Country	Key Organizations	Legislation	Regulations	Guidelines
		Act No XLVIII of 2003: http://abiweb.obh.hu/dpc/legislation/1992_LXIIIa.htm		
Human Biological Materials	Ministry of Health (EüM): http://www.eum.hu/?akt_menu=2&set_lang=2	Act LXXX of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Transplantation of Organs and Tissues of Human Origin		
Embryos, Stem Cells, and Cloning	1. Ministry of Health (EüM): http://www.eum.hu/?akt_menu=2&set_lang=2 2. Medical Research Council	Act VI of 2002 on the Promulgation of the Convention on Human Rights and Medicine and the Additional Protocol on Cloning	Decree No 30/1998 (VI 24) of the Minister of Welfare on Regulations on Specific Procedures for Human Reproduction	
Iceland				
General	Ministry of Health and Social Security (MOH): http://ministryofhealth.is National Bioethics Committee (NBC): www.visindasidanefnd.is , then select "English" in the upper-right hand corner.	Act on the Rights of Patients No. 74 (1997): http://ministryofhealth.is/laws-and-regulations//nr/34	MOH: Regulation on Scientific Research in the Health Sector, No. 552 (1999)	NBC: 1. Research Projects 2. Withdrawal
Drugs	Icelandic Medicines Control Agency (MCA): www.lyfjastofnun.is National Bioethics Committee (NBC): www.visindasidanefnd.is	Medicinal Products Act No. 93 (1994): http://ministryofhealth.is/media/Laws%20in%20english/The_Medicinal_Products_Act_No_93-1994.pdf	MCA: Regulation on Clinical Trials of Medicinal Products in Humans No. 443 (2004): http://eng.heilbrigdisraduneyti.is/media/Reglugerdir-enska/Regulation_on_clinical_trials_of_medicinal_products_in_humans_No443-2004.pdf	
Privacy/Data Protection	Data Protection Authority: http://www.personuvernd.is/tolvunefnd.nsf/pages/english	1. Judgement by the Supreme Court of Iceland Concerning the Health Sector Database (2003): http://www.personuvernd.is/tolvunefnd.nsf/pages/60CD0F820FBD71D700256E4D004B1108 2. Act on the Protection of Privacy as Regards the Processing of Personal Data, No. 77/2000, as Amended (2003):	Government Regulation on a Health Sector Database No. 32 (2000): http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/670	

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		

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		law of July 27, 2007 (French): http://www.legilux.public.lu/leg/a/archives/2007/1310808/131008.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)	