.bo/">http://www.sns.gov.bo/</a> 2. National Bioethics Committee (NBC)			MHS: Rule on Clinical Studies with Medicines or Products in the Clinical Investigation Stage (2005)  NBC: Projects that Involve Drugs or Therapeutic Products
<b>Brazil</b>				
<i>General</i>	1. National Health Council (CNS) (Portuguese): <a href="http://www.conselho.saude.gov.br/">http://www.conselho.saude.gov.br/</a> 2. National Commission on Research Ethics (CONEP) (Portuguese): <a href="http://conselho.saude.gov.br/web_comissoes/conep/index.html">http://conselho.saude.gov.br/web_comissoes/conep/index.html</a>	CNS: Decree 98 830: Collection by Foreigners of Data and Scientific Materials in Brazil (1990) (Portuguese): <a href="http://www.planalto.gov.br/ccivil_03/decreto/1990-1994/D98830.htm">http://www.planalto.gov.br/ccivil_03/decreto/1990-1994/D98830.htm</a>  Decree No. 065/2013 (Portuguese): <a href="http://www.planalto.gov.br/ccivil_03/_Ato2011-2014/2013/Decreto/D8065.htm">http://www.planalto.gov.br/ccivil_03/_Ato2011-2014/2013/Decreto/D8065.htm</a>	CNS/CONEP 1. Resolution MS/CNS No. 466/2012 (Portuguese): <a href="http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf">http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf</a> 2. Resolution No. 304/2000: <a href="http://conselho.saude.gov.br/resolucoes/2000/Res304_en.pdf">http://conselho.saude.gov.br/resolucoes/2000/Res304_en.pdf</a> 3. Resolution No. 301, 16th March 2002: <a href="http://conselho.saude.gov.br/resolucoes/2000/Res301_en.pdf">http://conselho.saude.gov.br/resolucoes/2000/Res301_en.pdf</a> 4. Resolution No. 446/2011 on	

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			<p>Composition of the National Commission on Research Ethics (Portuguese):  <a href="http://conselho.saude.gov.br/resolucoes/2011/Reso446.DOC">http://conselho.saude.gov.br/resolucoes/2011/Reso446.DOC</a></p> <p>5. Resolution CNS No. 421/09 (Portuguese):  <a href="http://conselho.saude.gov.br/resolucoes/2009/Reso421.doc">http://conselho.saude.gov.br/resolucoes/2009/Reso421.doc</a></p> <p>6. Regulation of Resolution CNS No. 292/99 on Research with Foreign Cooperation:  <a href="http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/regulation_res_292_english.doc">http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/regulation_res_292_english.doc</a></p> <p>7. Internal CONEP Regulation (Portuguese):  <a href="http://conselho.saude.gov.br/web_comissoes/conep/aquivos/conep/regimento.doc">http://conselho.saude.gov.br/web_comissoes/conep/aquivos/conep/regimento.doc</a></p> <p>8. Resolution CNS No. 370/07 on Registration and Accreditation or Renewal of Registration and Accreditation of CEP (Portuguese):  <a href="http://conselho.saude.gov.br/resolucoes/2007/Reso370.doc">http://conselho.saude.gov.br/resolucoes/2007/Reso370.doc</a></p> <p>9. Resolution No. 346/2005 on Multicenter Research:  <a href="http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf">http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf</a></p>	
<i>Drugs and Devices</i>	<p>1. National Health Council (CNS) (Portuguese):  <a href="http://www.conselho.saude.gov.br/">http://www.conselho.saude.gov.br/</a></p> <p>2. National Healthcare Surveillance Agency (Portuguese):  <a href="http://www.anvisa.gov.br">http://www.anvisa.gov.br</a></p>		<p>CNS:</p> <p>1. Resolution 251/1997: On Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests (1997):  <a href="http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf">http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf</a></p> <p>2. Resolution MS/CNS No. 466/2012:  <a href="http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf">http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf</a></p> <p>3. Resolution 404/2008: On Helsinki Declaration (2000)</p>	

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			(Portuguese): <a href="http://conselho.saude.gov.br/resolucoes/2008/Reso_404.doc">http://conselho.saude.gov.br/resolucoes/2008/Reso_404.doc</a>	
<i>Human Biological Materials</i>	National Commission on Research Ethics (CONEP) (Portuguese): <a href="http://conselho.saude.gov.br/web_comissoes/conep/index.html">http://conselho.saude.gov.br/web_comissoes/conep/index.html</a>	Ordinance No. 2.201/11: Establishing the National Guidelines for Biobanks of Human Biological Material for Research Purposes (2011) (Portuguese): <a href="http://www2.inca.gov.br/wps/wcm/connect/8b19d5804eb688ee9cb39ef11fae00ee/portaria_2201_de_14_de_set_2011.pdf?MOD=AJPERES&amp;CACHEID=8b19d5804eb688ee9cb39ef11fae00ee">http://www2.inca.gov.br/wps/wcm/connect/8b19d5804eb688ee9cb39ef11fae00ee/portaria_2201_de_14_de_set_2011.pdf?MOD=AJPERES&amp;CACHEID=8b19d5804eb688ee9cb39ef11fae00ee</a>	CONEP: 1. Resolution CNS No. 441 of 12 May 2011: <a href="http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/Resolucao441_English_contribuicao_pesquisadora.doc">http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/Resolucao441_English_contribuicao_pesquisadora.doc</a> 2. Ministry of Health Decree MS No. 2.201, of 14 September 2011: <a href="http://bvsmis.saude.gov.br/bvsmis/saudelegis/gm/2011/prt2201_14_09_2011.html">http://bvsmis.saude.gov.br/bvsmis/saudelegis/gm/2011/prt2201_14_09_2011.html</a>	CONEP: Approval Guidelines for Ethical Analysis of Research Projects Involving Storage of Materials or Use of Materials Stored by Previous Research: Resolution 441/11 (2011): <a href="http://conselho.saude.gov.br/resolucoes/2011/Reso441.pdf">http://conselho.saude.gov.br/resolucoes/2011/Reso441.pdf</a>
<i>Genetic Research</i>	1. National Commission on Research Ethics (CONEP) (Portuguese): <a href="http://conselho.saude.gov.br/web_comissoes/conep/index.html">http://conselho.saude.gov.br/web_comissoes/conep/index.html</a> 2. National Biosafety Technical Commission (CTNBio) (Portuguese): <a href="http://www.ctnbio.gov.br">http://www.ctnbio.gov.br</a>	Biosafety Law 11.105/05 (2005): <a href="http://www.ctnbio.gov.br/index.php/content/view/12847.html">http://www.ctnbio.gov.br/index.php/content/view/12847.html</a>	CONEP: Resolution 340/2004 : On Research on Human Genetics (2004): <a href="http://conselho.saude.gov.br/resolucoes/2004/Res340_en.pdf">http://conselho.saude.gov.br/resolucoes/2004/Res340_en.pdf</a>  CTNBio: 1. Decree No. 5,591 of 22 November 2005: <a href="http://www.ctnbio.gov.br/index.php/content/view/12848.html">http://www.ctnbio.gov.br/index.php/content/view/12848.html</a> 2. Instruction CTNBio No. 8 of 9 July 1997 (Portuguese): <a href="http://www.ctnbio.gov.br/index.php/content/view/11971.html">http://www.ctnbio.gov.br/index.php/content/view/11971.html</a> 3. Instruction CTNBio No. 9 of 10 October 1997 (Portuguese): <a href="http://www.ctnbio.gov.br/index.php/content/view/11972.html">http://www.ctnbio.gov.br/index.php/content/view/11972.html</a>	CONEP: Approval Guidelines for Ethical Analysis and Conduct of Research Projects in the Special Thematic Area of Human Genetics: Resolution 340/04 (2004): <a href="http://conselho.saude.gov.br/resolucoes/2004/Res340_en.pdf">http://conselho.saude.gov.br/resolucoes/2004/Res340_en.pdf</a>
<i>Embryos, Stem Cells, and Cloning</i>	National Biosafety Technical Commission (Portuguese): <a href="http://www.ctnbio.gov.br">http://www.ctnbio.gov.br</a>	Biosafety Law 11.105/05 (2005): <a href="http://www.ctnbio.gov.br/index.php/content/view/12847.html">http://www.ctnbio.gov.br/index.php/content/view/12847.html</a>	CTNBio: Resolution MS/CNS No. 466/2012: <a href="http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf">http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf</a>	
<b>Chile</b>				
<i>General</i>	Ministry of Health (Spanish): <a href="http://www.minsal.cl">http://www.minsal.cl</a>	Law N° 20584. Regulating the Rights and Duties Incumbent upon Persons in Connection with Actions Linked to their	1. Supreme Decree No. 42 (1986) 2. Supreme Decree No. 1.935 (1993) 3. General Technical Rule No. 2	

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		Health Care (2012) (Spanish): <a href="http://www.leychile.cl/Navegar?idNorma=1039348">http://www.leychile.cl/Navegar?idNorma=1039348</a>	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 and Devices</i>	Ministry of Health (Spanish): <a href="http://www.minsal.cl">http://www.minsal.cl</a>		Technical Rule No. 57: Regulation of the Conduct of Clinical Trials that Use Pharmaceutical Products in Human Beings (2001): <a href="http://www.ispch.cl/formularios/norma_tec/norm_tec_n_57.pdf">http://www.ispch.cl/formularios/norma_tec/norm_tec_n_57.pdf</a>	Ethical Guidelines for Clinical Trials with Pharmaceutical and Biological Products (2001)
<i>Research Injury</i>	Ministry of Health: <a href="http://www.minsal.cl">http://www.minsal.cl</a>		Technical Rule No. 57: Regulation of the Conduct of Clinical Trials that Use Pharmaceutical Products in Human Beings (2001): <a href="http://www.ispch.cl/formularios/norma_tec/norm_tec_n_57.pdf">http://www.ispch.cl/formularios/norma_tec/norm_tec_n_57.pdf</a>	
<i>Privacy/Data Protection</i>		Law for the Protection of Private Life No. 19.628 (1999) (Spanish): <a href="http://www.bcn.cl/leves/141599">http://www.bcn.cl/leves/141599</a>		
<i>Genetic Research</i>		Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2006): <a href="http://www.leychile.cl/Navegar?idNorma=253478">http://www.leychile.cl/Navegar?idNorma=253478</a>		
<i>Embryos, Stem Cells, and Cloning</i>		Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2007)		
<b>Colombia</b>				
<i>General</i>	Ministry of Health and Social Protection (Spanish): <a href="http://www.minsalud.gov.co">http://www.minsalud.gov.co</a>		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430 (1993):	

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			<a href="http://www.minsalud.gov.co/Normatividad/RESOLUCION%208430%20DE%201993.pdf">http://www.minsalud.gov.co/Normatividad/RESOLUCION%208430%20DE%201993.pdf</a>	
<i>Drugs and Devices</i>	<i>Drugs</i>		1. Resolution No. 2378 of 2008, Adapting Good Clinical Practices for Institutions that Conduct Research with Medicines in Human Beings: <a href="http://web.invima.gov.co/portal/documentos/portal/documents/root/resolucion2378_2008.pdf">http://web.invima.gov.co/portal/documentos/portal/documents/root/resolucion2378_2008.pdf</a> 2. Resolution No. 2011020764 June 10th, 2011: Regulation Related to the Content and Frequency of Adverse Event Reports in Clinical Investigation in Humans: <a href="http://web.invima.gov.co/portal/documentos/portal/documents/root/normatividad/Institucional/2011/Resolucion%202011020764.pdf">http://web.invima.gov.co/portal/documentos/portal/documents/root/normatividad/Institucional/2011/Resolucion%202011020764.pdf</a>	
	<i>Devices</i>			
	National Institute of Drug and Food Surveillance (Spanish): <a href="http://www.invima.gov.co/">http://www.invima.gov.co/</a>	Various: <a href="http://web.invima.gov.co/portal/faces/index.jsp?id=2283">http://web.invima.gov.co/portal/faces/index.jsp?id=2283</a>	Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapters I and III (1993)	Various guidelines: <a href="http://web.invima.gov.co/portal/faces/index.jsp?id=2285">http://web.invima.gov.co/portal/faces/index.jsp?id=2285</a>
<i>Research Injury</i>	Ministry of Health and Social Protection (Spanish): <a href="http://www.minsalud.gov.co">http://www.minsalud.gov.co</a>		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Art. 13 (1993)	
<i>Privacy/Data Protection</i>	Ministry of Health and Social Protection (Spanish): <a href="http://www.minsalud.gov.co">http://www.minsalud.gov.co</a>	Constitution of Colombia, Article 15 (2003)	Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Art. 8 (1993)	
<i>Human Biological Materials</i>	Ministry of Health and Social Protection (Spanish): <a href="http://www.minsalud.gov.co">http://www.minsalud.gov.co</a>		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter VI (1993)	
<i>Genetic Research</i>	Ministry of Health and Social Protection (Spanish):		Scientific, Technical, and Administrative Regulations for	

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	<a href="http://www.minsalud.gov.co">http://www.minsalud.gov.co</a>		Health Research, Resolution No. 008430, Title III, Chapter II (1993)	
<b>Costa Rica</b>				
<i>General</i>	Ministry of Health: <a href="http://www.ministeriodesalud.go.cr/">http://www.ministeriodesalud.go.cr/</a>	Law 5395, General Health Law, Articles 64-68 (1973) (Spanish): <a href="http://www.netsalud.sa.cr/leyes/libro1.htm">http://www.netsalud.sa.cr/leyes/libro1.htm</a>	Regulation for the Approval of Observational Studies in the CCSS: <a href="http://www.cendeisss.sa.cr/etica/06-REGULACa.html">http://www.cendeisss.sa.cr/etica/06-REGULACa.html</a>	
<i>Drugs and Devices</i>	Ministry of Health (Spanish): <a href="http://www.ministeriodesalud.go.cr">www.ministeriodesalud.go.cr</a>		Executive Decree 36068-S, 2010: Suspension of Filing Requirement <i>in vivo</i> Equivalence Studies	
<b>Dominica</b>				
<i>General</i>	Ministry of Health: <a href="http://www.dominica.gov.dm/cms/index.php?q=node/21">http://www.dominica.gov.dm/cms/index.php?q=node/21</a>			Guidelines for the Conduct of Research on Human Subjects (2005)
<b>Ecuador</b>				
<i>General</i>	Ministry of Public Health: <a href="http://www.msp.gov.ec/">http://www.msp.gov.ec/</a>	Organic Health Law, Articles 207-208, of 22 December 2006: <a href="http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf">http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf</a>		1. National Policy on Scientific Research. 2. Ministerial Accord 209 RO 87 of 23 August 2005
<i>Drugs and Devices</i>	Ministry of Public Health: <a href="http://www.msp.gov.ec/">http://www.msp.gov.ec/</a>		1. Regulation on Research, RO 292 2. Regulation for the Approval, Monitoring, Follow-up, and Evaluation of Health Research Projects	
<i>Biological Materials</i>	Ministry of Public Health: <a href="http://www.ontot.gob.ec/ontotweb">http://www.ontot.gob.ec/ontotweb</a>	Organic Health Law, Articles 81-86, of 22 December 2006: <a href="http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf">http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf</a>	Regulation for the Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells of 24 August 2011: <a href="http://www.ontot.gob.ec/ontotweb/index.php/descargas/reglamento?download=66:reglamento-general-a-la-ley-organica-de-donacion-y-trasplantes-de-organos-tejidos-y-celulas">http://www.ontot.gob.ec/ontotweb/index.php/descargas/reglamento?download=66:reglamento-general-a-la-ley-organica-de-donacion-y-trasplantes-de-organos-tejidos-y-celulas</a>	
<i>Genetic Research</i>	Ministry of Public Health: <a href="http://www.msp.gov.ec/">http://www.msp.gov.ec/</a>	Organic Health Law, Articles 209-210, of 22 December 2006: <a href="http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf">http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf</a>		

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<i>Embryos, Stem Cells, and Cloning</i>	Ministry of Public Health: <a href="http://www.msp.gov.ec/">http://www.msp.gov.ec/</a>	Organic Health Law, Article 214, of 22 December 2006: <a href="http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf">http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf</a>		
<b>Grenada</b>				
<i>General</i>	St. George's University/Windward Islands Research and Education Foundation (WINDREF): <a href="http://www.sgu.edu/research/research.html">http://www.sgu.edu/research/research.html</a>			Guidelines for the Conduct of Research of WINDREF
<b>Guatemala</b>				
<i>Drugs and Devices</i>	Ministry of Public Health and Social Assistance: <a href="http://www.mspas.gob.gt/">http://www.mspas.gob.gt/</a>		Rules for the Regulation of Human Clinical Trials. Ministerial Accord SP-M-466-2007: <a href="http://medicamentos.com.gt/index.php/legislacion-vigente/acuerdos">http://medicamentos.com.gt/index.php/legislacion-vigente/acuerdos</a>	
<b>Haiti</b>				
<i>General</i>	Ministry of Public Health and Population (French): <a href="http://www.mspp.gouv.ht/site/index.php">http://www.mspp.gouv.ht/site/index.php</a>			Internal Regulations (2010) (French)
<b>Honduras</b>				
<i>General</i>			Health Code, Decree No. 65-91, Articles 175 and 176	
<b>Jamaica</b>				
<i>General</i>	Ministry of Health: <a href="http://www.moh.gov.jm/legislation/gcrhs-link">http://www.moh.gov.jm/legislation/gcrhs-link</a>			Ministry of Health Guidelines for the Conduct of Research on Human Subjects (2012)
<i>Drugs and Devices</i>	Ministry of Justice: <a href="http://www.moj.gov.jm/law">http://www.moj.gov.jm/law</a>	Food and Drugs Act: <a href="http://www.moj.gov.jm/laws/statutes/The%20Food%20and%20Drugs%20Act.pdf">http://www.moj.gov.jm/laws/statutes/The%20Food%20and%20Drugs%20Act.pdf</a>	Food and Drugs Regulations (1975): <a href="http://www.moj.gov.jm/laws/subsidiary/Food%20and%20Drugs%20Act.pdf">http://www.moj.gov.jm/laws/subsidiary/Food%20and%20Drugs%20Act.pdf</a> and <a href="http://www.moj.gov.jm/laws/subsidiary/Food%20and%20Drugs%20Regulations,%201975.pdf">http://www.moj.gov.jm/laws/subsidiary/Food%20and%20Drugs%20Regulations,%201975.pdf</a>	



Country	Key Organizations	Legislation	Regulations	Guidelines	
<b>Mexico</b>					
Note: All websites and documents are in Spanish.					
<i>General</i>	1. Secretariat of Health: <a href="http://www.salud.gob.mx/">http://www.salud.gob.mx/</a> 2. General Health Council: <a href="http://www.csg.salud.gob.mx/">www.csg.salud.gob.mx/</a> 3. National Bioethics Commission (CNB): <a href="http://www.conbioetica-mexico.salud.gob.mx/">http://www.conbioetica-mexico.salud.gob.mx/</a>	General Health Law, Title V, Chapter I, Articles 96-103: Health Research (2013): <a href="http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatividad/8_NAL_LEY_GENERAL_DE_SALUD.pdf">http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatividad/8_NAL_LEY_GENERAL_DE_SALUD.pdf</a>	1. Regulation on the General Health Law in the Matter of Health Research (1984): <a href="http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatividad/10_NAL_Reglamento_de_Investigacion.pdf">http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatividad/10_NAL_Reglamento_de_Investigacion.pdf</a> 2. Rule NOM-012-SSA3-2012 Establishing Criteria for the Conduct of Health Research Projects (2012): <a href="http://dof.gob.mx/nota_detalle.php?codigo=5284148&amp;fecha=04/01/2013">http://dof.gob.mx/nota_detalle.php?codigo=5284148&amp;fecha=04/01/2013</a>	CNB: 1. National Guidelines for the Integration and Operation of Research Ethics Committees (2012): <a href="http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/registrocomites/Guia_CEI.pdf">http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/registrocomites/Guia_CEI.pdf</a> 2. Agreement by Which General Provisions are Issued for the Integration and Operation of Research Ethics Committees and Their Hospital Units, In Accordance with Criteria Established by the National Bioethics Commission (2012): <a href="http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatividad/AcuerdoCHB.pdf">http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatividad/AcuerdoCHB.pdf</a>	
<i>Drugs and Devices</i>	<i>Drugs</i>	Federal Commission for Protection Against Health Risks (COFEPRIS): <a href="http://www.cofepris.gob.mx/Paginas/Inicio.aspx">http://www.cofepris.gob.mx/Paginas/Inicio.aspx</a>	General Health Law, Title V, Chapter I, Articles 96-103: Health Research (2013): <a href="http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatividad/8_NAL_LEY_GENERAL_DE_SALUD.pdf">http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatividad/8_NAL_LEY_GENERAL_DE_SALUD.pdf</a>	Regulation on the General Health Law in the Matter of Health Research, Title Three (1984): <a href="http://www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html">www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html</a>	Guidelines for Good Clinical Practice: <a href="http://www.cofepris.gob.mx/AS/Documentos/Protocolos%20de%20Investigacion/Lineamientos%20Bioequivalencia/Lineamientos%20BPC%2031052012.pdf">http://www.cofepris.gob.mx/AS/Documentos/Protocolos%20de%20Investigacion/Lineamientos%20Bioequivalencia/Lineamientos%20BPC%2031052012.pdf</a>
	<i>Devices</i>	Federal Commission for Protection Against Health Risks (COFEPRIS): <a href="http://www.cofepris.gob.mx/Paginas/Inicio.aspx">http://www.cofepris.gob.mx/Paginas/Inicio.aspx</a>		Regulation on the General Health Law in the Matter of Health Research, Title Four, Chapter III (1984): <a href="http://www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html">www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html</a>	
<i>Privacy/Data Protection</i>	Federal Institute on Access to Public Information (Spanish): <a href="http://www.ifai.org.mx/">www.ifai.org.mx/</a>	1. Federal Law for the Protection of Personal Data in the Possession of Private Individuals (2010): <a href="http://www.diputados.gob.mx/LeyesBiblio/pdf/LFPDPPP.pdf">http://www.diputados.gob.mx/LeyesBiblio/pdf/LFPDPPP.pdf</a> 2. Federal Law on Transparency and Access to Public Governmental Information (2012): <a href="http://www.diputados.gob.mx/LeyesBiblio/pdf/244.pdf">http://www.diputados.gob.mx/LeyesBiblio/pdf/244.pdf</a>			

<b>Country</b>	<b>Key Organizations</b>	<b>Legislation</b>	<b>Regulations</b>	<b>Guidelines</b>
<i>Human Biological Materials</i>	Secretariat of Health: <a href="http://www.salud.gob.mx/">http://www.salud.gob.mx/</a>	General Health Law, Title XIV, Articles 313-342 (2005): <a href="http://www.salud.gob.mx/unidades/cdi/legis/lgs/index-indice.htm">http://www.salud.gob.mx/unidades/cdi/legis/lgs/index-indice.htm</a>		
<i>Genetic Research</i>	National Institute of Genomic Medicine: <a href="http://www.inmegen.gob.mx/es/">http://www.inmegen.gob.mx/es/</a>	1. Biosafety Law on Genetically Modified Organisms (2008) 2. Modifications to the General Health Law to Protect Genomic Sovereignty (2008)	Regulation on the General Health Law in the Matter of Health Research, Title Four, Chapter Two (1984): <a href="http://www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html">www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html</a>	
<b>Panama</b>				
<i>General</i>	1. Ministry of Health (MINSA) (Spanish): <a href="http://www.minsa.gob.pa/">http://www.minsa.gob.pa/</a> 2. ICGES Bioethics Research Committee (CBI): <a href="http://www.gorgas.gob.pa/index.php?option=com_content&amp;view=article&amp;id=54&amp;Itemid=103&amp;lang=es">http://www.gorgas.gob.pa/index.php?option=com_content&amp;view=article&amp;id=54&amp;Itemid=103&amp;lang=es</a>		MINSA: 1. Resolution No. 390 Adopting the Operational Guide for Research Bioethics, Official Gazette 24,938 (2003) (Spanish): <a href="http://www.gorgas.gob.pa/images/Gaceta%20N%2024%20938%20%20Resolucion390.doc">http://www.gorgas.gob.pa/images/Gaceta%20N%2024%20938%20%20Resolucion390.doc</a> 2. Executive Decree No. 1 on the National Research Ethics Committee of Panama (2013) (Spanish): <a href="http://www.gacetaoficial.gob.pa/pdfTemp/27207/40366.pdf">http://www.gacetaoficial.gob.pa/pdfTemp/27207/40366.pdf</a>	CBI : Various (Spanish): <a href="http://www.gorgas.gob.pa/index.php?option=com_content&amp;view=article&amp;id=54&amp;Itemid=103&amp;lang=es">http://www.gorgas.gob.pa/index.php?option=com_content&amp;view=article&amp;id=54&amp;Itemid=103&amp;lang=es</a>
<i>Privacy/Data Protection</i>		Law 68 of 2003, Official Gazette 24,935 (Spanish): <a href="http://www.asamblea.gob.pa/APPS/LEGISPAN/PDF_GACETAS/2000/2003/24935_2003.PDF">http://www.asamblea.gob.pa/APPS/LEGISPAN/PDF_GACETAS/2000/2003/24935_2003.PDF</a>		
<i>Human Biological Materials</i>		Law 3 of 2003, Official Gazette 26,468-B (Spanish): <a href="http://www.asamblea.gob.pa/APPS/LEGISPAN/PDF_GACETAS/2010/2010/26468-B_2010.PDF">http://www.asamblea.gob.pa/APPS/LEGISPAN/PDF_GACETAS/2010/2010/26468-B_2010.PDF</a>		
<i>Embryos, Stem Cells, and Cloning</i>			Executive Decree No. 2 on Stem Cells (2013) (Spanish): <a href="http://www.gacetaoficial.gob.pa/pdfTemp/27207/40367.pdf">http://www.gacetaoficial.gob.pa/pdfTemp/27207/40367.pdf</a>	
<b>Peru</b>				
<i>General</i>	1. National Institute of Health (Spanish): <a href="http://www.ins.gob.pe/">http://www.ins.gob.pe/</a> 2. National Network of Research Ethics Committees	General Health Law No. 26842, Article 28 (1997) (Spanish): <a href="http://www.digemid.minsa.gob.pe/normatividad/LEY2684202.HTM">http://www.digemid.minsa.gob.pe/normatividad/LEY2684202.HTM</a>		

<b>Country</b>	<b>Key Organizations</b>	<b>Legislation</b>	<b>Regulations</b>	<b>Guidelines</b>
<i>Drugs and Devices</i>	1. National Institute of Health (Spanish): <a href="http://www.ins.gob.pe/gxpsites/hgxpp001.aspx?2.13.326.O.S.O.MNU:E:1:14:20:10:MNU">http://www.ins.gob.pe/gxpsites/hgxpp001.aspx?2.13.326.O.S.O.MNU:E:1:14:20:10:MNU</a> 2. National Directorate of Drugs and Medical Devices: <a href="http://www.digemid.minsa.gob.pe">www.digemid.minsa.gob.pe</a>		1. Supreme Decree No. 017-2006-SA: Regulation on Clinical Trials in Peru (2006) (Spanish): 2. Supreme Decree No. 006-2007-SA: Modification of the Regulation on Clinical Trials in Peru (2007) (Spanish): <i>Access:</i> <a href="http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990">http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990</a>	
<i>Research Injury</i>	National Institute of Health (Spanish): <a href="http://www.ins.gob.pe/gxpsites/hgxpp001.aspx?2.13.326.O.S.O.MNU:E:1:14:20:10:MNU">http://www.ins.gob.pe/gxpsites/hgxpp001.aspx?2.13.326.O.S.O.MNU:E:1:14:20:10:MNU</a>		Regulation on Clinical Trials in Peru: Articles 26, 27 and 28 (Spanish): <a href="http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990">http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990</a>	
<i>Privacy/Data Protection</i>	National Directorate of Drugs and Medical Devices: <a href="http://www.digemid.minsa.gob.pe">www.digemid.minsa.gob.pe</a>	1. Law 29733 for the Protection of Personal Information: <a href="http://www.minjus.gob.pe/legislacion/">http://www.minjus.gob.pe/legislacion/</a> 2. Law for Electronic Medical Charts: <a href="http://elperuanolegal.blogspot.com/2013/05/ley-30024-ley-que-crea-el-registro.html">http://elperuanolegal.blogspot.com/2013/05/ley-30024-ley-que-crea-el-registro.html</a>		
<b>Uruguay</b>				
<i>General</i>	Ministry of Public Health (Spanish): <a href="http://www.msp.gub.uy/index_1.html">http://www.msp.gub.uy/index_1.html</a>	1. Decree 379/008: <a href="http://www.habeasdata.org.uy/wp-content/uploads/2008/08/decreto-379008.pdf">http://www.habeasdata.org.uy/wp-content/uploads/2008/08/decreto-379008.pdf</a> 2. Decree 189/998 <a href="http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF">http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF</a>	Decree No. 370/2008: Regulation Concerning Research with Humans	
<i>Drugs and Devices</i>	Ministry of Public Health (Spanish): <a href="http://www.msp.gub.uy/index_1.html">http://www.msp.gub.uy/index_1.html</a>	Decree 189/998: <a href="http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF">http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF</a>		
<i>Research Injury</i>	Ministry of Public Health (Spanish): <a href="http://www.msp.gub.uy/index_1.html">http://www.msp.gub.uy/index_1.html</a>	1. Decree 379/008: <a href="http://www.habeasdata.org.uy/wp-content/uploads/2008/08/decreto-379008.pdf">http://www.habeasdata.org.uy/wp-content/uploads/2008/08/decreto-</a>		

Country	Key Organizations	Legislation	Regulations	Guidelines
		<a href="#">379008.pdf</a> 2. Decree 189/998: <a href="http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF">http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF</a>		
<i>Privacy/Data Protection</i>	Ministry of Public Health (Spanish): <a href="http://www.msp.gub.uy/index_1.html">http://www.msp.gub.uy/index_1.html</a>	1. Law 18.331: <a href="http://www0.parlamento.gub.uy/leyes/ AccesoTextoLey.asp?Ley=18331">http://www0.parlamento.gub.uy/leyes/ AccesoTextoLey.asp?Ley=18331</a> 2. Decree 379/008: <a href="http://www.habeasdata.org.uy/wp-content/uploads/2008/08/decreto-379008.pdf">http://www.habeasdata.org.uy/wp-content/uploads/2008/08/decreto-379008.pdf</a>		
<i>Human Biological Materials</i>	1. Ministry of Public Health (Spanish): <a href="http://www.msp.gub.uy/index_1.html">http://www.msp.gub.uy/index_1.html</a> 2. Instituto Nacional de Donación y Trasplante (Spanish): <a href="http://www.indt.edu.uy">www.indt.edu.uy</a>	Decree 160/006: <a href="http://www.indt.edu.uy/documentos/documentacion_legal/decreto_160-006.pdf">http://www.indt.edu.uy/documentos/documentacion_legal/decreto_160-006.pdf</a>		
<b>Venezuela</b>				
<i>General</i>	1. National Fund on Science and Technology, Commission on Bioethics and Biosecurity (FONACIT) (Spanish): <a href="http://www.fonacit.gov.ve/">www.fonacit.gov.ve/</a> 2. Venezuelan Institute of Scientific Research, Bioethics Commission (IVIC)	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 and Devices</i>	National Institute of Hygiene “Rafael Rangel” (Spanish)	Medicines Act, Articles 72 and 73		
<i>Genetic Research</i>	Venezuelan Institute of Scientific Research, Bioethics Commission (Spanish)			1. Contract for Accessing Genetic Resources (2003) (Spanish) 2. Revised Outline of the International Declaration of Human Genetic Data (2003)