Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.personuvernd.is/tolvunefnd.nsf/pages/A6B42A045297151D00256DB40053600B		
Human Biological Materials	1. Ministry of Health and Social Security: http://ministryofhealth.is 2. National Bioethics Committee (NBC): www.visindasidanefnd.is	Act on Biobanks No. 110 (2000): http://ministryofhealth.is/laws-and-regulations/nr/31	Regulations on the Keeping and Utilization of Biological Samples in Biobanks No. 134 (2001): http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/684	NBC: 1. Biological Samples (2001) 2. Research Services
Ireland				
General	1. Irish Council for Bioethics (ICB): http://www.bioethics.ie 2. Irish Medicines Board (IMB): http://www.imb.ie/			ICB: Operational Procedures for Research Ethics Committees: Guidance 2004 IMB: Guide to Clinical Trials (2004)
Drugs	Irish Medicines Board: http://www.imb.ie/	1. Control of Clinical Trials and Drug Act (2006): http://www.irishstatutebook.ie/front.html 2. Statutory Instrument No. 190: European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations (2004)		
Privacy/Data Protection	Data Protection Commission	Data Protection Act (1988), as amended (2003)		
Human Biological Materials	Irish Council for Bioethics: http://www.bioethics.ie			Human Biological Material: Recommendations for Collection, Use, and Storage in Research (2005)
Embryos, Stem Cells, and Cloning		Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		
Italy				
General	1. National Federation of Ethics Committees (FNACE) (Italian): http://www.unich.it/fnace/ 2. National Monitoring Center for Clinical Trials (OSS): https://oss-sper-clin.agenziafarmaco.it/index_ingl.htm	Statute on the National Federation of Ethics Committees (1995) (Italian): http://www.unich.it/fnace/statuto.htm	FNACE: Regulation Implementing the Statute on the National Federal of Ethics Committees (1995) OSS: Ministerial Decree: Terms of	NBC: Opinion of the National Bioethics Committee on the European Protocol on Biomedical Research (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
	3. National Bioethics Committee (NBC): http://www.governo.it/bioetica/eng/index.html 4. Ministry of Health (Italian): http://www.ministerosalute.it		Reference for the Establishment and the Functioning of Ethics Committees (May 12, 2006)	
Drugs	1. National Monitoring Center for Clinical Trials: https://oss-sper-clin.agenziafarmaco.it/index_ingl.htm 2. Italian Medicines Agency (Italian): http://www.agenziafarmaco.it/ 3. Ministry of Health (MOH) (Italian): http://www.ministerosalute.it	1. Decree of the President of the Republic: Regulations to Simplify the Procedures and to Verify and Check New Systems and Experimental Therapeutic Protocols (September 21, 2001) (Italian): http://oss-sper-clin.agenziafarmaco.it/normativa/ , then select document in the left column. 2. Legislative Decree No. 211 (2003): Transposition of Directive 2001/20/EC Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Clinical Use (Italian): http://oss-sper-clin.agenziafarmaco.it/normativa/ , then select document in the left column. English: https://oss-sper-clin.agenziafarmaco.it/normativa/decreto_24062003_inglese.pdf	Italy has numerous regulations that govern drug research (Italian): http://oss-sper-clin.agenziafarmaco.it/normativa/ The following are the most important: 1. Ministerial Decree: Composition and Functions of Regional Bioethics Committees (November 1999) 2. Ministerial Decree: Controlled Clinical Trials in General Practice and Pediatrics (May 10, 2001) 3. Ministerial Decree: Non-profit Controlled Clinical Trials with Medicines (Dec. 17, 2004) 4. Ministerial Decree: Minimum Requirements or the Institution, Organization, and Functioning of Ethics Committees for Clinical Experimentation of Drugs (May 12, 2006)	
Privacy/Data Protection	Italian Data Protection Commission: http://www2.garanteprivacy.it/garante/frontdoor/1,1003,,00.html?LANG=2	Italian Personal Data Protection Code, Legislative Decree No. 196 of June 30, 2003: http://www.dataprotection.it/codice_privacy_english.htm	Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000)	
Genetic Research	1. Instituto Superiore di Sanita (ISS): http://www.iss.it/chis/?lang=2 2. Italian Society of Human Genetics (SIGU): http://www.sigu.net/news.php			ISS: Guidelines for Phase I Clinical Trials with Investigational Medicinal Products Employed in Gene Somatic Therapy (2004) (Italian): http://www.iss.it/binary/publ/publi/0478.1

Country	Key Organizations	Legislation	Regulations	Guidelines
				106653420.pdf SIGU: Guidelines for Genetic Biobanks (2003)
Latvia Note: For an overview of human subject protections in Latvia, see the report "National Regulations on Ethics and Research in Latvia:" http://ec.europa.eu/research/science-society/pdf/lv_eng_lr.pdf				
Drugs	State Agency of Medicines: http://www.vza.gov.lv/index.php?setlang=en&large=	Pharmaceutical Law, Amended June 15, 2004: http://www.ttc.lv/New/lv/tulkojumi/E0050.doc	Cabinet Regulation No. 172, Regulations Regarding the Conduct of Clinical Trials and Non-interventional Trials, the Procedures for the Labeling of Investigational Medicinal Products, and the Procedures for Inspection of Conformity with the Requirements of Good Clinical Practice (2006)	
Privacy/Data Protection	Data State Inspectorate: http://www.dvi.gov.lv/eng/	Personal Data Protection Law (2002): http://www.dvi.gov.lv/eng/legislation/pdp/		
Human Biological Materials	Central Medical Ethics Committee	Law on the Protection of Dead Human Beings and Use of Human Organs and Tissue (2001)	Cabinet Regulation No. 208 (2007)	
Genetic Research	1. Ministry of Health 2. Data State Inspectorate: http://www.dvi.gov.lv/eng/	Human Genome Research Law (2002): http://bmc.biomed.lu.lv/gene/print/Human%20Genome%20Research%20Law,%20Latvia.doc		
Embryos, Stem Cells, and Cloning	1. Ministry of Health 2. Ministry of Welfare	Sexual and Reproductive Health Law (2004): http://www.ttc.lv/New/lv/tulkojumi/E0750.doc	Cabinet Regulation No. 716 (2003)	
Lithuania Note: For an overview of human subject protections in Lithuania, see the report "National Regulations on Ethics and Research in Lithuania:" http://ec.europa.eu/research/science-society/pdf/lt_eng_lr.pdf				
General	1. Ministry of Health (MOH): http://www.sam.lt/en/ 2. Lithuanian Bioethics Committee (LBEC): http://be.sam.lt/btyr/eng/index.htm	1. Law on Ethics of Biomedical Research, No. VIII-1679 (2007): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=268769	MOH: 1. Decree on the Procedure to Issue Approvals to Conduct Biomedical Research, No. 570 (2000)	

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Oviedo Convention on Human Rights and Biomedicine (2002): http://conventions.coe.int/treaty/en/treaties/html/164.htm	2. Decree on the Procedure for the Estimation and Covering of Expenses Incurred by Research Subjects, No. 23 (2000) 3. Decree on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor No. 745 (2000) 4. Decree on the List of the Documents to be Presented by the Sponsor of Biomedical Research and (or) by the Principal Investigator in Order to be Authorized to Conduct Biomedical Research, No. 29 (2001) LBEC: Decree on the List of Documents to be Presented by the Sponsor of Medical Research and (or) by the Principal Investigator in Order to be Authorized to Conduct Biomedical Trial No. V-21 (2004)	
Drugs	1. State Medicines Control Agency (SMCA): http://www.vvkt.lt/?1950175871 2. Lithuanian Bioethics Committee (LBEC): http://be.sam.lt/btyr/eng/index.htm 3. Ministry of Health (MOH): http://www.sam.lt/en/	1. Law on Ethics of Biomedical Research, No. VIII-1679 (2000): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=268769 2. Law on Pharmacy, No. X-709 (2006) (Lithuanian): http://www3.lrs.lt/pls/inter2/dokpaieska.susije_l?p_id=280067&p_rys_id=14	SMCA: 1. Decree on Pediatric Clinical Trials No. 70 (2002) 2. Detailed Guidance for the Request for Authorisation of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authorities, Notification of Substantial Amendments, and Declaration of the End of the Trial (2006) LBEC: Decree on the Regulation for the Submission of the Documents to the Lithuanian Bioethics Committee to Issue Favourable Opinion to Conduct a Clinical Trial on Medicinal Products No.	LBEC: Recommendations on the Advertisements for Trial Subjects

Country	Key Organizations	Legislation	Regulations	Guidelines
			V-11 (2004) MOH: Health Care Ministry Decree on the Procedure to Issue Approvals to Conduct Clinical Trial on Medicinal Product, No. V-435 (2006)	
Privacy/Data Protection	State Data Protection Protectorate: http://www.cnpd.lu/en/index.html	Law on Legal Protection of Personal Data, No. IX-1296 (2004): http://www.ada.lt/images/cms/File/pers.data.prot.law.doc		
Human Biological Materials		Law on Human Tissue and Organ Donation and Transplantation (2000): http://www3.lrs.lt/pls/inter2/dokpaieska.showdoc_l?p_id=112278		
Embryos, Stem Cells, and Cloning	Ministry of Health (MOH): http://www.sam.lt/en/	1. Law on Ethics of Biomedical Research, No. VIII-1679, Article 3 (2000): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=268769 2. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings No. IX-1085 (2002): http://conventions.coe.int/Treaty/EN/Treaties/Html/168.htm	MOH: Decree on the Procedure to Issue Authorization for the Transit of Tissues of Human Embryonic Tissue, Embryonic Stem Cells and their Lines, Fetal Tissue, and Fetal Stem Cells throughout the Territory of the Republic of Lithuania, No. V-660 (2007)	
Luxembourg				
Drugs	1. Ministry of Health (French): http://www.ms.etat.lu/ 2. National Committee on Ethics in Research (CNER)	Hospitals Act of 1998, Article 25	Grand-Ducal Decree of 30th of May, 2005 on Good Clinical Practice	
Privacy/Data Protection	National Commission for Data Protection (French and German): http://www.cnpd.lu/	Law of August 2, 2002 on the Protection of Persons with Regard to the Processing of Personal Data as amended by a		

Country	Key Organizations	Legislation	Regulations	Guidelines
		law of July 27, 2007 (French): http://www.legilux.public.lu/leg/a/archives/2007/1310808/131080 8.pdf#page=11		
Macedonia				
General	Ministry of Health of Macedonia: http://www.zdravstvo.gov.mk/index.php			
Drugs	Macedonian Drug Agency	Drug Law (1998) (Macedonian): http://www.zdravstvo.gov.mk/documents/documents/zakon_za_lekovi.pdf	Regulations on Clinical Trials of Medicinal Products on Human Subjects (1998)	
Privacy/Data Protection	Directorate for Personal Data Protection	Law on Personal Data Protection (2005): http://www.ceecprivacy.org/pdf/Law%20on%20Personal%20Data%20Protection.pdf		
Malta Note: For an overview of human subject protections in Malta, see "National Regulations on Ethics and Research in Malta:" http://ec.europa.eu/research/science-society/pdf/mt_eng_lr.pdf				
General	Health Ethics Committee: http://sahha.gov.mt/pages.aspx?page=134			
Drugs	Medicines Authority: http://medicinesauthority.gov.mt/	Medicines Act, 2003 (English translation begins on page 66): http://www.doi.gov.mt/EN/parliamentacts/2003/Act%203.pdf As amended by Act No. III of 2004: http://www.doi.gov.mt/EN/parliamentacts/2004/ACTIIIe.pdf	Legal Notice 490: Clinical Trials Regulations, 2004 (Maltese): http://www.doi.gov.mt/EN/legalnotices/2004/11/LN490.pdf	Guidance Notes on Good Clinical Practice (2005)
Privacy/Data Protection	Office of the Data Protection Commissioner	Data Protection Act (2006)		
Moldova Note: For an overview of human subject protections in Moldova, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 7: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
Drugs	Ministry of Public Health, National Ethics Committee	Moldova Republic Law on Medicines of December 17, 1997, Articles 11 and 12	Ordnance No. 10: On Performance of Clinical Trials in the Republic of Moldova (2002)	
Montenegro				
Drugs	Ministry of Health of Montenegro: www.mz.cg.yu	Law for Drugs and Pharmacies of Montenegro, Articles 37-39		

Country	Key Organizations	Legislation	Regulations	Guidelines
Netherlands				
General	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl	1. Population Screening Act (1996): http://www.gr.nl/wbo.php?phpLang=en 2. Medical Research Involving Human Subjects Act (2006). 1998 version: http://www.ccmo-online.nl/hipe/uploads/downloads/WMO-English.doc 3. Medical Research (Human Subjects) Compulsory Insurance Decree (2003): http://www.ccmo-online.nl/hipe/uploads/downloads/Verzekeringsbesluit_2003-ENG(1).pdf	1. Concerning the Use of a Special Form (2002) 2. Concerning Requirements of Expertise of Accredited Review Board Members (2002) 3. Concerning the Organization and Working Method of Accredited Review Board Members (2003) 4. External Review Guideline (2004)	Manual for the Review of Medical Research Involving Human Subjects (2002)
Drugs	1. Ministry of Health, Welfare, and Sport (MHWS) 2. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl 3. Medicines Evaluation Board (MEB): http://www.cbg-meb.nl/uk/overcbg/index.htm	Medicines Act (2007) (Dutch): http://wetten.overheid.nl/cgi-bin/deeplink/law1/title=Geneesmiddelenwet	MHWS: 1. Medicines Act Decree (2007) (Dutch): http://wetten.overheid.nl/cgi-bin/deeplink/law1/title=Besluit%20Geneesmiddelenwet 2. Medicines Act Regulation (2007) (Dutch): http://wetten.overheid.nl/cgi-bin/deeplink/law1/title=Regeling%20Geneesmiddelenwet	CCMO: Clinical Research with Medicinal Products in the Netherlands: Instructional Manual (2005): http://www.ccmo-online.nl/hipe/uploads/downloads_cati/Instruction%20manual%20versie%202.pdf
Privacy/Data Protection	1. Federation of Biomedical Scientific Societies (FMWV) (Dutch): http://www.federa.org/ 2. Dutch Data Protection Authority: http://www.dutchdpa.nl/index.stm	Personal Data Protection Act (2004) (Dutch): http://www.cbpweb.nl/indexen/ind_wetten_wbp_wbp.stm English translation of 2000 version: http://home.planet.nl/%7Eprivacy1/wbp_en_rev.htm		FMWV: Code for Adequate Secondary Use of Data (2004): http://www.federa.org/DB_FILES/productie/general/1_78_301/Code%20of%20conduct%20for%20medical%20research%20.pdf
Human Biological Materials	Federation of Biomedical Scientific Societies (Dutch): http://www.federa.org/	Civil Code, Article 467 (1994) (Dutch): http://www.healthlaw.nl/wgboeng.html		Code for Proper Secondary Use of Human Tissue in the Netherlands (2002): http://www.federa.org/DB_FILES/productie/general/1_78_389/CodeProperSecondaryUseOfHumanTissue.pdf
Genetic Research	1. Research for Man and Environment (RIVM): http://www.rivm.nl	Medical Research Involving Human Subjects Act (2006).		RIVM, VROM, IGZ, and CCMO: Guidelines for Researchers on the

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of Housing, Spatial Planning, and Environment (VROM): www.vrom.nl 3. Dutch Health Care Inspectorate (IGZ): http://www.igz.nl/ 4. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/	1998 version: http://www.ccmo-online.nl/hipe/uploads/downloads/WMO-English.doc		Evaluation by Official Agencies of Gene Therapy Research (2005) (Dutch)
Embryos, Stem Cells, and Cloning	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl	1. Foetal Tissue Act (2001) 2. Embryo Act (2002)		
Norway Note: For an overview of human subject protections in Norway, see "Research Ethical Review in Norway": http://www.etikkom.no/English/NEM/REK/RREC				
General	1. Regional Committees for Medical Research Ethics (REK): http://www.etikkom.no/English/NEM/REK 2. National Committee for Medical Research Ethics (NEM): http://www.etikkom.no/English 3. National Committee for Research Ethics in the Social Sciences and the Humanities (NESH): http://www.etikkom.no/English/NESH 4. National Committee for Research Ethics in Science and Technology (NENT): http://www.etikkom.no/English/NENT	Law regarding Ethics and Integrity in Research (2006) (Norwegian): http://www.lovdata.no/all/hl-20060630-056.html	REK: Terms of Reference for the Regional Committees for Medical Research Ethics, Norway (2003) http://www.etikkom.no/English/NEM/REK/reference	NEM: 1. Research Ethical Review in Norway (1998) 2. NEM: Standard Operating Procedures for the Regional Committees for Medical Research Ethics (2002) NESH: Guidelines for Research Ethics in the Social Sciences, Law, and the Humanities (2001) NENT: Research Ethics Guidelines for Science and Technology (2007) (Norwegian): www.etikkom.no/retningslinjer/nent
Drugs	Norwegian Medicines Agency: http://www.regjeringen.no/en/dep/hod/About-the-Ministry/Subordinate-institutions/The-Norwegian-Medicines-Agency.html?id=279753		Regulation Relating to Clinical Trials on Medicinal Products for Human Use (2003)	1. Guidelines for the Regulations Concerning Clinical Trials of Human Drugs (1999) 2. Guidance to the Regulation (2004) (Norwegian): www.legemiddelverket.no/upload/78182/Endelig%20veiledning%202004.doc
Privacy/Data Protection	1. Data Inspectorate (DI): http://www.datatilsynet.no/templates/Page____194.aspx 2. National Committee for Research Ethics in the Social Sciences and the Humanities (NESH): http://www.etikkom.no/English/NESH	Personal Data Act No. 31 (2000): http://www.datatilsynet.no.htest.osl.basefarm.net/upload/Dokumenter/regelverk/lov_forskrift/lov-20000414-031-eng.pdf	DI: Regulations on the Processing of Personal Data (2003): http://www.datatilsynet.no.htest.osl.basefarm.net/upload/Dokumenter/regelverk/lov_forskrift/lov-20000414-031-eng.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	1. Ministry of Health and Care Services (MHCS): http://www.odin.no/hod/english/bn.html 2. Ministry of Education and Research (MER): http://www.odin.no/kd/english/bn.html	Act on Biobanks (February 21, 2003, No. 12): http://www.regjeringen.no/upload/kilde/hod/red/2005/0078/ddd/pdfv/242629-act_relating_to_biobanks_biobankloven_.pdf Act Relating to the Application of Biotechnology in Human Medicine, etc. (December 5, 2003, No. 100)	MHCS: Guidelines for the Norwegian Act on Biobanks (2003) (Norwegian): http://odin.dep.no/hod/norsk/publ/rundskriv/042051-990014/	
Genetic Research	1. Ministry of Health and Care Services (MHCS): http://www.odin.no/hod/english/bn.html 2. Norwegian Biotechnology Advisory Board: http://www.bion.no/index_eng.shtml 3. Regional Committees for Medical Research Ethics (REK): http://www.etikkom.no/English/NEM/REK	Act Relating to the Application of Biotechnology in Human Medicine, etc. (December 5, 2003, No. 100): http://www.odin.no/hod/english/doc/legislation/acts/048051-990012/dok-bn.html		
Embryos, Stem Cells, and Cloning	Directorate for Health and Social Affairs	Revised Act Relating to the Application of Biotechnology in Human Medicine (June 15, 2007) Regarding Changes in the Act Related to Stem Cell Research and Pre-implantation Diagnostics (2007)		
Poland Note: For an overview of human subject protections in Poland, see "National Regulations on Ethics and Research in Poland:" http://ec.europa.eu/research/science-society/pdf/pl_eng_lr.pdf				
General	1. Ministry of Health, Bioethics Appeals Commission (MOH): http://www.kb.mz.gov.pl/index_en.html 2. Supreme Council of Doctors (SCD) (Polish): www.nil.org.pl/xml/index	1. Constitution of the Republic of Poland, Article 39 (1997) 2. Medical Profession Act, Articles 21-29 (1997)	MOH: Order of the Minister of Health and Social Welfare on How to Establish, Finance, and the Mode of Action of Bioethics Committees (1999)	SCD: Code of Medical Ethics, Chapter II (2003)
Drugs	Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products (Polish): http://www.urpl.eu/english/	1. Pharmaceutical Law, Act of Sept. 6, 2001, Article 6 2. Act on Amendment of Pharmaceutical Law (2004)	1. Order of the Minister of Health in the Matter of Central Register of Clinical Trials (2004) 2. Decree of the Minister of Health on Clinical Trials on Minors (2004)	

Country	Key Organizations	Legislation	Regulations	Guidelines
			3. Order of the Minister of Finance Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2004) 4. March 11, 2005 Order of the Minister of Health Concerning Detailed Requirements of Good Clinical Practice (2005) 5. Concerning the Nature and Extent of Inspection of Clinical Trials (2005)	
Privacy/Data Protection	Inspector General for the Protection of Personal Data: http://www.giodo.gov.pl/168/j/en/	Act on the Protection of Personal Data (2006): http://www.giodo.gov.pl/data/filemanager_en/61.doc		
Human Biological Materials		1. Act of 26 October 1995 on the Collection and Transplantation of Cells 2. Act of 22 August 1997 on the Public Blood Service		
Portugal				
General	National Council of Ethics for the Life Sciences			1. Opinion 4/CNE/93 on Clinical Trials (1993) 2. Opinion 9/CNE/94 on Ethics Commissions (1994) 3. Doc. 13/CNECV/95 on Legislation on Clinical Trials and Ethics Committees (1995) 4. Doc. 34/CNECV/2001 on the Helsinki Declaration (2001)
Drugs	1. National Institute of Pharmacy and Medicines: http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH 2. Ethics Commission for Clinical Research (CEIC): http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/CEIC	1. Approval of the Applicable Legal Standards for the Conduct of Clinical Trials of Medicines for Human Use, Law No. 46/2004 2. Approval of the Composition, Operations, and Financing of the Ethics Commission for Clinical Research, Decree No. 57/2005 (Portuguese): http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FAR	Decree-Law No. 102/2007 of April 2	

Country	Key Organizations	Legislation	Regulations	Guidelines
		MACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/portaria_57-2005.pdf		
Privacy/Data Protection	National Data Protection Commission: http://www.cnpd.pt/english/index_en.htm	1. Constitution, Article 35 (1997) 2. Act on the Protection of Personal Data, No. 67/98 (1998): http://www.cnpd.pt/english/bin/legislation/Law6798EN.HTM		
Genetic Research	Ministry of Health	Law 12/2005		
Embryos, Stem Cells, and Cloning	National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/CNECV/SiteEntry/	Oviedo Convention on Human Rights and Biomedicine, Additional Protocol on Prohibition of Human Cloning (2002)		1. Opinion 15/CNECV/95 on Embryo Research (1995) 2. Opinion 47/CNECV/2005 on Stem Cell Research (2005)
Romania Note: For an overview of human subject protections in Romania, see "National Regulations on Ethics and Research in Romania:" http://ec.europa.eu/research/science-society/pdf/ro_eng_lr.pdf				
General	Ministry of Health (MOH) (Romanian): http://www.ms.ro/	1. Law 336/2002 2. Oviedo Convention on Human Rights and Biomedicine (2001)	Ordinance No. 57/16.08.2002 (2002)	
Drugs	1. Ministry of Health (MOH) (Romanian): http://www.ms.ro/ 2. National Medicines Agency: http://www.anm.ro/en/home.html		MOH: 1. Emergency Ordinance 152/1999 on Medicinal Products for Human Use 2. Order of MOH No. 615/2004 Transposing Directive 2001/20/EC of the European Parliament and of the Council (2004) 3. Order of MOH No. 1300/2004: Detailed Guidance on the Application Format and Documentation to be Submitted in an Application for an Ethics Committee Opinion on the Clinical Trial on Medicinal Products for Human Use (2004) 4. Order of MOH No. 1117/2004: Detailed Guidance for the Request for Authorization of a Clinical Trial on a Medicinal	MOH: Guideline for Clinical Trials in Pediatric Populations (CPMP/ICH/2711/99) (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
			Product for Human Use to the Competent Authorities, Approval of Substantial Amendments and Declaration of the End of the Trial (2004)	
Privacy/Data Protection	Romanian Ombudsman: http://www.avp.ro/indexen.html	Law No. 667/2001 On the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data	Regulations from April 17, 2002 on the Organization and Functioning of the Institution of the Advocate of the People: http://www.avp.ro/indexen.html Go to "Legislation," then "Regulations."	
Embryos, Stem Cells, and Cloning		Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		
Russia Note: For an overview of human subject protections in Russia, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 8: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
General	1. Federal Service on Surveillance in Healthcare and Social Development (Russian): http://www.roszdravnadzor.ru/ 2. National Ethics Committee	Constitution of the Russian Federation, Article 21 (1993): http://www.constitution.ru/en/10003000-03.htm	Federal Service on Surveillance in Healthcare and Social Development: Order No. 2314-Pr/07 17 on August 2007 About the Ethics Committee (Russian): http://www.roszdravnadzor.ru/about/news/11698	
Drugs	1. Ministry of Health (MOH) (Russian): http://www.minzdrav-rf.ru/ 2. Federal Agency for Technical Regulation and Metrology (GOST) (Russian): http://www.gost.ru 3. Ethics Committee of the Federal Service on Surveillance in Healthcare and Social Development (Russian): http://www.roszdravnadzor.ru/ 4. Scientific Center for Expertise of the Remedies for Medicinal Use (Russian): http://www.regmed.ru/	On Medicinal Products, Federal Law No. 86-FZ, Articles 35-41 (2006) (1998 version in Russian): http://www.medtran.ru/rus/trials/gov/zakon_86.htm	MOH: 1. Ministry of Health Order No. 103 (March 24, 2000) 2. Clinical Practice Rules in the Russian Federation, Minister's Decree #266 (2003) GOST: Good Clinical Practice. GOST-R 52379-2005 (September 27, 2005)	
Privacy/Data Protection		1. Federal Law of the Russian Federation on Information, Information Technologies, and Protection of Information (2006)		

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Federal Law of the Russian Federation on Personal Data (2006)		
Genetic		Federal Law of July 5, 1996, N OF 8'-FZ "About the Government Control in the Area of Genetic-Engineering Activity" (With changes of July 12, 2000) (Russian)		
Serbia				
Drugs	1. Ministry of Health (MOH) 2. Serbian Drug Agency	Law for Drugs and Pharmacies of the Republic of Serbia No. 84/2004	MOH: 1. Regulation on Conducting Drug Clinical Trials on Human Subjects 2. Regulation for Conducting Clinical Trials	
Slovak Republic Note: For an overview of human subject protections in the Slovak Republic, see "National Regulations on Ethics and Research in Slovak Republic:" http://ec.europa.eu/research/science-society/pdf/sk_eng_lr.pdf				
General	1. Ethics Committee of the Ministry of Health (Slovak): http://www.health.gov.sk/ 2. Institute of Medical Ethics and Bioethics: http://www.imeb.sk/en/index_en.htm	1. Act No. 576/2004 Coll., as amended by Act No. 282/2006 Coll. 2. Oviedo Convention on Human Rights and Biomedicine (1997)		
Drugs	State Institute for Drug Control: http://www.sukl.sk/	Act on Drugs and Medical Devices No. 140/1998, Coll., as amended by Act No. 545/2006	Ministerial Regulation No. 239/2004 Coll. on Clinical Investigations and Requirements for Good Clinical Practice (2004)	
Privacy/Data Protection	Office for Personal Data Protection: http://www.dataprotection.gov.sk/buxus/generate_page.php3?page_id=413	Act No. 428/2002 Coll. on Protection of Personal Data, as Amended (2005): http://www.privireal.org/content/dp/documents/SlovakiaAct428_2002%20_2005_PersonalData.pdf		
Human Biological Materials		Law No. 277/1994 Coll. on Health Care, Sections 45-47.		
Embryos, Stem Cells, and Cloning		Oviedo Convention on Human Rights and Biomedicine, Additional Protocol on Prohibition of Human Cloning (2002)		

Country	Key Organizations	Legislation	Regulations	Guidelines
Slovenia Note: For an overview of human subject protections in Slovenia, see "National Regulations on Ethics and Research in Slovenia:" http://ec.europa.eu/research/science-society/pdf/sl_eng_lr.pdf				
General		Oviedo Convention on Human Rights and Biomedicine (1997)		Slovenian Code of Medical Deontology, Articles 47-50 (1992)
Drugs	1. National Medical Ethics Committee (NMEC): http://www.mf.uni-lj.si/kme-nmec/ 2. Agency for Medicinal Products and Medical Devices (Slovenian): http://www2.gov.si/mz/mz-splet.nsf/f1?OpenFrameSet&Frame=main&Src=/mz/mz-splet.nsf/0/6A4C3562F6E310A4C1256B1E004D1B8F?OpenDocument		NMEC: 1. Ministerial Decree No. 30 (1995) 2. Statutory Notes (1998) 3. Slovenian Directive on Clinical Drug Testing No. 67.8372-8385 (2000) 4. On the Ethical Review of Phase IV Clinical Studies (2003) (Slovenian): http://www.mf.uni-lj.si/kme-nmec/Docu/Ocenjevanje_klin_studij_IV_faze.pdf	
Privacy/Data Protection	Inspectorate for Personal Data Protection	1. Personal Data Protection Act No. 59 (1999) 2. Act Amending the Personal Data Protection Act No. 57/2001		
Human Biological Materials	National Medical Ethics Committee (NMEC): http://www.mf.uni-lj.si/kme-nmec/		On Interventions into the Human Corpse Which are not Part of the Routine Autopsy and on Handling with Biologic Material of Human Origin (2004)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999)
Embryos, Stem Cells, and Cloning		Law on Biomedically Assisted Fertilization No. 70 (2000)		
Spain Note: For an overview of human subject protections in Spain, see "National Information – Spain": http://www.eurecnet.org/information/spain.html#6 . Spain is divided into 17 autonomous communities, many of which have their own laws and regulations pertaining to drug research and privacy/data protection.				
General	Coordinating Center for Ethical Committees on Clinical Research (Spanish): http://www.msc.es/profesionales/farmacia/ceic/home.htm			
Drugs	1. Spanish Agency for Medications and Health Products (Spanish): http://www.agemed.es/ 2. General Direction of Pharmacy – Autonomous Communities: http://www.agemed.es/en/actividad/in	1. Royal Decree 223/2004: Regulation of Medication Clinical Trials (Spanish): http://www.agemed.es/actividad/legislacion/espana/docs/RCL_2004_325Vigente2005-2.pdf	Clarification on the Application of the Law on Clinical Trials, Beginning May 1, 2004 (Version No. 3, September 2005)	

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

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Swedish Research Council (SRC): http://www.vr.se/english	3_460.aspx	http://www.epn.se/eng/start/2003_615.aspx 2. Statute No. 616 Containing Instructions for Regional Ethical Review Boards (2003): http://www.epn.se/eng/start/2003_616.aspx 3. Statute No. 617 Containing Instructions for the Central Ethical Review Boards (2003): http://www.epn.se/eng/start/2003_617.aspx	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)
Drugs	Medical Products Agency: http://www.lakemedelsverket.se/Tpl/StartPage____395.aspx	Pharmaceuticals Act No. 1992: 859 (Swedish): http://www.notisum.se/rnp/SLS/LAG/19920859.HTM	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)	
Privacy/Data Protection	Swedish Data Inspection Board: http://www.datainspektionen.se/in_english/start.shtml	Personal Data Act No. 204 (2002): http://www.datainspektionen.se/pdf/ovrigt/pul-eng.pdf		
Human Biological Materials	1. National Board of Health and Welfare (SOS) 2. Swedish Research Council (SRC): http://www.vr.se/english 3. Swedish National Biobank Program: http://www.biobanks.se/	Biobanks in Medical Care Act No. 297 (2002): http://www.sweden.gov.se/content/1/c6/02/31/26/f69e36fd.pdf	SOS: 1. Regulation No. 746 (2002) 2. SOSFS No. 11 (2002) 3. SOSFS No. 2 (2004)	SRC: Research Ethics Guidelines for Using Biobanks (2003)
Genetic Research	1. Ministry of Health and Social Affairs: http://www.sweden.gov.se/sb/d/2061 2. National Board of Health and Welfare	Act on Genetic Integrity (2006:351): http://www.notisum.se/rnp/sls/lag/20060351.htm		Genetics and Gene Technology in the Health Care: State of the Art and Guidelines for Ethical Considerations (1999)
Embryos, Stem Cells, and Cloning		Act on Genetic Integrity (2006:351): http://www.notisum.se/rnp/sls/lag/20060351.htm	Legal Regulation of Stem Cell Research 2002:119: http://www.regeringen.se/sb/d/108/a/2717	
Switzerland				
General	1. Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/		Many of the Swiss cantons have implemented regulations regarding human subject research	SAMS: Guidelines on Human Research (1997)

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

Country	Key Organizations	Legislation	Regulations	Guidelines
Turkey Note: For an overview of human subject protections in Turkey, see "National Regulations on Ethics and Research in Turkey:" http://ec.europa.eu/research/science-society/pdf/tr_eng_lr.pdf				
General	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)	
Drugs	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)
Human Biological Materials		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)
Genetic Research			Regulation on Centers for Diagnosis and Genetic Diseases, No. 23368 (1998)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14 (1999)
Embryos, Stem Cells, and Cloning			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)
Ukraine 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: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
General	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)	
Drugs	1. State Pharmacological Center: http://www.pharma-center.kiev.ua/old/index_a.html 2. Ukrainian Ministry of Health,	On Medicines, Articles 7 and 8 No. 123/96BP (1996): http://www.pharma-center.kiev.ua/view/ua/zakon	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)

Country	Key Organizations	Legislation	Regulations	Guidelines
	Central Ethics Committee: http://www.moz.gov.ua/en/main/siterubr/		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): http://www.pharma-center.kiev.ua/old/orders/Order_66.doc	
Privacy/Data Protection		Information Act from the Cabinet of Ministers of the Ukraine (1992)		
Human Biological Materials	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/main/siterubr/		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)	
Genetic Research	Academy of Medical Sciences of the Ukraine			Medical and Ethical Guidelines for Genetic Investigations in Humans
Embryos, Stem Cells, and Cloning	National Bioethics Committee of the National Academy of Sciences of the Ukraine (NBC) Ukrainian Ministry of Health: http://www.moz.gov.ua/en/main/siterubr/	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)
United Kingdom Note: Unless otherwise noted, all laws, regulations, and guidelines listed for England apply to the entire United Kingdom.				
General	*England:*			
	1. Department of Health (DH): http://www.dh.gov.uk/Home/fs/en 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)

Country	Key Organizations	Legislation	Regulations	Guidelines
	(NRES): http://www.nres.npsa.nhs.uk/index.htm 3. Medical Research Council (MRC): http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm 4. Royal College of Physicians: http://www.rcplondon.ac.uk/ 5. Association of Research Ethics Committees: http://www.arec.org.uk/ 6. Appointing Authority for Phase 1 Ethics Committees (AAPEC) http://www.aapec.org.uk/ 7. Economic and Social Research Council (ESRC): http://www.esrc.ac.uk/	http://www.opsi.gov.uk/acts/acts2005/20050009.htm		http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962 2. Governance Arrangements for NHS Research Ethics Committees (2001) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005727 NRES: 1. Standard Operating Procedures for Research Ethics Committees in the United Kingdom (2007) 2. NRES Guidance on Information Sheets and Consent Forms (2007) 3. NRES Guidance on Research Involving Adults Unable to Consent for Themselves (Including Guidance on the Mental Capacity Act 2005) (2007) 4. Guidance for Applicants to NRES (2007) 5. NRES Leaflets (2007): • Building on Improvement • Research Ethics Timeline • Defining Research • Explaining Research MRC: 1. MRC Guidelines for Good Clinical Practice in Clinical Trials (1998) 2. Interim Guidelines for Research Involving Human Participants in Developing Societies, Ethical Guidelines for MRC-Sponsored Studies (1999) 3. Good Research Practice (2000) 4. Personal Information in Medical Research (2000) 5. Research Involving Human Participants in Developing Societies (2004) 6. Medical Research Involving Children (2004) RCP: Guidelines on the Practice of Ethics

Country	Key Organizations	Legislation	Regulations	Guidelines
				Committees in Medical Research with Human Participants (2007) ESRC: Research Ethics Framework
	Northern Ireland:			
	Northern Ireland Health and Personal Social Services: http://www.dhsspsni.gov.uk/			Research Governance Framework for Health and Social Care (2002)
	Scotland:			
	NHSScotland, Chief Scientist Office: http://www.show.scot.nhs.uk/cso/	Adults with Incapacity (Scotland) Act 2000, Section 51: http://www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm	Adults with Incapacity (Ethics Committee) (Scotland) Regulations (2002): http://www.scotland-legislation.hmso.gov.uk/legislation/scotland/ssi2002/20020190.htm	Research Governance Framework for Health and Community Care (2006)
	Wales:			
	Wales Office of Research and Development for Health and Social Care: http://www.word.wales.gov.uk/			Research Governance Framework for Health and Social Care in Wales (2001)
Drugs	1. Medicines and Healthcare Products Regulatory Agency (MHRA): http://www.mhra.gov.uk 2. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm 3. National Research Ethics Service (NRES): http://www.nres.npsa.nhs.uk/index.htm	Medicines Act (1968)	MHRA: 1. The Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004): http://www.uk-legislation.hmso.gov.uk/si/si2004/20041031.htm 2. Amendment Regulations (SI 2006/1928) http://www.opsi.gov.uk/si/si2006/20061928.htm 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): http://www.opsi.gov.uk/si/si2006/20062984.htm	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) http://www.nres.npsa.nhs.uk/docs/guidance/MoU.pdf
Privacy/Data Collection	*England:*			
	1. Information Commissioner Office: http://www.informationcommissioner	Data Protection Act (1998): http://www.opsi.gov.uk/acts/acts		MRC: Personal Information in Medical Research

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

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ASIA/PACIFIC/MIDDLE EAST				
Australia				
General	National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/ethics/human/ahec/index.htm	National Health and Medical Research Council Act (1992): http://scaleplus.law.gov.au/html/pasteact/0/379/top.htm		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)
Drugs	Therapeutic Goods Administration: http://www.tga.gov.au/ct/index.htm	Therapeutic Goods Act (1989): http://www.comlaw.gov.au/comlaw/Legislation/ActCompilation1.nsf/0/697A52AA408416B4CA256FBF000F43EC?OpenDocument	Therapeutic Goods Regulations (1991)	Human Research Ethics Committees and the Therapeutic Goods Administration (2001)
Privacy/Data Protection	*Federal:*			
	Office of the Privacy Commissioner: http://www.privacy.gov.au/	Privacy Act No. 119 (1998), Incorporating Amendments up to Act No. 49 (2004): http://www.privacy.gov.au/publications/privacy88_030504.doc		
	New South Wales:			
		Privacy and Personal Information Protection Act (2005): http://www.austlii.edu.au/au/legis/nsw/consol_act/papipa1998464/index.html		
	Victoria:			
		Information Privacy Act No. 98 (2000): http://www.dms.dpc.vic.gov.au/Domino/Web_Notes/LDMS/PubLawToday.nsf?OpenDatabase Select "Acts," then the letter "I," then "Information Privacy Act."		

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Human Biological Materials	National Health and Medical Research Council, Australian Health Ethics Committee (AHEC): http://www.nhmrc.gov.au/ethics/human/ahec/index.htm			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
Genetic Research	National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/ethics/human/ahec/index.htm	Genetic Privacy and Non-Discrimination Act (1998): http://www.aph.gov.au/parlinfo/billsnet/98021.pdf		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)
Embryos, Stem Cells, and Cloning	1. National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/ethics/human/ahec/index.htm 2. National Health and Medical Research Council Embryo Research Licensing Committee	1. Prohibition of Human Cloning for Reproduction Act (2002): http://www.austlii.edu.au/au/legis/cth/consol_act/pohcfra2002465/ 2. Research Involving Human Embryos Act (2006): http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/03F95E485D04231DCA2572F80003B1C3/$file/ResearchInvolvingHumanEmbryosAct2002_WD02.pdf	Research Involving Human Embryos Regulations (2003): http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/all/search/5D4B2F1A72744D3DCA257340000A1339	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)
Bangladesh				
General	Bangladesh Medical Research Council, Ethics Review Committee			
Drugs	Bangladesh Directorate of Drug Administration: http://www.ddabd.org	1. The Drugs Act (1964) 2. Drugs (Control) Ordinance 1982, Ordinance No. VIII: http://www.ddabd.org/ordinance_1982.htm		
Human Biological Materials	Bangladesh Medical Research Council, Ethics Review Committee			Guidelines for Transfer of Human Biological Materials Abroad for Research Purposes (2004)
China, People's Republic of				
General	1. Ministry of Health (MOH) (Mandarin): http://www.moh.gov.cn/ 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

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

Country	Key Organizations	Legislation	Regulations	Guidelines
	Committee on Human Research: http://www.icmr.nic.in/human_ethics.htm			
Genetic Research	1. Department of Biotechnology (DBT): http://dbtindia.nic.in/ 2. Indian Council of Medical Research (ICMR), Central Ethics Committee on Human Research: http://www.icmr.nic.in/human_ethics.htm	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)
Embryos, Stem Cells, and Cloning	Indian Council of Medical Research (ICMR), Central Ethics Committee on Human Research: http://www.icmr.nic.in/human_ethics.htm			National Guidelines for Stem Cell Research and Therapy (2006)
Indonesia				
Drugs	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)
Iran				
General	Ministry of Health and Medical Education, Office for the Study of Humanistic and Islamic Science in Medicine and Medical Ethics: http://www.mohme.gov.ir/		Protection Code for Human Subjects in Medical Research (1999)	
Israel				
General	Ministry of Health: http://www.health.gov.il/english/		Public Health Regulations (Medical Experiments Involving Human Subjects) (1999) (Hebrew): http://www.health.gov.il/pages/default.asp?maincat=11&catid=301&pageid=2203	
Drugs	Ministry of Health, Pharmaceutical Administration: http://www.health.gov.il/english/Pages_E/default.asp?maincat=10	Public Health Order (1940)	1. Public Health Regulations (Clinical Studies in Human Subjects) – 1980 (Hebrew): http://www.health.gov.il/download/forms/a365_si12r_81.pdf	Guidelines for Clinical Trials in Human Subjects (2006) (English): http://www.health.gov.il/Download/pages/GuidelinesforClinicalTrials.doc

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

Country	Key Organizations	Legislation	Regulations	Guidelines
Privacy/Data Protection	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)		
Genetic Research	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)
Jordan				
Drugs	Jordan Food and Drug Administration: http://www.jfda.jo/en/default/	1. Narcotic and Psychotropic Law No. 11 (1988) 2. Clinical Trial Law No. 67 (2001) 3. Pharmacy and Drug Law No. 80 (2001)		
Kazakhstan Note: For an overview of human subject protections in Kazakhstan, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 5: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
General	Bioethics Commission			Guidelines on Ethics in Health Research. (2007)
Drugs	Ministry of Health, Committee of Pharmacy (Kazakh): http://www.mz.gov.kz/	Drug Law (13.01.2004 No. 522-2), Articles 19 and 20 (2004) (Kazakh): http://www.zakon.kz/	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)
Privacy/Data protection	Ministry of Health (Kazakh): http://www.mz.gov.kz/	Law on the Health Care System (4.06.2003 # 430-II) (2003) (Kazakh): http://www.zakon.kz/		

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Korea				
Drugs	Korea Food and Drug Administration: www.kfda.go.kr/	Pharmaceutical Affairs Law (1999)	Regulation for Evaluation on Safety and Efficacy of Drugs (2002)	
Privacy/Data Protection	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)		
Genetic Research	Ministry of Health and Welfare: http://english.mohw.go.kr/	Bioethics and Safety Act, Chapters 4 -6 (2004): http://www.ruhr-uni-bochum.de/kbe/BioethicsBiosafetyAct-SouthKorea-v1.0.pdf		Guidelines for Research Involving Recombinant DNA Molecules (1997)
Embryos, Stem Cells, and Cloning	1. Ministry of Health and Welfare: http://english.mohw.go.kr/ 2. Ministry of Science and Technology	Bioethics and Safety Act, Chapter 3 (2004): http://www.ruhr-uni-bochum.de/kbe/BioethicsBiosafetyAct-SouthKorea-v1.0.pdf		
Kuwait				
General	Ministry of Health, Kuwait Institute for Medical Specialization: http://www.kims.org.kw/			Ethical Guidelines for Biomedical Research: http://www.kims.org.kw/Ethical%202.doc
Nepal				
General	Nepal Health Research Council: http://www.nhrc.org.np/			National Ethical Guidelines for Health Research in Nepal (2001): http://www.nhrc.org.np/guidelines/nhrc_ethicalguidelines_2001.pdf
Drugs	Nepal Health Research Council: http://www.nhrc.org.np/			National Guidelines on Clinical Trials with the Use of Pharmaceutical Products (2005): https://webapps.sph.harvard.edu/live/gremap/files/np_pharmaceutical_trial_guidelines.pdf
New Zealand				
General	1. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ 2. National Ethics Advisory Committee (NEAC): http://www.neac.health.govt.nz/ 3. Ministry of Health (MOH): http://www.moh.govt.nz/ 4. Health and Disability	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): http://www.hdc.org.nz/	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

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

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

Country	Key Organizations	Legislation	Regulations	Guidelines
				Research on Populations Traumatized in Emergencies and Disasters g. Ethical Guidelines for HIV/AIDS Research h. Ethical Guidelines for Research on Assisted Reproductive Technology
Drugs	Bureau of Food and Drugs: http://www.bfad.gov.ph/		Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products (Administrative Order No. 47-a) (2001)	Ethical Guidelines for Clinical Trials on Drugs, Devices, and Diagnostics (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf
Genetic Research	Philippine Council for Health Research and Development, National Ethics Committee (PCHRD)			PCHRD: Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf
Embryos, Stem Cells, and Cloning	Philippine Council for Health Research and Development, National Ethics Committee (PCHRD): http://www.pchrd.dost.gov.ph/pchrd/			PCHRD: Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf
Singapore				
General	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Ministry of Health National Medical Ethics Committee (NMEC) 3. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org 4. Singapore Medical Council (SMC): http://www.smc.gov.sg	Medical Registration Act (Cap. 174) (1985): http://statutes.agc.gov.sg/	MOH: Directive of June 25, 1998: Hospital Ethics Committees	NMEC: Ethical Guidelines on Research Involving Human Subjects (1997) BAC: Research Involving Human Subjects: Guidelines for IRBs (2004) MOH: 1. Governance Framework for Human Biomedical Research (2007) 2. Operational Guidelines for IRBs (2007)
Drugs	1. Ministry of Health National Medical Ethics Committee (NMEC) 2. Health Sciences Authority of Singapore (HSA): http://www.hsa.gov.sg	1. Medicines Act Section 74 (Cap. 176) (1975): http://statutes.agc.gov.sg/ 2. Medicines (Clinical Trials) Regulations (2000)	Singapore Guideline for Good Clinical Practice (1998)	NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)

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

Country	Key Organizations	Legislation	Regulations	Guidelines
				(2006) 4. Announcement of Human Research Ethics Policy Guidelines (2007): http://www.doh.gov.tw/EN2006/DM/DM1_p01.aspx?class_no=246&now_fod_list_no=246&level_no=1&doc_no=50681
Drugs	1. Department of Health: http://www.doh.gov.tw/EN2006/index_EN.aspx 2. Center for Drug Evaluation: http://www.cde.org.tw		DOH: Guideline for Good Clinical Practice (2005)	DOH: 1. Operational Guideline for Drug Clinical Trials (2002) 2. Structure and Content of Clinical Study Reports (2003) 3. The Criteria for IRB review (2004) 4. Guidelines for Informed Consent Form of Pharmacogenetic Study (2005)
Privacy/Data Protection	Ministry of Justice	Computer-Processed Personal Data Protection Law (1995): http://www.privacyexchange.org/legal/nat/omni/taiwan.html		
Human Biological Materials				1. Good Tissue Practice (2002) 2. Guidelines for Collection and Use of Human Specimens for Research (2006): http://www.doh.gov.tw/EN2006/DM/DM1_p01.aspx?class_no=246&now_fod_list_no=246&level_no=1&doc_no=46850
Genetic Research	1. Department of Health: http://www.doh.gov.tw/EN2006/index_EN.aspx 2. National Science Council: http://web.nsc.gov.tw/default.asp?mp=7			Guidance for Informed Consent Form for Pharmacogenetic Research (2005)
Embryos, Stem Cells, and Cloning	Department of Health: http://www.doh.gov.tw/EN2006/index_EN.aspx			Policy Instructions on the Ethics of Human Embryo and Embryonic Stem Cell Research (2007): http://www.doh.gov.tw/ufile/doc/Policy%20Instructions%20on%20the%20Ethics%20of%20Human%20Embryos.pdf
Tajikistan Note: For an overview of human subject protections in Tajikistan, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 9: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
General	1. Ministry of Public Health 2. Republic Committee on Medical Ethics		1. Order of the Ministry of Public Health of the Republic Tajikistan of 10 March, 2005 No. 118: About the Assertion of the Normative Documents of	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Republic Committee on Medical Ethics (Russian) 2. Position of the Republic Committee on Medical Ethics, Affirmed by the Order of the Ministry of Public Health of Republic Tajikistan of March 10, 2005, No. 118 (Russian)	
Thailand				
General	1. National Research Council of Thailand (NCRT): http://www.nrct.net/eng 2. Medical Council of Thailand (MCT) (Thai): http://www.tmc.or.th		NCRT: Regulation on the Permission of Foreign Researchers (1982) MCT: Rule of the Medical Council on the Observance of Medical Ethics (2006)	MCT: National Guideline for Ethical Research on Human Subjects (2002)
Drugs	Food and Drug Administration, Drug Control Division: http://www.fda.moph.go.th/eng/index.stm/			Thailand Good Clinical Practice Guidelines (2002)
Privacy/Data Protection		1. Official Information Act, B.E. 2540 (1997) 2. National Health Act, B.E. 2549 (2006)		

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