

Country	Key Organizations	Legislation	Regulations	Guidelines
	<a href="#">vClinica/docs/contactosCCAA-agosto06.pdf</a>	2. Law 29/2006 of July 26 on Assurances and Rational Use of Medications and Health Products		
<i>Privacy/Data Protection</i>	Spanish Data Protection Authority (Spanish): <a href="https://www.agpd.es/index.php">https://www.agpd.es/index.php</a>	1. Organic Law 15/1999 of December 13 on the Protection of Personal Data: <a href="https://www.agpd.es/upload/Ley%20Org%E1nica%2015-99_ingles.pdf">https://www.agpd.es/upload/Ley%20Org%E1nica%2015-99_ingles.pdf</a> 2. Royal Decree 994/99 Regarding Databases with Personal Information		
<i>Human Biological Materials</i>	Ministry of Health and Consumption (MOH): <a href="http://www.msc.es/en/home.htm">http://www.msc.es/en/home.htm</a>	1. Royal Decree 411/1996, of March 1, By Which Activities Regarding the Use of Human Tissues are Regulated (1996) (Spanish): <a href="http://europa.eu.int/comm/research/biosociety/pdf/spanish_act411.pdf">http://europa.eu.int/comm/research/biosociety/pdf/spanish_act411.pdf</a> 2. Royal Decree 2070/1999 of December 30, Regarding Activities of Collection and Clinical Use of Human Organs for Organ Transplants and Tissues	1. Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples (2006)	
<i>Embryos, Stem Cells, and Cloning</i>		1. Assisted Reproduction Techniques (1988) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		
<b>Srpska</b>				
<i>Drugs</i>	Ministry of Health and Social Welfare, Agency for Medicines	Law on Drugs and Pharmacies of the Republic of Srpska	Regulation on Conducting Clinical Trials (2005)	Guidelines of Good Clinical Practice
<b>Sweden</b>				
Note: For an overview of human subject protections in Sweden, see "CODEX: Rules and Guidelines for Research:" <a href="http://www.codex.uu.se/codex_eng/codex/index.html">http://www.codex.uu.se/codex_eng/codex/index.html</a>				
<i>General</i>	1. Central Ethical Review Board (CEPN): <a href="http://www.epn.se/eng/start/index.asp">http://www.epn.se/eng/start/index.asp</a> x	Law No. 460 on the Ethical Review of Research Involving Humans (2003): <a href="http://www.epn.se/eng/start/200">http://www.epn.se/eng/start/200</a>	CEPN: 1. Ordinance No. 615 Concerning the Ethical Vetting of Research Involving Humans (2003):	CEPN: Information for Research Participants SRC:

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	2. Swedish Research Council (SRC): <a href="http://www.vr.se/english">http://www.vr.se/english</a>	3. 460.aspx	<a href="http://www.epn.se/eng/start/2003_615.aspx">http://www.epn.se/eng/start/2003_615.aspx</a> 2. Statute No. 616 Containing Instructions for Regional Ethical Review Boards (2003): <a href="http://www.epn.se/eng/start/2003_616.aspx">http://www.epn.se/eng/start/2003_616.aspx</a> 3. Statute No. 617 Containing Instructions for the Central Ethical Review Boards (2003): <a href="http://www.epn.se/eng/start/2003_617.aspx">http://www.epn.se/eng/start/2003_617.aspx</a>	1. Ethical Guidelines of Epidemiological Research (1994) 2. Guidelines for Good Medical Research (1996) 3. Guidelines for the Ethical Evaluation of Medical Research on Humans (2003) 4. Policy Statement Regarding the Assessment of Scientific Studies in which Patients or Healthy Subjects are to Undergo Invasive Operations (2003)
<i>Drugs</i>	Medical Products Agency: <a href="http://www.lakemedelsverket.se/Tpl/StartPage_395.aspx">http://www.lakemedelsverket.se/Tpl/StartPage_395.aspx</a>	Pharmaceuticals Act No. 1992: 859 (Swedish): <a href="http://www.notisum.se/mp/SLS/LAG/19920859.HTM">http://www.notisum.se/mp/SLS/LAG/19920859.HTM</a>	1. Medical Products Agency's Provisions and Guidelines on the Clinical Trials of Medicinal Products (1999) 2. Medical Product Agency's Provisions and Guidelines on Clinical Trials of Medicinal Products for Human Use, Code of Statutes No. 6 (2003)	
<i>Privacy/Data Protection</i>	Swedish Data Inspection Board: <a href="http://www.datainspektionen.se/in_english/start.shtml">http://www.datainspektionen.se/in_english/start.shtml</a>	Personal Data Act No. 204 (2002): <a href="http://www.datainspektionen.se/pdf/ovrigt/pul-eng.pdf">http://www.datainspektionen.se/pdf/ovrigt/pul-eng.pdf</a>		
<i>Human Biological Materials</i>	1. National Board of Health and Welfare (SOS) 2. Swedish Research Council (SRC): <a href="http://www.vr.se/english">http://www.vr.se/english</a> 3. Swedish National Biobank Program: <a href="http://www.biobanks.se/">http://www.biobanks.se/</a>	Biobanks in Medical Care Act No. 297 (2002): <a href="http://www.sweden.gov.se/content/1/c6/02/31/26/f69e36fd.pdf">http://www.sweden.gov.se/content/1/c6/02/31/26/f69e36fd.pdf</a>	SOS: 1. Regulation No. 746 (2002) 2. SOSFS No. 11 (2002) 3. SOSFS No. 2 (2004)	SRC: Research Ethics Guidelines for Using Biobanks (2003)
<i>Genetic Research</i>	1. Ministry of Health and Social Affairs: <a href="http://www.sweden.gov.se/sb/d/2061">http://www.sweden.gov.se/sb/d/2061</a> 2. National Board of Health and Welfare	Act on Genetic Integrity (2006:351): <a href="http://www.notisum.se/mp/sls/lag/20060351.htm">http://www.notisum.se/mp/sls/lag/20060351.htm</a>		Genetics and Gene Technology in the Health Care: State of the Art and Guidelines for Ethical Considerations (1999)
<i>Embryos, Stem Cells, and Cloning</i>		Act on Genetic Integrity (2006:351): <a href="http://www.notisum.se/mp/sls/lag/20060351.htm">http://www.notisum.se/mp/sls/lag/20060351.htm</a>	Legal Regulation of Stem Cell Research 2002:119: <a href="http://www.regeringen.se/sb/d/108/a/2717">http://www.regeringen.se/sb/d/108/a/2717</a>	
<b>Switzerland</b>				
<i>General</i>	1. Swiss Academy of Medical Sciences (SAMS): <a href="http://www.samv.ch/">http://www.samv.ch/</a>		Many of the Swiss cantons have implemented regulations regarding human subject research	SAMS: Guidelines on Human Research (1997)

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	<p>2. Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE): <a href="http://www.nek-cne.ch/?langId=2">http://www.nek-cne.ch/?langId=2</a></p> <p>3. Swiss Ethics Committees for Research: <a href="http://www.swissethics.ch">http://www.swissethics.ch</a></p>		<p>(French): <a href="http://www.swissethics.ch/fileadmin/user_upload/Dokumente/f_RegelungenKant.doc">http://www.swissethics.ch/fileadmin/user_upload/Dokumente/f_RegelungenKant.doc</a></p>	
<i>Drugs</i>	<p>Swiss Agency for Therapeutic Products (Swissmedic): <a href="http://www.swissmedic.ch/?lang=2">http://www.swissmedic.ch/?lang=2</a></p>	<p>Federal Law on Medicinal Products and Medical Devices (2002): <a href="http://www.swissmedic.ch/files/pdf/HMB_English_New_version.pdf">http://www.swissmedic.ch/files/pdf/HMB_English_New_version.pdf</a></p>	<p>Ordinance on Clinical Trials of Therapeutic Products, RS 812.214.2 (2004): <a href="http://www.swissmedic.ch/files/pdf/VKlin%20e%202005-03-14.pdf">http://www.swissmedic.ch/files/pdf/VKlin%20e%202005-03-14.pdf</a></p>	
<i>Privacy/Data Protection</i>	<p>Federal Data Protection Commissioner: <a href="http://www.edoeb.admin.ch/index.html?lang=en">http://www.edoeb.admin.ch/index.html?lang=en</a></p>	<p>1. Federal Law on Data Protection (1992) (French): <a href="http://www.admin.ch/ch/f/rs/c235_1.html">http://www.admin.ch/ch/f/rs/c235_1.html</a></p> <p>2. Regulation of June 14, 1993 Regarding the Release of Professional Secrets in the Area of Medical Research, RS 235.154 (French): <a href="http://www.admin.ch/ch/f/rs/235_154/index.html">http://www.admin.ch/ch/f/rs/235_154/index.html</a></p> <p>3. Confidentiality in Medical Research (2006) (French): <a href="http://www.admin.ch/ch/f/rs/311_0/a321bis.html">http://www.admin.ch/ch/f/rs/311_0/a321bis.html</a></p> <p>Note: Many Swiss cantons have enacted laws regarding data collection in the public sector.</p>		
<i>Human Biological Materials</i>	<p>Swiss Academy of Medical Sciences (SAMS): <a href="http://www.samw.ch/">http://www.samw.ch/</a></p>			<p>SAMS: Biobanks: Obtainment, Preservation and Utilization of Human Biological Material (2006)</p>
<i>Genetic Research</i>	<p>1. Swiss Academy of Medical Sciences: <a href="http://www.samw.ch/">http://www.samw.ch/</a></p> <p>2. Swiss Society of Medical Genetics: <a href="http://www.ssgm.ch/">http://www.ssgm.ch/</a></p>	<p>Swiss Federal Constitution, Article 119 (2006): <a href="http://www.oefre.unibe.ch/law/icl/sz00000_.html">http://www.oefre.unibe.ch/law/icl/sz00000_.html</a></p>	<p>Ordinance on Clinical Trials of Therapeutic Products RS 812.214.2, Section 2 (2004): <a href="http://www.swissmedic.ch/files/pdf/VKlin%20e%202005-03-14.pdf">http://www.swissmedic.ch/files/pdf/VKlin%20e%202005-03-14.pdf</a></p>	

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<b>Turkey</b>				
Note: For an overview of human subject protections in Turkey, see "National Regulations on Ethics and Research in Turkey." <a href="http://ec.europa.eu/research/science-society/pdf/tr_eng_lr.pdf">http://ec.europa.eu/research/science-society/pdf/tr_eng_lr.pdf</a>				
<i>General</i>	Ministry of Health	1. Turkish Constitution, Article 17 2. Health Services Basic Law No. 3359 (1987) 3. Oviedo Convention on Human Rights and Biomedicine, Articles 15-18 (1999)	1. Regulation on Medical Deontology, Article 11 (1960) 2. Regulation on Medical Research (1993) 3. Bylaw on Patient Rights No. 23420 (1998)	
<i>Drugs</i>	Ministry of Health	Turkish Penal Law, Article 90 (2005)	1. Bylaw on the Clinical Trials Conducted by Medical Products Used in Humans (1995) 2. Bylaw on the Evaluation and Monitoring of the Safety of Medical Products (2005)	1. Guideline of Good Clinical Practice (1995) 2. Guideline of Compassionate Use of Experimental Drugs (2006)
<i>Human Biological Materials</i>		1. Law on Procurement, Preservation, Grafting, and Transplantation of Organs and Tissues, No. 2238 (1979) 2. Law on Blood and Blood Products, No. 2857 (1983)	Regulation on Blood and Blood Products, No. 7314 (1983)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999)
<i>Genetic Research</i>			Regulation on Centers for Diagnosis and Genetic Diseases, No. 23368 (1998)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14 (1999)
<i>Embryos, Stem Cells, and Cloning</i>			Regulation on Centers for Medically Assisted Procreation, No. 19551 (1987)	1. Circular on Research of Embryonic Stem Cells (2005) 2. Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)
<b>Ukraine</b>				
Note: For an overview of human subject protections in the Ukraine, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 10: <a href="http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf">http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf</a>				
<i>General</i>	1. Ethical Commission with the Higher Education Committee (EC-HEC)		EC-HEC: Order of this Committee for Requirements of Ethical Review of All Dissertation Theses on Science, Degree in Biology, Medicine, and Veterinary Medicine (2005)	
<i>Drugs</i>	1. State Pharmacological Center: <a href="http://www.pharmaceutical-center.kiev.ua/old/index_a.html">http://www.pharmaceutical-center.kiev.ua/old/index_a.html</a> 2. Ukrainian Ministry of Health,	On Medicines, Articles 7 and 8 No. 123/96BP (1996): <a href="http://www.pharmaceutical-center.kiev.ua/view/ua/zakon">http://www.pharmaceutical-center.kiev.ua/view/ua/zakon</a>	1. Ukrainian Ministry of Health Decree No. 373 About Approval of Documents Related to the Standardization, Registration and	Central Ethics Committee: On Ethics Questions of Clinical Trials and Implementation of Medicines (2006)

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	Central Ethics Committee: <a href="http://www.moz.gov.ua/en/main/siterubr/">http://www.moz.gov.ua/en/main/siterubr/</a>		Conduct of Clinical Trials of Study Drugs 42-7.0:2005 (2005) 2. Ukrainian Ministry of Health Order No. 66 About Approval of Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials and Model Regulations of the Ethics Committee (2006): <a href="http://www.pharma-center.kiev.ua/old/orders/Order_66.doc">http://www.pharma-center.kiev.ua/old/orders/Order_66.doc</a>	
<i>Privacy/Data Protection</i>		Information Act from the Cabinet of Ministers of the Ukraine (1992)		
<i>Human Biological Materials</i>	Ukrainian Ministry of Health: <a href="http://www.moz.gov.ua/en/main/siterubr/">http://www.moz.gov.ua/en/main/siterubr/</a>		Order of Ministry of Health: For the Improvement of Ukrainian Regulations and Harmonization of Legislation for European Transplantation Standards in Organs, Tissues, and Cell Procurement and Transplantations No. 650 (2006)	
<i>Genetic Research</i>	Academy of Medical Sciences of the Ukraine			Medical and Ethical Guidelines for Genetic Investigations in Humans
<i>Embryos, Stem Cells, and Cloning</i>	National Bioethics Committee of the National Academy of Sciences of the Ukraine (NBC) Ukrainian Ministry of Health: <a href="http://www.moz.gov.ua/en/main/siterubr/">http://www.moz.gov.ua/en/main/siterubr/</a>	1. About the Ban of Human Reproductive Cloning (2004) 2. About Organs and Other Human Materials Transplantology No. 1007-XIV (2007)	1. Recommendation No. 1046, Use of the Human Fetus for the Purpose of Diagnosis, Therapy, Research, Industrial Purchase, and Trading (1986) 2. Order of the Ministry of Health: For Adoption of the Regulations Concerning the Investigations of Human Stem Cells, Clinical Trials for Cells, and Tissue Transplantations (2006)	NBC: Ethical Regulations and Problems of Embryo-Tissue Storage (Recommendations)
<b>United Kingdom</b>				
Note: Unless otherwise noted, all laws, regulations, and guidelines listed for England apply to the entire United Kingdom.				
<i>General</i>	<i>England:</i>			
	1. Department of Health (DH): <a href="http://www.dh.gov.uk/Home/fs/en">http://www.dh.gov.uk/Home/fs/en</a> 2. National Research Ethics Service	Mental Capacity Act 2005, Sections 30-34 (England and Wales):		DH: 1. Research Governance Framework for Health and Social Care (2005)

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	<p>(NRES):  <a href="http://www.nres.npsa.ults.uk/index.htm">http://www.nres.npsa.ults.uk/index.htm</a></p> <p>3. Medical Research Council (MRC):  <a href="http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm">http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm</a></p> <p>4. Royal College of Physicians:  <a href="http://www.rcplondon.ac.uk/">http://www.rcplondon.ac.uk/</a></p> <p>5. Association of Research Ethics Committees: <a href="http://www.arec.org.uk/">http://www.arec.org.uk/</a></p> <p>6. Appointing Authority for Phase 1 Ethics Committees (AAPEC)  <a href="http://www.aapec.org.uk/">http://www.aapec.org.uk/</a></p> <p>7. Economic and Social Research Council (ESRC):  <a href="http://www.esrc.ac.uk/">http://www.esrc.ac.uk/</a></p>	<p><a href="http://www.opsi.gov.uk/acts/acts2005/20050009.htm">http://www.opsi.gov.uk/acts/acts2005/20050009.htm</a></p>		<p><a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962">http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962</a></p> <p>2. Governance Arrangements for NHS Research Ethics Committees (2001)  <a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005727">http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005727</a></p> <p>NRES:</p> <ol style="list-style-type: none"> <li>1. Standard Operating Procedures for Research Ethics Committees in the United Kingdom (2007)</li> <li>2. NRES Guidance on Information Sheets and Consent Forms (2007)</li> <li>3. NRES Guidance on Research Involving Adults Unable to Consent for Themselves (Including Guidance on the Mental Capacity Act 2005) (2007)</li> <li>4. Guidance for Applicants to NRES (2007)</li> <li>5. NRES Leaflets (2007): <ul style="list-style-type: none"> <li>• Building on Improvement</li> <li>• Research Ethics Timeline</li> <li>• Defining Research</li> <li>• Explaining Research</li> </ul> </li> </ol> <p>MRC:</p> <ol style="list-style-type: none"> <li>1. MRC Guidelines for Good Clinical Practice in Clinical Trials (1998)</li> <li>2. Interim Guidelines for Research Involving Human Participants in Developing Societies, Ethical Guidelines for MRC-Sponsored Studies (1999)</li> <li>3. Good Research Practice (2000)</li> <li>4. Personal Information in Medical Research (2000)</li> <li>5. Research Involving Human Participants in Developing Societies (2004)</li> <li>6. Medical Research Involving Children (2004)</li> </ol> <p>RCP:  Guidelines on the Practice of Ethics</p>

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				Committees in Medical Research with Human Participants (2007)  ESRC: Research Ethics Framework
	<i>Northern Ireland:</i>			
	Northern Ireland Health and Personal Social Services: <a href="http://www.dhsspsni.gov.uk/">http://www.dhsspsni.gov.uk/</a>			Research Governance Framework for Health and Social Care (2002)
	<i>Scotland:</i>			
	NHSScotland, Chief Scientist Office: <a href="http://www.show.scot.nhs.uk/cso/">http://www.show.scot.nhs.uk/cso/</a>	Adults with Incapacity (Scotland) Act 2000, Section 51: <a href="http://www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm">http://www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm</a>	Adults with Incapacity (Ethics Committee) (Scotland) Regulations (2002): <a href="http://www.scotland-legislation.hmsso.gov.uk/legislation/scotland/ssi2002/20020190.htm">http://www.scotland-legislation.hmsso.gov.uk/legislation/scotland/ssi2002/20020190.htm</a>	Research Governance Framework for Health and Community Care (2006)
	<i>Wales:</i>			
	Wales Office of Research and Development for Health and Social Care: <a href="http://www.word.wales.gov.uk/">http://www.word.wales.gov.uk/</a>			Research Governance Framework for Health and Social Care in Wales (2001)
<i>Drugs</i>	1. Medicines and Healthcare Products Regulatory Agency (MHRA): <a href="http://www.mhra.gov.uk">http://www.mhra.gov.uk</a> 2. Medical Research Council (MRC): <a href="http://www.mrc.ac.uk/index.htm">http://www.mrc.ac.uk/index.htm</a> 3. National Research Ethics Service (NRES): <a href="http://www.nres.npsa.nhs.uk/index.htm">http://www.nres.npsa.nhs.uk/index.htm</a>	Medicines Act (1968)	MHRA: 1. The Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004): <a href="http://www.uk-legislation.hmsso.gov.uk/si/si2004/20041031.htm">http://www.uk-legislation.hmsso.gov.uk/si/si2004/20041031.htm</a> 2. Amendment Regulations (SI 2006/1928) <a href="http://www.opsi.gov.uk/si/si2006/20061928.htm">http://www.opsi.gov.uk/si/si2006/20061928.htm</a> 3. Amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 and Adults with Incapacity (Scotland) Act 2000 to Facilitate Clinical Research in Emergency Settings (SI 2006/2984): <a href="http://www.opsi.gov.uk/si/si2006/20062984.htm">http://www.opsi.gov.uk/si/si2006/20062984.htm</a>	MHRA: Consultation Letter on the Medicines for Human Use (Clinical Trials) Regulations (2003)  MRC: 1. MRC Guidelines for Good Clinical Practice in Clinical Trials (1998) 2. MRC Policy on Antiretroviral Therapy for People Infected with HIV and Involved in AIDS Research in Developing Countries (2003)  NRES: Memorandum of Understanding between MHRA, COREC, and GTAC (2006) <a href="http://www.nres.npsa.nhs.uk/docs/guidance/MoU.pdf">http://www.nres.npsa.nhs.uk/docs/guidance/MoU.pdf</a>
<i>Privacy/Data Collection</i>	<i>England:</i>			
	1. Information Commissioner Office: <a href="http://www.informationcommissioner">http://www.informationcommissioner</a>	Data Protection Act (1998): <a href="http://www.opsi.gov.uk/acts/acts">http://www.opsi.gov.uk/acts/acts</a>		MRC: Personal Information in Medical Research

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	<a href="http://www.gov.uk/">.gov.uk/</a> 2. Medical Research Council (MRC): <a href="http://www.mrc.ac.uk/index.htm">http://www.mrc.ac.uk/index.htm</a>	<a href="http://www.opsi.gov.uk/acts/acts1998/19980029.htm">1998/19980029.htm</a>  A number of Statutory Instruments have been developed to implement the Data Protection Act: <a href="http://www.dca.gov.uk/ccpd/dpsubleg.htm">http://www.dca.gov.uk/ccpd/dpsubleg.htm</a>		(2003)
	<i>Scotland:</i> NHS Scotland: <a href="http://www.show.scot.nhs.uk/">http://www.show.scot.nhs.uk/</a>			Protecting Patient Confidentiality (2002)
<i>Human Biological Materials</i>	1. Royal College of Physicians (RCP): <a href="http://www.replondon.ac.uk/index.asp">http://www.replondon.ac.uk/index.asp</a> 2. Medical Research Council (MRC): <a href="http://www.mrc.ac.uk/index.htm">http://www.mrc.ac.uk/index.htm</a> 3. Department of Health (DH): <a href="http://www.dh.gov.uk/Home/fs/en">http://www.dh.gov.uk/Home/fs/en</a> 4. Human Tissue Authority (HTA): <a href="http://www.hta.gov.uk/">http://www.hta.gov.uk/</a>	1. Human Tissue Act (2004): <a href="http://www.opsi.gov.uk/acts/acts2004/20040030.htm">http://www.opsi.gov.uk/acts/acts2004/20040030.htm</a> 2. Statutory Instrument 2006 No. 1260: The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006: <a href="http://www.opsi.gov.uk/si/si2006/20061260.htm">http://www.opsi.gov.uk/si/si2006/20061260.htm</a> 3. Statutory Instrument 2006 No. 1659: The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006: <a href="http://www.opsi.gov.uk/si/si2006/20061659.htm">http://www.opsi.gov.uk/si/si2006/20061659.htm</a>		RCP: Research Based on Archived Information and Samples (1999)  MRC: Human Tissue and Biological Samples for Use in Research (2001)  DH: The Use of Human Organs and Tissue: An Interim Statement (2003): <a href="http://www.nres.npsa.nhs.uk/docs/guidance/MoU.pdf">http://www.nres.npsa.nhs.uk/docs/guidance/MoU.pdf</a>  HTA: Codes of Practice 2006
<i>Genetics Research</i>	1. Advisory Committee on Genetic Testing (ACGT): <a href="http://www.advisorybodies.doh.gov.uk/genetics/acgt/">http://www.advisorybodies.doh.gov.uk/genetics/acgt/</a> 2. Public Health Genetics Unit: <a href="http://www.phgu.org.uk/index.php">http://www.phgu.org.uk/index.php</a>			ACGT: Advice to Research Ethics Committees (1998)
<i>Embryos, Stem Cells, and Cloning</i>	Human Fertilisation and Embryology Authority: <a href="http://www.hfea.gov.uk/">http://www.hfea.gov.uk/</a>	Human Fertilisation and Embryology Act (1990): <a href="http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm">http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm</a>	Human Fertilisation and Embryology (Research Purposes) Regulation (2001)	



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<b>ASIA/PACIFIC/MIDDLE EAST</b>				
<b>Australia</b>				
<i>General</i>	National Health and Medical Research Council, Australian Health Ethics Committee: <a href="http://www.nhmrc.gov.au/ethics/human/ahec/index.htm">http://www.nhmrc.gov.au/ethics/human/ahec/index.htm</a>	National Health and Medical Research Council Act (1992): <a href="http://scaleplus.law.gov.au/html/pasteact/0/379/top.htm">http://scaleplus.law.gov.au/html/pasteact/0/379/top.htm</a>		1. Human Research Ethics Handbook – Commentary on the National Statement on Ethical Conduct in Research Involving Humans (2001) 2. Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) 3. Australian Code for the Responsible Conduct of Research (2007) 4. National Statement on Ethical Conduct in Human Research (2007)
<i>Drugs</i>	Therapeutic Goods Administration: <a href="http://www.tga.gov.au/ct/index.htm">http://www.tga.gov.au/ct/index.htm</a>	Therapeutic Goods Act (1989): <a href="http://www.comlaw.gov.au/comlaw/Legislation/ActCompilation1.nsf/0/697A52AA408416B4CA256FBF000F43EC?OpenDocument">http://www.comlaw.gov.au/comlaw/Legislation/ActCompilation1.nsf/0/697A52AA408416B4CA256FBF000F43EC?OpenDocument</a>	Therapeutic Goods Regulations (1991)	Human Research Ethics Committees and the Therapeutic Goods Administration (2001)
<i>Privacy/Data Protection</i>	<i>Federal:</i>			
	Office of the Privacy Commissioner: <a href="http://www.privacy.gov.au/">http://www.privacy.gov.au/</a>	Privacy Act No. 119 (1998), Incorporating Amendments up to Act No. 49 (2004): <a href="http://www.privacy.gov.au/publications/privacy88_030504.doc">http://www.privacy.gov.au/publications/privacy88_030504.doc</a>		
	<i>New South Wales:</i>			
		Privacy and Personal Information Protection Act (2005): <a href="http://www.austlii.edu.au/au/legis/nsw/consol_act/papipa1998464/index.html">http://www.austlii.edu.au/au/legis/nsw/consol_act/papipa1998464/index.html</a>		
<i>Victoria:</i>				
	Information Privacy Act No. 98 (2000): <a href="http://www.dms.dpc.vic.gov.au/Domino/Web_Notes/LDMS/PublicLawToday.nsf?OpenDatabase">http://www.dms.dpc.vic.gov.au/Domino/Web_Notes/LDMS/PublicLawToday.nsf?OpenDatabase</a>  Select “Acts,” then the letter “I,” then “Information Privacy Act.”			

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<i>Human Biological Materials</i>	National Health and Medical Research Council, Australian Health Ethics Committee (AHEC): <a href="http://www.nhmrc.gov.au/ethics/human/ahec/index.htm">http://www.nhmrc.gov.au/ethics/human/ahec/index.htm</a>			AHEC: National Statement on Ethical Conduct in Human Research (2007): Chapter 3.2 Databanks Chapter 3.4 Human Tissue Samples Chapter 4.1 Women Who are Pregnant and the Human Foetus
<i>Genetic Research</i>	National Health and Medical Research Council, Australian Health Ethics Committee: <a href="http://www.nhmrc.gov.au/ethics/human/ahec/index.htm">http://www.nhmrc.gov.au/ethics/human/ahec/index.htm</a>	Genetic Privacy and Non-Discrimination Act (1998): <a href="http://www.aph.gov.au/parlinfo/billsnet/98021.pdf">http://www.aph.gov.au/parlinfo/billsnet/98021.pdf</a>		AHEC: 1. Essentially Yours: The Protection of Human Genetic Information in Australia (2003) 2. National Statement on Ethical Conduct in Human Research, Chapter 3.5 Human Genetics (2007)
<i>Embryos, Stem Cells, and Cloning</i>	1. National Health and Medical Research Council, Australian Health Ethics Committee: <a href="http://www.nhmrc.gov.au/ethics/human/ahec/index.htm">http://www.nhmrc.gov.au/ethics/human/ahec/index.htm</a> 2. National Health and Medical Research Council Embryo Research Licensing Committee	1. Prohibition of Human Cloning for Reproduction Act (2002): <a href="http://www.austlii.edu.au/au/legis/cth/consol_act/pohcfra2002465/">http://www.austlii.edu.au/au/legis/cth/consol_act/pohcfra2002465/</a> 2. Research Involving Human Embryos Act (2006): <a href="http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/3F95E485D04231DCA2572F80003B1C3/\$file/ResearchInvolvingHumanEmbryosAct2002_WD02.pdf">http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/3F95E485D04231DCA2572F80003B1C3/\$file/ResearchInvolvingHumanEmbryosAct2002_WD02.pdf</a>	Research Involving Human Embryos Regulations (2003): <a href="http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/all/search/5D4B2F1A72744D3DCA257340000A1339">http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/all/search/5D4B2F1A72744D3DCA257340000A1339</a>	AHEC: 1. National Statement on Ethical Conduct in Human Research (2007): Chapter 3.6 Human Stem Cells 2. Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2007)
<b>Bangladesh</b>				
<i>General</i>	Bangladesh Medical Research Council, Ethics Review Committee			
<i>Drugs</i>	Bangladesh Directorate of Drug Administration: <a href="http://www.ddabd.org">http://www.ddabd.org</a>	1. The Drugs Act (1964) 2. Drugs (Control) Ordinance 1982, Ordinance No. VIII: <a href="http://www.ddabd.org/ordinance_1982.htm">http://www.ddabd.org/ordinance_1982.htm</a>		
<i>Human Biological Materials</i>	Bangladesh Medical Research Council, Ethics Review Committee			Guidelines for Transfer of Human Biological Materials Abroad for Research Purposes (2004)
<b>China, People's Republic of</b>				
<i>General</i>	1. Ministry of Health (MOH) (Mandarin): <a href="http://www.moh.gov.cn/">http://www.moh.gov.cn/</a> 2. Chinese Association for Science	Law on Practicing Doctors (June 26, 1998), Articles 26 and 37		MOH: Guidelines on Ethical Review of Biomedical Research Involving Human

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	and Technology (CAST) 3. Ministry of Science and Technology			Subjects (2007)  CAST: Moral Standards for Scientists (2007)
<i>Drugs</i>	State Food and Drug Administration: <a href="http://www.sfda.gov.cn/">http://www.sfda.gov.cn/</a>	Drug Administration Law (2001)	1. Chinese Good Clinical Practice (2003) 2. Qualification and Evaluation of Clinical Trial Sites 3. Regulation on Drug Registration (2007)	Guideline for HIV Vaccine Research Technology (2003)
<i>Privacy/Data Protection</i>	<i>Hong Kong:</i> Privacy Commissioner for Personal Data: <a href="http://www.pco.org.hk">www.pco.org.hk</a>	Personal Data (Privacy) Ordinance (1996): <a href="http://www.pco.org.hk/english/ordinance/ordfull.html">http://www.pco.org.hk/english/ordinance/ordfull.html</a>		
<i>Human Biological Materials</i>	Ministry of Health (Mandarin): <a href="http://www.moh.gov.cn/">http://www.moh.gov.cn/</a>		See: Procedures for Exporting Human and Animal Specimens from China (2003): <a href="http://www.usembassy-china.org.cn/sandt/Specimen-Export.htm">http://www.usembassy-china.org.cn/sandt/Specimen-Export.htm</a>	
<i>Genetic Research</i>	1. Ministry of Health (MOH) (Mandarin): <a href="http://www.moh.gov.cn/">http://www.moh.gov.cn/</a> 2. Ministry of Science and Technology (MOST)		MOH and MOST: Interim Measures for the Administration of Human Genetic Resources (1998)	
<i>Embryos, Stem Cells, and Cloning</i>	1. Ministry of Health (MOH) (Mandarin): <a href="http://www.moh.gov.cn/">http://www.moh.gov.cn/</a> 2. Ministry of Science and Technology (MOST)			MOH and MOST: Ethical Guideline for Researchers Involving Human Embryo Stem Cells (2004)
<b>India</b>				
<i>General</i>	1. National Committee for Ethics in Social Science Research in Health (NCESSRH) 2. Indian Council of Medical Research (ICMR), Central Ethics Committee on Human Research: <a href="http://www.icmr.nic.in/human_ethics.htm">http://www.icmr.nic.in/human_ethics.htm</a>			NCESSRH: Ethical Guidelines for Social Science Research (2000)  ICMR: Ethical Guidelines for Biomedical Research on Human Subjects (2006)
<i>Drugs</i>	1. Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): <a href="http://cdsco.nic.in">http://cdsco.nic.in</a> 2. Indian Council of Medical Research (ICMR), Central Ethics	Drugs and Cosmetics Act, Schedule Y (2005)	DCGI: Good Clinical Practices for Clinical Research in India (2001): <a href="http://cdsco.nic.in/html/GCP.htm">http://cdsco.nic.in/html/GCP.htm</a>	ICMR: Ethical Guidelines for Biomedical Research on Human Subjects: Statement of Specific Principles for Clinical Evaluation of Drugs/Devices/Diagnostics/Vaccines/Herbal Remedies (2006)

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	Committee on Human Research: <a href="http://www.icmr.nic.in/human_ethics.htm">http://www.icmr.nic.in/human_ethics.htm</a>			
<i>Genetic Research</i>	1. Department of Biotechnology (DBT): <a href="http://dbtindia.nic.in/">http://dbtindia.nic.in/</a> 2. Indian Council of Medical Research (ICMR), Central Ethics Committee on Human Research: <a href="http://www.icmr.nic.in/human_ethics.htm">http://www.icmr.nic.in/human_ethics.htm</a>	Environmental Protection Act		DBT: 1. Recombinant DNA Safety Guidelines (1990) 2. Ethical Policies on the Human Genome, Genetic Research, and Services (2002)  ICMR: Ethical Guidelines for Biomedical Research on Human Subjects: Statement of Specific Principles for Human Genetics and Genomics Research (2006)
<i>Embryos, Stem Cells, and Cloning</i>	Indian Council of Medical Research (ICMR), Central Ethics Committee on Human Research: <a href="http://www.icmr.nic.in/human_ethics.htm">http://www.icmr.nic.in/human_ethics.htm</a>			National Guidelines for Stem Cell Research and Therapy (2006)
<b>Indonesia</b>				
<i>Drugs</i>	Ministry of Health, National Institute of Health Research and Development	Indonesian Health Act No. 23 (1992)	Regulation No. 39/19 on Health Research and Development (1995)	Guidelines for Ethics in Health Research and Development (2002)
<b>Iran</b>				
<i>General</i>	Ministry of Health and Medical Education, Office for the Study of Humanistic and Islamic Science in Medicine and Medical Ethics: <a href="http://www.mohme.gov.ir/">http://www.mohme.gov.ir/</a>		Protection Code for Human Subjects in Medical Research (1999)	
<b>Israel</b>				
<i>General</i>	Ministry of Health: <a href="http://www.health.gov.il/english/">http://www.health.gov.il/english/</a>		Public Health Regulations (Medical Experiments Involving Human Subjects) (1999) (Hebrew): <a href="http://www.health.gov.il/pages/default.asp?maincat=11&amp;catid=301&amp;pageid=2203">http://www.health.gov.il/pages/default.asp?maincat=11&amp;catid=301&amp;pageid=2203</a>	
<i>Drugs</i>	Ministry of Health, Pharmaceutical Administration: <a href="http://www.health.gov.il/english/Pages/Default.asp?maincat=10">http://www.health.gov.il/english/Pages/Default.asp?maincat=10</a>	Public Health Order (1940)	1. Public Health Regulations (Clinical Studies in Human Subjects) – 1980 (Hebrew): <a href="http://www.health.gov.il/download/forms/a365_si12r_81.pdf">http://www.health.gov.il/download/forms/a365_si12r_81.pdf</a>	Guidelines for Clinical Trials in Human Subjects (2006) (English): <a href="http://www.health.gov.il/Download/pages/GuidelinesforClinicalTrials.doc">http://www.health.gov.il/Download/pages/GuidelinesforClinicalTrials.doc</a>

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			2. 1990 Amendment (Hebrew): <a href="http://www.health.gov.il/download/forms/a1962_mr98_90.pdf">http://www.health.gov.il/download/forms/a1962_mr98_90.pdf</a> 3. 1992 Amendment (Hebrew): <a href="http://www.health.gov.il/download/forms/a2117_mr23_92.pdf">http://www.health.gov.il/download/forms/a2117_mr23_92.pdf</a> 4. 2005 Amendment (Hebrew): <a href="http://www.health.gov.il/download/forms/a2672_mk07_05.pdf">http://www.health.gov.il/download/forms/a2672_mk07_05.pdf</a>	
<i>Privacy/Data Protection</i>	Registrar of Databases, Ministry of Justice	1. Privacy Protection Law No. 5741 (1981) (Hebrew): <a href="http://www.itpolicy.gov.il/topics_security/privacy.htm">http://www.itpolicy.gov.il/topics_security/privacy.htm</a> 2. Protection of Privacy Law No. 5741, as Amended by Law No. 5745 (1985)		
<i>Genetic Research</i>	Ministry of Health: <a href="http://www.health.gov.il/english/">http://www.health.gov.il/english/</a>	Genetic Information Law (2000) (Hebrew): <a href="http://www.moital.gov.il/NR/exeres/66F4DD4E-FA4A-4B76-94BC-DC29543471DE.htm">http://www.moital.gov.il/NR/exeres/66F4DD4E-FA4A-4B76-94BC-DC29543471DE.htm</a>		The Instruction of the Supreme Committee for Clinical Studies on Humans Regarding Establishment and Usage of Genetic Samples Reservoir (Hebrew): <a href="http://www.health.gov.il/download/forms/a2658_mk01_05.pdf">http://www.health.gov.il/download/forms/a2658_mk01_05.pdf</a> Amendment (Hebrew): <a href="http://www.health.gov.il/download/forms/a3037_mk17_07.pdf">http://www.health.gov.il/download/forms/a3037_mk17_07.pdf</a>
<i>Embryos, Stem Cells, and Cloning</i>		Genetic Intervention Prohibition Law (Human Cloning and Genetic Changes in Reproduction Cells) (1999)		
<b>Japan</b>				
<i>General</i>	1. Ministry of Education, Culture, Sports, Science, and Technology (MEXT) 2. Ministry of Health, Labor, and Welfare (MHLW)			MEXT and MHLW: Ethics Guidelines for Epidemiological Research (2007)  MHLW: Ethical Guidelines for Clinical Research (2004)
<i>Drugs</i>	1. Ministry of Health, Labor, and Welfare (MHLW) 2. Pharmaceuticals and Medical Devices Agency: <a href="http://www.pmda.go.jp/english/index.html">http://www.pmda.go.jp/english/index.html</a>	Pharmaceutical Affairs Law, Article 80-2 (2006)	MHLW: Good Clinical Practice Guidelines (2006)	

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<i>Privacy/Data Protection</i>	Several ministries have been designated to oversee this issue, including: 1. Ministry of Health, Labor, and Welfare 2. Ministry of Economy, Trade, and Industry 3. Ministry of Internal Affairs and Communications	Personal Information Protection Act (2003)		
<i>Genetic Research</i>	1. Ministry of Education, Culture, Sports, Science, and Technology (MEXT) 2. Ministry of Health, Labor, and Welfare (MHLW) 3. Ministry of Economy, Trade, and Industry (METI)			MEXT, MHLW, and METI: Ethics Guidelines for Human Genome/Gene Analysis Research (2005)  MEXT and MHLW: Guidelines for Clinical Research in Gene Therapy (2004)
<b>Jordan</b>				
<i>Drugs</i>	Jordan Food and Drug Administration: <a href="http://www.jfda.jo/en/default/">http://www.jfda.jo/en/default/</a>	1. Narcotic and Psychotropic Law No. 11 (1988) 2. Clinical Trial Law No. 67 (2001) 3. Pharmacy and Drug Law No. 80 (2001)		
<b>Kazakhstan</b>				
Note: For an overview of human subject protections in Kazakhstan, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 5: <a href="http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf">http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf</a>				
<i>General</i>	Bioethics Commission			Guidelines on Ethics in Health Research. (2007)
<i>Drugs</i>	Ministry of Health, Committee of Pharmacy (Kazakh): <a href="http://www.mz.gov.kz/">http://www.mz.gov.kz/</a>	Drug Law (13.01.2004 No. 522-2), Articles 19 and 20 (2004) (Kazakh): <a href="http://www.zakon.kz/">http://www.zakon.kz/</a>	1. Order 14.02.2005 No. 53 Instruction on the Conduct of Clinical Trials in Kazakhstan (2005) 2. Order 25.06.2007 # 442 Rules on Preclinical, Medico-Biological Experiments, and Clinical Trials in Kazakhstan (2007)	Guidelines on Clinical Trials in Kazakhstan (2003)
<i>Privacy/Data protection</i>	Ministry of Health (Kazakh): <a href="http://www.mz.gov.kz/">http://www.mz.gov.kz/</a>	Law on the Health Care System (4.06.2003 # 430-II) (2003) (Kazakh): <a href="http://www.zakon.kz/">http://www.zakon.kz/</a>		

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<b>Korea</b>				
<i>Drugs</i>	Korea Food and Drug Administration: <a href="http://www.kfda.go.kr/">www.kfda.go.kr/</a>	Pharmaceutical Affairs Law (1999)	Regulation for Evaluation on Safety and Efficacy of Drugs (2002)	
<i>Privacy/Data Protection</i>	1. Ministry of Government Administration and Home Affairs 2. Ministry of Health and Welfare	Act on the Protection of Personal Information Maintained by Public Agencies No. 4734 (1994)		
<i>Genetic Research</i>	Ministry of Health and Welfare: <a href="http://english.mohw.go.kr/">http://english.mohw.go.kr/</a>	Bioethics and Safety Act, Chapters 4 -6 (2004): <a href="http://www.ruhr-uni-bochum.de/kbe/Bioethics&amp;BiosafetyAct-SouthKorea-v1.0.pdf">http://www.ruhr-uni-bochum.de/kbe/Bioethics&amp;BiosafetyAct-SouthKorea-v1.0.pdf</a>		Guidelines for Research Involving Recombinant DNA Molecules (1997)
<i>Embryos, Stem Cells, and Cloning</i>	1. Ministry of Health and Welfare: <a href="http://english.mohw.go.kr/">http://english.mohw.go.kr/</a> 2. Ministry of Science and Technology	Bioethics and Safety Act, Chapter 3 (2004): <a href="http://www.ruhr-uni-bochum.de/kbe/Bioethics&amp;BiosafetyAct-SouthKorea-v1.0.pdf">http://www.ruhr-uni-bochum.de/kbe/Bioethics&amp;BiosafetyAct-SouthKorea-v1.0.pdf</a>		
<b>Kuwait</b>				
<i>General</i>	Ministry of Health, Kuwait Institute for Medical Specialization: <a href="http://www.kims.org.kw/">http://www.kims.org.kw/</a>			Ethical Guidelines for Biomedical Research: <a href="http://www.kims.org.kw/Ethical%202.doc">http://www.kims.org.kw/Ethical%202.doc</a>
<b>Nepal</b>				
<i>General</i>	Nepal Health Research Council: <a href="http://www.nhrc.org.np/">http://www.nhrc.org.np/</a>			National Ethical Guidelines for Health Research in Nepal (2001): <a href="http://www.nhrc.org.np/guidelines/nhrc_ethicalguidelines_2001.pdf">http://www.nhrc.org.np/guidelines/nhrc_ethicalguidelines_2001.pdf</a>
<i>Drugs</i>	Nepal Health Research Council: <a href="http://www.nhrc.org.np/">http://www.nhrc.org.np/</a>			National Guidelines on Clinical Trials with the Use of Pharmaceutical Products (2005): <a href="https://webapps.sph.harvard.edu/live/gremap/files/np_pharmaceutical_trial_guidelines.pdf">https://webapps.sph.harvard.edu/live/gremap/files/np_pharmaceutical_trial_guidelines.pdf</a>
<b>New Zealand</b>				
<i>General</i>	1. Health Research Council (HRC) Ethics Committee: <a href="http://www.hrc.govt.nz/">http://www.hrc.govt.nz/</a> 2. National Ethics Advisory Committee (NEAC): <a href="http://www.neac.health.govt.nz/">http://www.neac.health.govt.nz/</a> 3. Ministry of Health (MOH): <a href="http://www.moh.govt.nz/">http://www.moh.govt.nz/</a> 4. Health and Disability	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	HDC: The Code of Health and Disability Services Consumers' Rights (the Code of Rights) (2004): <a href="http://www.hdc.org.nz/">http://www.hdc.org.nz/</a>	HRC: 1. Guidelines for Researchers on Health Research Involving Māori (1998) 2. Guidelines on Ethics in Health Research (2005)  NEAC: 1. Goals, Objectives, and Desired Outcomes of an Ethical Review System