Country	Key Organizations	Legislation	Regulations	Guidelines
EUROPE				
European-wide				
General	1. Council of Europe, Bioethics Division (CoE): http://www.coe.int/bioethics 2. European Commission Ethics Review (ECER): http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1289 3. European Commission Group on Ethics in Science and New Technologies (EGE): http://ec.europa.eu/european_group_ethics/index_en.htm			CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG ECER: Various: http://cordis.europa.eu/fp7/ethics_en.html EGE: Ethical Aspects of Clinical Research in Developing Countries (2003): http://ec.europa.eu/bepa/european-group-ethics/docs/avis17_en.pdf
Drugs and Devices	*Drugs*			
	1. European Commission, SANCO Pharmaceuticals Unit (EC): http://ec.europa.eu/health/index_en.htm 2. European Medicines Agency (EMA): http://www.ema.europa.eu/	EC: 1. Directive 2001/20/EC: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF 2. Directive 2005/28/EC: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_091/l_09120050409en00130019.pdf 3. Directive 3003/94/EC: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:262:0022:0026:EN:PDF 4. Directive 2001/83/EC: http://eur-	EC: EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/health/documents/eudralex/vol-10/index_en.htm	EC: EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/health/documents/eudralex/vol-10/ EMA: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997)

Country	Key Organizations	Legislation	Regulations	Guidelines
		lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0083:20121116:EN:PDF		
	Devices			
	European Commission, SANCO Cosmetics and Medical Devices: http://ec.europa.eu/health/medical-devices/index_en.htm	1. Directive 93/42/EEC Concerning Medical Devices: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF 2. Directive 98/79/EC on in vitro Diagnostic Medical Devices (IVDD): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:331:0001:0037:EN:PDF 3. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 Amending Council Directive 90/385/EEC on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices: http://ec.europa.eu/consumers/sectors/medical-devices/files/revision_docs/2007-47-en_en.pdf		Various: http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm
Research Injury	1. Council of Europe, Bioethics Division (CoE): http://www.coe.int/bioethics 2. European Medicines Agency (EMA): http://www.emea.europa.eu/	Clinical Trials Directive 2001/20/EC, Articles 3.2.f, 6.3.h, and 6.3.i: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF		CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, Article 13, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG
Privacy/Data Protection	1. European Commission (EC): http://europa.eu.int/ 2. Council of Europe (CoE), Data	EC: Data Protection Directive 95/46/EC of the European		CoE: 1. Convention for the Protection of Individuals with Regard to Automatic

Country	Key Organizations	Legislation	Regulations	Guidelines
	Protection and Cybercrime Division: http://www.coe.int/t/dghl/standardsetting/dataprotection/default_EN.asp 3. Council of Europe (CoE), Bioethics Division: http://www.coe.int/bioethics	Parliament and of the Council (1995): http://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf		Processing of Personal Data (1981): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=108&CL=ENG 2. Recommendation No. R (97) 5 on the Protection of Medical Data (1997): https://wcd.coe.int/ViewDoc.jsp?id=571075&Site=CM&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383
Human Biological Samples	1. European Commission (EC): http://europa.eu.int/ 2. Council of Europe, Bioethics Division (CoE): http://www.coe.int/bioethics 3. European Group on Ethics in Science and New Technologies (EGE): http://ec.europa.eu/bepa/european-group-ethics/welcome/index_en.htm 4. European Medicines Agency (EMEA): http://www.ema.europa.eu/	EC: Directive 2004/23/EC on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage, and Distribution of Human Tissues and Cells: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0023:EN:HTML		CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Recommendation Rec (2006) 4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin (2006): http://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75 EMA: Concept Paper on the Development of a Guideline on Biobanks Issues Relevant to Pharmacogenetics (2005) EGE: Ethical Aspects of Human Tissue Banking (1998)
Genetic Research	Council of Europe, Bioethics Division: http://www.coe.int/bioethics			1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol Concerning Biomedical Research, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG 3. Recommendation No. R (92) on

Country	Key Organizations	Legislation	Regulations	Guidelines
				Genetic Testing and Screening for Health Care Purposes (1992): http://wcd.coe.int/ViewDoc.jsp?id=612007&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75 4. Recommendation Rec (2006)4 of the Committee of Ministers to Members States on Research on Biomedical Materials of Human Origin (2006)4: http://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75
Embryos, Stem Cells, and Cloning	1. Council of Europe, Bioethics Division (CoE): http://www.coe.int/bioethics 2. European Group on Ethics in Science and New Technologies (EGE): http://ec.europa.eu/bepa/european-group-ethics/welcome/index_en.htm	EC: Decision No. 1982/2006/EC: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_412/l_41220061230en00010041.pdf		CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol on Prohibition of Human Cloning, ETS No. 168 (1998): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=168&CM=7&DF=9/15/2008&CL=ENG EGE: 1. Opinion No. 15 - Ethical Aspects of Human Stem Cell Research and Use (2000): http://ec.europa.eu/bepa/european-group-ethics/docs/avis15_en.pdf 2. Opinion No. 22 - The Ethics Review of hESC FP7 Research Projects (2007): http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_22_final_follow_up_en.pdf
Armenia Note: For an overview of human subject protections in Armenia, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 1: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf				
Drugs and Devices	1. Drug and Medical Technology Agency (Armenian): http://www.pharm.am/ 2. National Ethics Committee	1. Law of the Republic of Armenia of May 4, 1996: About Medical Aid, The Maintenance of the Population, Article 21 2. Resolution of the Government		

Country	Key Organizations	Legislation	Regulations	Guidelines
		of Armenia of January 24, 2002: Procedure for Clinical Trials of New Medications in Armenia		
Austria				
General	1. Ministry of Health (German): http://www.bmg.gv.at 2. Forum of Austrian Ethics Committees (German): http://www.ethikkommissionen.at 3. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	1. University Act (2011): http://www.ris.bka.gv.at/Dokumente/Erv/ERV_2002_1_120/ERV_2002_1_120.pdf 2. Hospitals Act (2011) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010285&ShowPrintPreview=True	Regulation on Leading Ethics Committees (2004) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20003352&ShowPrintPreview=True	Forum of Austrian Ethics Committees (German): Various: http://www.ethikkommissionen.at
Drugs and Devices	*Drugs*			
	1. Ministry of Health (German): http://www.bmg.gv.at 2. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/en/ages-austrian-agency-for-health-and-food-safety/ 3. Austrian Federal Office for Safety in Health Care: http://www.basg.at/en/austrian-federal-office-for-safety-in-health-care/	Austrian Drug Law (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True		Various (German): http://www.basg.at/arzneimittel/vor-der-zulassung/klinische-pruefungen/
	Devices			
	Same as Drugs.	Medical Devices Act (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003		Various (German): http://www.basg.at/medizinprodukte/formulare/klinische-pruefung/
Research Injury	1. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/en/ages-austrian-agency-for-health-and-food-safety/ 2. Austrian Federal Office for Safety in Health Care: http://www.basg.at/en/austrian-federal-office-for-safety-in-health-care/	Austrian Drug Law, Article 32 (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True Austrian Medical Devices Law, Article 47 (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003&ShowPrintPreview=True		

Country	Key Organizations	Legislation	Regulations	Guidelines
Privacy/Data Protection Note: The Austrian states also have privacy/data protection laws (German): http://www.dsk.gv.at/site/6202/default.aspx	Austrian Data Protection Commission: http://www.dsk.gv.at/DesktopDefault.aspx?alias=dsken	1. Federal Act Concerning the Protection of Personal Data (2014): http://www.ris.bka.gv.at/Dokumente/Erv/ERV_1999_1_165/ERV_1999_1_165.pdf		
Human Biological Materials	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	1. Law on Safety of Blood (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011145&ShowPrintPreview=True 2. Law on Quality and Safety of Human Tissue and Cells (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005698&ShowPrintPreview=True	Regulation on Tissue Banks (2008) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005848&ShowPrintPreview=True	Bioethics Commission: 1. Opinion of the Bioethics Commission at the Federal Chancellery: Biobanks for Medical Research (2007): http://www.bundeskanzleramt.at/DocView.axd?CobId=25510 2. Ruling of the Bioethics Commission: Cord Blood Banking (2008): http://www.bundeskanzleramt.at/DocView.axd?CobId=31001 3. Biobanks for Medical Research - Amendments to the Bioethics Commission Report of May 2007 (2011): http://www.bka.gv.at/DocView.axd?CobId=42719
Genetic Research	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	Gene Technology Act (2006) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826&ShowPrintPreview=True		
Embryos, Stem Cells, and Cloning	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	Reproductive Medicine Act (2010) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10003046&ShowPrintPreview=True		Bioethics Commission: Research on Human Embryonic Stem Cells (2009) (German): http://www.bundeskanzleramt.at/DocView.axd?CobId=34240
Belarus For an overview of human subject protections in Belarus, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 3: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf				
General	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. National Bioethics Committee	1. Constitution of the Republic of Belarus, Article 25 (2004) (Russian): http://www.pravo.by/WEBNPA/text.asp?RN=v19402875	MOH: 1. Decree No. No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html	MOH: 1. Code of Medical Ethics (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37726.html

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Law on Health Care System, Articles 40, 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	2. Ordinance No. 274 on Establishing the National Bioethics Committee (2006)	2. Guidelines for Ethics Committees on Standard Operational Proceedings (No. 55-0004, 2000) (Russian): http://www.levonevski.net/pravo/norm2009/num35/d35896/index.html 3. Methodological Guidelines of Health Ministry (2000)
Drugs and Devices	*Drugs*			
	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. State Pharmacological Committee 3. Centre for Expertise and Testing in Health Care (Russian): http://rceth.by/	1. Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435 2. Law on Drugs, Articles 15,16 (2009) (Russian): http://pravo.by/webnpa/text.asp?RN=h10600161	MOH: 1. Decree No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html 2. Ordinance No. 254 on Clinical Drug Trials and Good Clinical Practice (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num36/d36922/index.html 3. Decree No. 50 on certain aspects of Clinical Drug Trials (2009) (Russian): http://86.57.250.247/data/pravo/ipb_prikazmz/N50_2009.html 4. Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37336.html	MOH: Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004) (Russian): http://www.levonevski.net/pravo/norm2009/num24/d24926.html
	Devices			
	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. Centre for Expertise and Testing in Health Care (Russian): http://rceth.by/	Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: 1. Decree No. 216 on certain aspects of Clinical Trials of Medical Devices (2008) (Russian): http://86.57.250.247/data/pravo/ipb_prikazmz/N216_2008.htm 2. Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of	MOH: Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004) (Russian): http://www.levonevski.net/pravo/norm2009/num24/d24926.html

Country	Key Organizations	Legislation	Regulations	Guidelines
			Drugs and Medical devices (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37336.html	
Privacy/Data Protection	1. Ministry of Health: http://minzdrav.by/en/ 2. National Bioethics Committee	1. Constitution of the Republic of Belarus, Article 28 (2004) (Russian): http://www.pravo.by/WEBNPA/text.asp?RN=v19402875 2. Law on Health Care System, Article 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435		
Human Biological Materials	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. National Bioethics Committee 3. National Pathology Service 4. State Service of Forensic Medicine (SSFM)	Law on Health Care System, Articles 40 and 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: Ordinance No. 111 on Further Development of National Pathology Service (1993) (Russian): http://86.57.250.247/data/pravo/ipb_prikaznew/N111_1993(1994).doc SSFM: Ordinance No. 38-c on Rules for Conducting Morphological Examinations (1999)	
Belgium				
General	Belgium Advisory Committee on Bioethics (BACB): http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Commitees/Bioethics/?fodnlang=en	Law Relating to Experimentation on Humans (2004): http://www.erasme.ulb.ac.be/page.asp?id=11365&langue=EN		BACB (French): http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Commitees/Bioethics/Opinions/index.htm 1. Opinion No. 13: Regarding Experimentation on Man (2001) 2. Opinion No. 31: Regarding Experimentation Involving Pregnant and Breastfeeding Women (2004)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	Medicines Directorate-General (French): https://portal.health.fgov.be/portal/page?_pageid=56,512460&_dad=portal&_schema=PORTAL		1. Royal Decree of September 27, 1994. 2. Royal Decree of June 30, 2004 Determining the Implementation Measures of the Law 3. Royal Decree of June 30, 2004 Modifying the Royal Decree of June 6, 1960 4. Royal Decree of July 15, 2004 Determining Payments for Ethical Opinions or Authorization for the Conduct of a Clinical Trial or Experiment. 5. Application of the Law of May 7, 2004 Relating to Experiments on Human Volunteers who Participate in Phase I Trials (2004) 6. Explanations Concerning the Submission of a Request for an Ethical Opinion or Authorization for the Conduct of a Clinical Trial (2004)	
Research Injury		Law Relating to Experimentation on Humans, Chapter XVII (Responsibility and Insurance) Article 29 (2004)		
Privacy/Data Protection	Commission for the Protection of Privacy (French and Flemish): http://www.privacy.fgov.be/	Law of December 8, 1992 on Privacy Protection in Relation to the Processing of Personal Data as Modified by the Law of December 11, 1998 Implementing Directive 95/46/EC: http://www.law.kuleuven.ac.be/icri/itl/12privacylaw.php	Decree of February 13, 2001 Implementing the Law of December 8, 1999	
Human Biological Materials	1. Conseil Supérieur de la Santé/Hoge Gezondheidsraad (CSS) (French and Dutch): http://www.health.fgov.be/CSS_HGR 2. Federal Public Service: www.health.fgov.be	1. Royal Decree (1987) Regarding the Expression of Consent for the Removal of Organs and Tissues on Living Donors 2. Royal Decree (1997) Regarding the Removal and		CSS: Common Quality Standards for All Tissues and Cells of Human Origin Intended for Human Application (2007) (French): https://portal.health.fgov.be/pls/portal/docs/PAGE/INTERNET_PG/HOMEPAGE_MENU/ABOUTUS1_MENU/INSTITUTIONSAPPARE

Country	Key Organizations	Legislation	Regulations	Guidelines
		Allocation of Organs of Human Origin 3. Act on the Removal and Transplantation of Organs (2006) (French): http://www.staatsbladclip.be/lois/2006/08/28/loi-2006022815.html 4. 2007 Amendment (French): http://www.staatsbladclip.be/lois/2007/04/13/loi-2007022504.html		NTEES1_MENU/HOGEGEZONDHEIDSRAAD1_MENU/ADVIEZENENAANBEVELINGEN1_MENU/ADVIEZENENAANBEVELINGEN1_DOCS/7691_SQ_COMMUNS_2007_FR.PDF
Embryos, Stem Cells, and Cloning	1. Federal Public Service: www.health.fgov.be 2. Federal Commission for Medical and Scientific Research on Embryos in Vitro: http://health.belgium.be/eportal/Healthcare/Consultativebodies/Commissions/Embryoinvitro/19076630?ie2Term=research&ie2section=83	1. Royal Decree Fixing the Criteria for the Program Applicable to the Care Programs 'Reproductive Medicine' (15/02/1999) 2. Act on Research on Embryos in Vitro (2003): http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Belgium/page.aspx/164 3. Law on Medically Assisted Reproduction and the Destination of Supernumerary Embryos and Gametes (2007) (French): http://www.staatsbladclip.be/lois/2007/07/17/loi-2007023090.html		
Bosnia and Herzegovina				
General		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (2007): 2. Additional Protocol Concerning Biomedical Research, CETS No. 195 (2007)		
Drugs and Devices	*Federation of Bosnia and Herzegovina:* 1. Ministry of Health: http://www.fmoh.gov.ba/ 2. Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Law on Drugs No. 51/01: http://www.almbih.gov.ba/_doc/regulative/fbih/Zakon_o_lijekovima-sluzbene_novine_FBiH_broj_51-01.pdf 2. Law on Changes and Amendments of the Law on Drugs No. 29/05:	1. Regulation about Clinical testing of IMP and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf 2. Regulation about Medical Devices (2010): http://www.almbih.gov.ba/_doc/regul	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.almbih.gov.ba/_doc/regulative/fbih/Zakon_o_lijekovima-sluzbene_novine_FBiH_broj_29-05.pdf	ative/pravilnik_ms_bos.pdf 3. Standards of GCP in Conducting CTs (2012): http://www.almbih.gov.ba/_doc/regulative/Smjernice_dobre_klinicke_prakse-bo.pdf	
	Republic of Srpska: 1. Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx 2. Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Law on Drugs No. 19/01: http://www.almbih.gov.ba/_doc/regulative/rs/Zakon_o_lekovima.pdf 2. Law on Changes and Amendments of Law on Drugs No. 34/08: http://www.almbih.gov.ba/_doc/regulative/rs/ID_Zakona_o_lijekovima_34_08.pdf	1. Regulation about Clinical testing of IMP and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf 2. Regulation about Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_ms_bos.pdf 3. Standards of GCP in Conducting CTs (2012): http://www.almbih.gov.ba/_doc/regulative/Smjernice_dobre_klinicke_prakse-bo.pdf	
Research Injury	*Federation of Bosnia and Herzegovina:* Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.al.rs.ba	Medicinal Products and Medicinal Devices Act, Article 116: http://www.almbih.gov.ba/_doc/regulative/zakon_o_lijekovima_bih_bos.pdf	Regulation about Clinical Testing of IMP and Medical Devices, 4/10: http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf	
	Republic of Srpska: Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/	Law on Health Insurance of the Republic of Srpska, Official Gazette Republic of Srpska No. 51/01, 70/01, 51/03, 17/08, 1/09		
Privacy/Data Protection	Personal Data Protection Agency of Bosnia and Herzegovina: http://www.azlp.gov.ba/Default.aspx?langTag=en-US&template_id=147&pageIndex=1	1.Law on the Protection of Personal Data in Bosnia and Herzegovina (2001): http://www.azlp.gov.ba/images/PropisiBOS/Zakon_o_%20zastiti_licnih_podataka_u_BiH_BOS.pdf 2. Law about Amendments of Law on the Protection of Personal Data in Bosnia and Herzegovina, Official Gazette of Bosnia and Herzegovina No. 76/11: http://www.azlp.gov.ba/index.php?type=1&a=pages&id=2		

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells and Cloning		1. Law on Blood and Blood Products, Official Gazette of Bosnia and Herzegovina No. 09/10: http://www.fbihvlada.gov.ba/bosanski/zakoni/2010/zakoni/8bos.htm 2. Law on Transplantation of Organs and Tissues, Official Gazette of Bosnia and Herzegovina No. 75/09: http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-transplantaciji-organa-i-tkiva-u-svrhu-lijecenja		
Bulgaria				
General	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	1. Constitution of the Republic of Bulgaria, Article 29 (2007) 2. Oviedo Convention on Human Rights and Biomedicine (2001) 3. Law Ratifying the Additional Protocol on Biomedical Research (2006) 4. Healthcare Act, Articles 197 and 206 (2012) 5. Law on Medicinal Products in Human Medicine (2013)		
Drugs and Devices	*Drugs*			
	1. Ministry of Healthcare (MOH) (Bulgarian): http://www.mh.government.bg/ 2. Bulgarian Drug Agency (BDA) (Bulgarian): http://www.bda.bg/	Law for Medicinal Products in Human Medicine, Chapter 4 (2013)	MOH: Regulation No. 31 on the Rules for GCP (2012)	
	Devices			
	Bulgarian Drug Agency (BDA) (Bulgarian): http://www.bda.bg/			Various: http://www.bda.bg/index.php?option=com_content&view=category&layout=blog&id=60&Itemid=117&lang=en
Research Injury	Bulgarian Drug Agency (BDA) (Bulgarian): http://www.bda.bg/	Law on Medicinal Products in Human Medicine, Chapter 4, Articles 91 and 92 (2013): http://www.bda.bg/images/stories/d	Regulation 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice, Section 5.8 (2012): http://www.bda.bg/images/stories/doc	

Country	Key Organizations	Legislation	Regulations	Guidelines
		ocuments/regulations/zakoni/ZLPHM.pdf	uments/regulations/naredbi/naredba31.pdf	
Privacy/Data Protection	1. Bulgarian Commission for Personal Data Protection: http://www.ceecprivacy.org/main.php?s=2&k=bulgaria 2. Ombudsman: www.ombudsman.bg	Personal Data Protection Act (2006): http://www.ceecprivacy.org/pdf/law_bulgaria.pdf		
Human Biological Materials:	1. Executive Agency for Transplantation (Bulgarian): http://bgtransplant.bg/ 2. Council of Ministers, Ethics Committee for Transplantation	Law on Transplantation of Organs, Tissues, and Cells (2012): https://www.cpdp.bg/?p=element&aid=373	Regulation No. 13 of 04 April 2007 for the Terms and Conditions of Informing Bulgarian Citizens on the Activities regarding the Transplantation of Organs, Tissues and Cells	
Embryos, Stem Cells, and Cloning	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	Law Ratifying the Convention for Human Rights (2007) 2. SG No. 13/8, Article 134 (2008)		
Croatia Note: All websites and standards are in Croatian.				
General		1. Patient Protection Act, Article 20: http://narodne-novine.nn.hr/clanci/sluzbeni/313593.html 2. Oviedo Convention on Human Rights and Biomedicine (2003)		Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG
Drugs and Devices	*Drugs*			
	1. Ministry of Health and Social Welfare (MZSS): http://www.mspm.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.almp.hr/#	Medicinal Product Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html	MZSS: 1. Ordinance on Clinical Trials and Good Clinical Practice (2007): http://narodne-novine.nn.hr/clanci/sluzbeni/2010_01_14_347.html 2. Rule Book on Amendments to Ordinance on CTs and GCP: http://narodne-novine.nn.hr/clanci/sluzbeni/2010_11_127_3314.html	
	Devices			
	1. Ministry of Health and Social Welfare (MZSS): http://www.mzss.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.almp.hr/#	Medical Devices Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1521.html		

Country	Key Organizations	Legislation	Regulations	Guidelines
Research Injury	1. Agency for Medicinal Products and Medical Devices of Croatia: http://www.almp.hr/ 2. Ministry of Health: http://www.zdravlje.hr/	1. Law on Mandatory Health Insurance (2013): http://www.hzzo-net.hr/dload/zakoni/2013_06_80_1666.pdf 2. Medicinal Product Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html	Rules about Clinical Trials and Good Clinical Practice, Articles 12 and 13 (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2010_01_14_347.html	
Privacy/Data Protection	Croatian Personal Data Protection Agency: http://www.azop.hr/	1. Personal Data Protection Act (2012): http://www.legal500.com/c/croatia/developments/4908 http://narodne-novine.nn.hr/clanci/sluzbeni/2012_09_106_2300.html 2. Law about the Right to Access Personal Information (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_02_25_403.html		
Embryos, Stem Cells, and Cloning	Ministry of Health: http://www.zdravlje.hr/	1. 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 (2003) 2. Law about Blood and Blood Products from 2006: http://narodne-novine.nn.hr/clanci/sluzbeni/2006_07_79_1916.html 3. Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (2007) 4. Medical Fertilization Act: (2012): http://www.hzzo-net.hr/dload/zakoni/20_01.pdf 5. Rule Book on Amendments to Law about Blood and Blood Products (2011): http://narodne-novine.nn.hr/clanci/sluzbeni/2011_11_124_2476.html 6. Law on the Implementation of		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Human Tissues and Cells (2012): http://www.hzzo-net.hr/dload/zakoni/21.pdf		
Cyprus				
General		1. The Safeguarding and Protection of Patients' Rights Law (2004): http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/6960B7A5AA76C4A3C22571C9002B99F0?OpenDocument 2. Law No. 31 (III)/2001: Oviedo Convention on Human Rights and Biomedicine		
Drugs and Devices	1. Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/moh/moh.nsf/pharm_en/pharm_en?OpenDocument 2. Ministry of Health, National Bioethics Committee: http://www.moh.gov.cy	Law for Good Clinical Practice (2004)		
Research Injury	Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/moh/moh.nsf/pharm_en/pharm_en?OpenDocument	Legislation Concerning Medicinal Products of Human Use (Good Clinical Practice) No. 452/2004, Regulation No. 11 (8)		
Privacy/Data Protection	Commissioner's Office for the Protection of Personal Data: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/index_en/index_en?opendocument	1. Processing of Personal Data (Protection of Individuals) Law of 2001: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/138(I)-2001_en.pdf 2. Amended in 2003: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/37(I)-2003_en.pdf		
Embryos, Stem Cells, and Cloning		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		

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		Cloning Human Beings (2002)		
Czech Republic				
General	Ministry of Health, Central Ethics Committee (Czech): http://www.mzcr.cz	1. Oviedo Convention on Human Rights and Biomedicine (2001) 2. Act No. 130/2002 Collection on Research and Development Support, as Amended 3. Act No. 372/2011 on Healthcare Services 4. Act. No. 373/2011 on Specific Healthcare Services		
Drugs and Devices	*Drugs*			
	1. Ministry of Health (MOH) (Czech): http://www.mzcr.cz 2. State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lred=1	Act No. 378/2007 Collection on Pharmaceuticals	MOH: Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products	SUKL: Various: http://www.sukl.cz/medicinal-products-clinical-trials-guidelines-1
	Devices			
	State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lred=1	1. Act No 123/2000 Coll., on Medical Devices and on Amendments to Some Related Acts, as Amended 2. Act No 22/1997 Coll., on Technical Requirements for Products and Amendments to Some Related Acts	Various: http://www.sukl.cz/medical-devices?highlightWords=501%2F2000	Various: http://www.sukl.cz/medical-devices-guidelines
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
Privacy/Data Protection	Office for Personal Data Protection: http://www.uoou.cz/uoou.aspx	Act on the Protection of Personal Data and on Amendment to Some Related Acts (No. 101 of April 4, 2000): http://www.uoou.cz/uoou.aspx?menu=4&submenu=5	Position No. 3/2004 Personal Data Processing in the Context of Clinical Testing of Drugs and Other Medical Substances	
Embryos, Stem Cells, and Cloning	1. Ministry of Education, Youth, and Sport: http://www.msmt.cz/index.php?lchan=1&lred=1 2. Research and Development Council, Bioethical Commission:	1. Act of 26 April 2006 on Research on Human Embryonic Stem Cells No. 227/2006 Sb. (Coll.): http://www.eshre.com/ESHRE/English/Legal-Matters-and-		

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	http://www.vyzkum.cz/FrontClanek.aspx?idsekce=15908	Guidelines/Legal-documentation/Czech-Rep/page.aspx/165		
Denmark For an overview of human subject protections in Denmark, see http://www.cvk.sum.dk/cvk/site.aspx?p=119 .				
General	Danish National Committee on Biomedical Research Ethics (CVK): http://www.cvk.sum.dk/CVK/Home/English.aspx	1. Oviedo Convention on Human Rights and Biomedicine (1999) 2. Act on Research Ethics Review of Health Research Projects (2011): http://www.cvk.sum.dk/English/actonabiomedicalresearch.aspx	Ministerial Order No. 806 of 12 July 2004 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects (2004): http://www.cvk.sum.dk/English/ministerialorder806.aspx	1. Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics (2011): http://www.cvk.sum.dk/English/guidelinesaboutnotification.aspx 2. Appendices (2011)
Drugs and Devices	Danish Medicines Agency: http://www.dkma.dk	Medicinal Product Act No. 506 (2013)	1. Executive Order No. 935 on Informed Consent from Patients in Biomedical Trials (2011) 2. Executive Order on Clinical Trials on Medicinal Products, Human Use (2004) 3. Danish Guideline on Notification of Clinical Trials of Medicinal Products in Humans (2011)	Guideline on Informed Consent from Patients in Biomedical Trials (2011)
Research Injury	Danish Patient Insurance Association: http://www.patientforsikringen.dk/en.aspx	1. Liability for Damages Act (2007): http://www.patientforsikringen.dk/en/Love-og-Regler/Lov-om-klage-og-erstatningsadgang/Behandlingsskader.aspx 2. Danish Act on the Right to Complain and Receive Compensation within the Health Service No. 904 (2013): http://www.patientforsikringen.dk/en/Love-og-Regler/Lov-om-klage-og-erstatningsadgang/Lægemiddelskader.aspx		
Privacy/Data Protection	1. Danish Council of Ethics (DCE): http://www.etiskraad.dk/da-DK.aspx?sc_lang=en 2. Danish Data Protection Agency (DPA): http://www.datatilsynet.dk/english/	1. Act on Processing of Personal Data (Act No. 429) (2007): http://www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/ 2. Health Law Chapter 9 (2010)		DCE: Protection of Sensitive Personal Information Other:

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.privireal.group.shef.ac.uk/content/dp/denmark.php
Human Biological Materials	Danish National Committee on Biomedical Research Ethics (CVK): http://www.cvk.sum.dk/CVK/Home/English.aspx	Health Law, Chapter 7 (2005)		
Genetic Research		Act on the DNA Profile Register, Act No. 434 of 31 May 2000		
Embryos, Stem Cells, and Cloning	Danish Council of Ethics (DCE): http://www.etiskraad.dk/da-DK.aspx?sc_lang=en	1. Act on Medically Assisted Procreation No. 602 (2012) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002) 3. Health Law No. 913, Chapter 7 (2010)		DCE: 1. Cloning (2001) 2. Research in Human Gametes, Fertilized Ova, Embryos and Fetuses (2004)
Estonia				
General	Estonian Council on Bioethics	1. Constitution of the Republic of Estonia, Paragraph 18 (1992) 2. Oviedo Convention on Human Rights and Biomedicine (2002)		Code of Ethics of Estonian Scientists: http://www.akadeemia.ee/_repository/File/ALUSDOKUD/Code-ethics.pdf
Drugs and Devices	1. State Agency of Medicines: http://www.sam.ee/index.aw?set_lang_id=2 2. Minister of Social Affairs (MSA): http://www.sm.ee/eng.html	Medicinal Products Act, Chapter 5 (2005): http://www.sam.ee/en/clinical-trials-medicinal-products-estonia	MSA: 1. RTL 2001, 90, 1258: Requirements for Membership of Medical Ethics Committees for Clinical Trials, Rules of Procedures for Committee, Rate of Fee for Evaluation of Clinical Trials, and List of Information to be Submitted in Order to Obtain Approval (2001) 2. Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 (2005): http://www.sam.ee/627	
Research Injury	1. Minister of Social Affairs (MSA): http://www.sm.ee/eng.html 2. Estonian Health Insurance Fund: http://www.haigekassa.ee/eng/	Medicinal Products Act, Section 90: http://www.legaltext.ee/et/andmebas/tekst.asp?loc=text&dok=X90009	Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 of the Minister of Social	

Country	Key Organizations	Legislation	Regulations	Guidelines
		k2&keel=en&pg=1&ptyyp=RT&tyyp=X&query=ravimiseadus	Affairs of (2005): http://www.sam.ee/en/clinical-trials-medicinal-products-estonia	
Privacy/Data Protection	Estonian Data Protection Inspectorate: http://www.aki.ee/eng/	Personal Data Protection Act (2008): http://www.aki.ee/eng/?part=html&id=105		
Genetic Research		Human Genes Research Act (RT I 2000, 104, 685) (2000): http://www.geenivaramu.ee/index.php?id=98		
Embryos, Stem Cells, and Cloning		1. 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 (2002) 2. Artificial Insemination and Embryo Protection Act (2003)		
Finland				
General	1. Ministry of Social Affairs and Health (MSAH): http://www.stm.fi/en/frontpage 2. National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en 3. National Advisory Board on Research Ethics (TENK): http://www.tenk.fi/en/index.html	Medical Research Act No. 488/1999 (amended 295/2004 and 794/2010): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488	MSAH: 1. Decree on the National Committee on Medical Research Ethics No. 820/2010 2. Decree on the National Research Ethics Council of Finland No. 1347/2002 3. Decree on Medical Research and Subsidiary Regulations Issued in Pursuance Hereof, No. 313/2004 4. Decree on Clinical Trials on Medicinal Products No. 841/2010 5. Decree on Fees, No. 650/2013	TUKIJA: 1. Checklist for Researchers and Members of Ethics Committees (2009) (Finnish): http://www.tukija.fi/fi/julkaisut/ohjeet_ja_suositukset 2. Operating Procedures of National Committee on Medical Research Ethics (2010): http://www.tukija.fi/en/publications
Drugs and Devices	*Drugs*			
	1. Finnish Medicines Agency (FIMEA): http://www.fimea.fi/ 2. Ministry of Social Affairs and Health (MSAH): http://www.stm.fi	Medicines Act No. 395/1987 (Finnish): http://www.finlex.fi/fi/laki/smur/1987/19870395	FIMEA: 1. Several Decrees: http://www.finlex.fi/fi/laki/smur/1987/19870395#nojalla 2. Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2012 (Finnish): http://www.fimea.fi/download/22302	

Country	Key Organizations	Legislation	Regulations	Guidelines
			_Maarays_2-2012_kliiniset_laaketutkimukset.pdf	
	Devices			
	National Supervisory Authority for Welfare and Health (VALVIRA): http://www.valvira.fi/en/licensing/medical_devices	Medical Devices Act No. 629/2010 (Finnish): http://www.finlex.fi/fi/laki/kokoelma/2010/20100085.pdf	VALVIRA Various: http://www.valvira.fi/en/licensing/medical_devices/legislation	
Research Injury	1. Finnish Patient Insurance Centre (Finnish): http://www.potilasvakuutuskeskus.fi/www/page/pvk_www_2181 2. Pharmaceutical Injuries Insurance http://www.laakevahinko.fi/in-english/	Patient Injuries Act No. 585/1986 (Finnish): http://www.finlex.fi/fi/laki/ajantasa/1986/19860585		Pharmaceutical Injuries Insurance: General Terms and Conditions (2013): http://www.laakevahinko.fi/in-english/terms-and-conditions/
Privacy/Data Protection	Office of the Data Protection Ombudsman: http://www.tietosuoja.fi/1560.htm	Personal Data Act No. 523/1999 (Finnish): http://www.finlex.fi/fi/laki/ajantasa/1999/19990523		
Human Biological Materials	National Supervisory Authority for Welfare and Health (Finnish): http://www.valvira.fi/luvat/kudosluvat	Act on the Medical Use of Human Organs ,Tissues and Cells No. 101/2001 (Finnish): http://www.finlex.fi/fi/laki/ajantasa/2001/20010101 2. Law on Biobanks, No 688/2012 (Finnish and Swedish): http://www.finlex.fi/fi/laki/ajantasa/2012/20120688 3. Act of Medical Use of Human Organs and Tissues No 101/2001 (Finnish and Swedish): http://www.finlex.fi/fi/laki/ajantasa/2001/20010101	1. Decree on Consent for Biobank No. 643/2013 2. Decree on information on Biobank No. 649/2013	National Supervisory Authority for Welfare and Health (Finnish): http://www.valvira.fi/luvat/kudosluvat/lupa_elimien_kudoksien_ja_solujen_laaketieteelliseen_kayttoon
Genetic Research	1. National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en 2. Board for Gene Technology http://www.geenitekniikanlautakunta.fi/en	1. Medical Research Act No. 488/1999 (amended 295/2004 and 794/2010): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488 2. Gene Technology Act No. 377/1995		
Embryos, Stem Cells, and Cloning	1. National Supervisory Authority for Welfare and Health: http://www.valvira.fi/luvat/ 2. National Advisory Board on Research Ethics (TENK): http://www.tenk.fi/en/index.html	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002) 2. Medical Research Act No.		Report on Stem Cells, Cloning, and Research (2005): http://www.tukija.fi/en/publications/publications

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	3. National Committee on Medical Research Ethics (TUKIJA) http://www.tukija.fi/en 4. National Advisory Board on Social Welfare and Health Care Ethics (ETENE): http://www.etene.fi/en	488/1999 (amended 295/2004 and 749/2010): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488 3. Act on Assisted Fertility Treatments No. 1237/2006 http://www.finlex.fi/fi/laki/ajantasa/2006/20061237		
France				
General	1. Ministry of Social affairs and Health (French): http://www.sante.gouv.fr/ 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr/en 3. National Commission for Informatics and Freedoms (CNIL): http://www.cnil.fr/english/the-cnil/	1. Decree No. 97-555 Concerning the National Consultative Ethics Committee for Health and Life Sciences (1997): http://www.ccne-ethique.fr/decree_n_97555.php 2. Law No. 2004-806 of 9 August 2004 on Biomedical Research: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000441469&dateTexte=&categorieLien=id	Public Health Code Articles L1241-1: http://www.legifrance.gouv.fr/initRechCodeArticle.do	CCNE: Various: http://www.ccne-ethique.fr/opinions.php
Drugs and Devices	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr 2. National Health Products Safety Agency (ANSM): http://ansm.sante.fr/	Medications for Human Use, Articles L5121-11, L5124-1, and L5126-1) (2004): http://www.legifrance.gouv.fr/		CCNE: 1. Phase I Trials in Cancer (2002) 2. Transposition into French Law of the European Directive Relating to Clinical Trials on Medicinal Products: A New Ethical Framework for Human Research (2003)
Privacy/Data Protection	1. National Commission of Information and Liberty (CNIL): http://www.cnil.fr/index.php?id=4 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	Law 2004-801 of August 6, 2004 Modifying Law 78-17 of January 6, 1978 Relating to the Protection of Data Subjects as Regards the Processing of Personal Data	CNIL: Decree No. 2005-1309 of 20 October 2005 Enacted for the Application of Act No. 78-17 of 6 January 1978 on Data Processing, Files and Individual Liberties (Amended by Decree 2007-451 of 25 March 2007): http://www.cnil.fr/fileadmin/documents/en/Decree%202005-1309.pdf	CCNE: 1. Ethical Questions Arising from the Transmission of Scientific Information Concerning Research in Biology and Medicine (1995) 2. Biometrics, Identifying Data and Human Rights (2007)
Human Biological Materials	National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-	1. Donation and Use of the Components and Products of the Human Body, Articles L1211-1		CCNE: 1. Umbilical Cord Blood Banks for Autologous Use for Research (2002)

Country	Key Organizations	Legislation	Regulations	Guidelines
	ethique.fr	to L1274-3 (2004) (French): http://www.legifrance.gouv.fr/ 2. Public Health Code Articles L1241-1 and Following: (2010)		2. Ethical Issues Raised by Collections of Biological Material and Associated Information Data: "Biobanks," "Biolibraries" (2003)
Genetic Research	National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	Civil Code Articles 16-10 to 16-13: http://www.legifrance.gouv.fr/affichCode.do;jsessionid=D2DE023194483D3384DE19DE8959BDDA.tpdjo17v_3?idSectionTA=LEGISCTA000006136513&cidTexte=LEGITEXT000006070721&dateTexte=20131006		CCNE: 1. Opinion on Gene Therapy (1990) 2. Opinion regarding the Application of Genetic Testing to Individual Studies, Family Studies and Population Studies. (Problems Related to DNA "Banks," Cell "Banks," and Computerization) (1991) 3. Opinion that the Human Genome should not be Used for Commercial Purposes. Report. Thoughts Relating to Ethical Problems of Human Genome Research (1991) 4. Opinion on the Use of Somatic Gene Therapy Procedures. Report (1993)
Embryos, Stem Cells, and Cloning	National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	Law No. 2013-715 of 6th August 2013: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000027811435&dateTexte=&categorieLien=id		CCNE: 1. Commercialization of Human Stem Cells and Other Cell Line (2006) 2. Opinion on the Ethical Reflection Concerning Research on Human Embryonic Cells and on Human Embryos in Vitro (2010)
Georgia For an overview of human subject protections in Georgia, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 4: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf				
General		1. Oviedo Convention on Human Rights and Biomedicine ETS No.164 (2001) 2. Additional Protocol to the Convention's on Human Rights and Biomedicine, concerning Biomedical Research, ETS No. 195 (2010) 3. Law on Health Care, Chapter XIX (1997)		

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	Drug Agency of the Ministry of Labor, Health, and Social Affairs: http://www.healthministry.ge/eng/index.php	1. Drug and Pharmacy Law No. 659 (1997) 2. Licenses and Approvals Law (2005) 3. Law of Drug and Pharmaceutical Activity (2008)	Regulation about the Rules and Conditions of Issuing of the Approval of Clinical Trials Approved #176 (2005)	Order of Health Minister about Implementation of "ICH: E6 Good Clinical Practice: Consolidated Guidance (1996) including WMA: Declaration of Helsinki (2010)
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
Embryos, Stem Cells, and Cloning		1. Law on Health Care, Article 142 (1997) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning ETS No. 168 (2001)		
Germany For an overview of human subject protections in Germany, see http://www.eurecnet.org/information/germany.html				
General	1. German Medical Association (BÄK): http://www.bundesaerztekammer.de/page.asp?his=4.3569 2. Central Ethics Commission of the BÄK (German): www.zentrale-ethikkommission.de/ 3. Working Group of the Medical Ethics Committees in Germany (German): http://www.ak-med-ethik-komm.de/ 4. German Ethics Council (NER): http://www.ethikrat.org/?set_language=en 5. Federal Ministry of Health (BMG): http://www.bmg.bund.de/ministerium/english-version.html			BÄK: (Model) Professional Code of Conduct, Section 15 (2006) (German): http://www.bundesaerztekammer.de/page.asp?his=1.100.1143
Drugs and Devices	*Drugs*			
	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html 2. Federal Ministry of Education and Research (BMBF): http://www.bmbf.de/en/index.php 3. Paul Ehrlich Institute (PEI) (German):	Medicinal Products Act, Sections 40-42 (2013): http://www.bmg.bund.de/fileadmin/redaktion/pdf_gesetze/amg-engl.pdf	BfArM : 1. Promulgation on the Principles of the Conduct of Clinical Trials of Drugs According to the Rules (1987) 2. Second Promulgation on the Clinical Trial of Drugs in Human (1997)	BfArM: Third Announcement on Clinical Trials of Medicinal Products in Humans (2006): http://www.bfarm.de/EN/drugs/1_befAuth/clinTrials/clintrials-node_en.html

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.pei.de/cln_048/DE/home/de-node.html?__nnn=true 4. Federal Ministry of Health (BMG): http://www.bmg.bund.de/ministerium/english-version.html		3. Regulation for the Application of Good Clinical Practice of Clinical Medications for Human Use (2006) BMBF: Principles and Responsibilities Related to Clinical Studies (2003): http://www.bmbf.de/en/1173.php http://www.bmbf.de/en/4861.php	
	Devices			
	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html 2. Paul Ehrlich Institute (PEI) http://www.pei.de/EN/home/node.html	Act on Medical Devices (2013) (German): http://bundesrecht.juris.de/mpg/index.html Also see (German): http://www.dimdi.de/static/de/mpg/recht/index.htm	Various: http://www.dimdi.de/static/de/mpg/recht/index.htm	
Research Injury		Medicinal Products Act, Sections Section 40, Sub-section 3 (2013): http://www.bmg.bund.de/fileadmin/redaktion/pdf_gesetze/amg-engl.pdf		
Privacy/Data Protection Note: The 16 German states also have data protection laws (German): http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html	Federal Commissioner for Data Protection and Freedom of Information: http://www.bfdi.bund.de/EN/Home/homepage_node.html	Federal Data Protection Act, as Amended (2009): http://www.bfdi.bund.de/EN/DataProtectionActs/DataProtectionActs_node.html		
Human Biological Materials	1. German Society of Surgery (DGCH) (German): http://www.dgch.de/ 2. German Ethics Council (NER): http://www.ethikrat.org/welcome?set_language=en 3. Central Ethics Commission of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/	1. Transplantation Law (2012) (German): http://www.gesetze-im-internet.de/tpg/ 2. Transfusion Law (2009) (German): http://www.gesetze-im-internet.de/bundesrecht/tfg/gesamt.pdf 3. Act of Quality and Security of Human Tissue and Cells (2007)	DGCH Rule for the Production of Human Tissues (German)	NER: Opinion on Biobanks for Research (2004): http://www.ethikrat.org/_english/publications/Opinion_Biobanks-for-research.pdf ZEKO: Opinion of the Central Ethics Commission (2003) (German): http://www.zentrale-ethikkommission.de/downloads/Koerpermat.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
	4. German Institute for Cell and Tissue Replacement (DIZG) (German): http://www.dizg.de	(German): http://www.gesetze-im-internet.de/gewebeg/BJNR157400007.html		DIZG: 1. Ethical Code (2000) 2. Common Standards: Tissues and Cell Banking (2004)
Genetic Research	1. German Medical Association (BÄK): http://www.bundesaerztekammer.de/page.asp?his=4.3569 2. German Society of Human Genetics (GFHEV): http://www.gfhev.de/en/gfh/ 3. Paul-Ehrlich-Institut (PEI) (English): http://www.pei.de/EN/home/node.html	Law of 20 June 1990/16.12.1993 to Regulate Matters Related to Gene Technology (2006)		BÄK: Guideline on Gene Transfer (1995) (German) http://www.bundesaerztekammer.de/downloads/Gentransferpdf.pdf GFHEV: 1. Position Paper of the German Society of Human Genetics (1996) 2. DNA Banking and Personal Data in Biomedical Research: Technical, Social, and Ethical Questions (2004) PEI – Various: http://www.pei.de/DE/service/linklisten/links-gentherapie/links-thema-gentherapie-node.html
Embryos, Stem Cells, and Cloning	1. Federal Ministry of Education and Research (BMBF): http://www.bmbf.de/en/index.php 2. German Ethics Council (NER): http://www.ethikrat.org/welcome?set_language=en 3. Central Ethics Commission of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/ 4. German Research Foundation (DFG): http://www.dfg.de/en/ 5. Central Ethics Committee for Stem-Cell Research (ZES): http://www.rki.de/EN/Content/Institute/DepartmentsUnits/StemCell/StemCell_node.html	1. Embryo Protection Act (2011): http://www.auswaertiges-amt.de/cae/servlet/contentblob/480804/publicationFile/5162/EmbryoProtectionAct.pdf 2. Stem Cell Act (2013): English translation of 2002 version: http://www.bmj.bund.de/files/-/1146/Stammzellgesetz%20englisch.pdf BMBF: Law Allowing the Import of Embryonic Stem Cells (2002): http://www.bmbf.de/en/1056.php	Implementation Regulation for the Stem Cell Act (German): http://bundesrecht.juris.de/zesv/index.html	NER: 1. On the Import of Human Embryonic Stem Cells (2001): http://www.ethikrat.org/dateien/pdf/Stn_Stammzellgesetz.pdf 2. Cloning for Reproductive Purposes and Cloning for the Purposes of Biomedical Research (2004): http://www.ethikrat.org/dateien/pdf/Stn_Stammzellgesetz.pdf 3. Should the Stem Cell Law be Amended? (2007): http://www.ethikrat.org/dateien/pdf/Stn_Stammzellgesetz.pdf ZEKO: 1. Stem Cell Research (2002) (German): http://www.zentrale-ethikkommission.de/downloads/Stammzell.pdf 2. Cloning (2006) (German): http://www.zentrale-ethikkommission.de/downloads/TherapKlonen.pdf DFG: Opinion on Stem Cell Research (2006)

Country	Key Organizations	Legislation	Regulations	Guidelines
				(German): http://www.dfg.de/download/pdf/dfg_magazin/forschungspolitik/stammzellforschung/stammzellforschung_deutschland_lang_0610.pdf
Greece				
General	National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3			1. Template Code of Research Ethics for Biological Sciences (2008): http://www.bioethics.gr/media/pdf/recommendations/research_ethics_code.pdf 2. A Guide for Research Ethics Committees for Biological Research (2008): http://www.bioethics.gr/media/pdf/recommendations/guide.pdf
Drugs and Devices	1. National Organization for Medicines (NOM): http://www.eof.gr/web/guest/home, then click on "EN" in upper left hand section for English 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 2. Act 3418/2005 Code on Medical Ethics (Greek): http://www.bioethics.gr/media/pdf/biolaw/human/code_of_practice_new_gr.pdf	1. Ministerial Decision ΔΥΓ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC: http://www.bioethics.gr/media/pdf/biolaw/human/clinical_trials_directive_gr.pdf 2. Ministerial Decision ΔΥΓ 3 α/79602/2007: Harmonization of the Greek Legislation with EU Legislation, according to the Directive 2005/28/EC: http://www.bioethics.gr/media/pdf/biolaw/human/DYG3a-79602.pdf	NBC: 1. A Guide for Research Ethics Committees for Biological Research (2009): http://www.bioethics.gr/document.php?category_id=55&document_id=808 2. Recommendation on Clinical Trials: http://www.bioethics.gr/media/pdf/recommendations/recom_clinical_trials_en.pdf
Research Injury	National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 2. Act 3418/2005 Code on Medical Ethics (Greek): http://www.bioethics.gr/media/pdf/biolaw/human/code_of_practice_new_gr.pdf	1. Ministerial Decision ΔΥΓ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC: http://www.bioethics.gr/media/pdf/biolaw/human/clinical_trials_directive_gr.pdf 2. Ministerial Decision ΔΥΓ 3 α/79602/2007 Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2005/28/EC: http://www.bioethics.gr/media/pdf/biolaw/human/DYG3a-79602.pdf	NBC: 1. A Guide for Research Ethics Committees for Biological Research (2009): http://www.bioethics.gr/document.php?category_id=55&document_id=808 2. Recommendation on Clinical Trials: http://www.bioethics.gr/media/pdf/recommendations/recom_clinical_trials_en.pdf Various: http://www.eof.gr/web/guest/clinicalmedical

Country	Key Organizations	Legislation	Regulations	Guidelines
Privacy/Data Protection	Hellenic Data Protection Authority (Greek): http://www.dpa.gr/	1. Greek Constitution 1975/1986/2001 Article 9.1 2. Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998) 3. Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by Laws 2819/2000 and 2915/2000) (Greek): http://www.dpa.gr/Documents/Eng/2472engl_all.doc 4. Act 3418/2005 Code on Medical Ethics (Greek): http://www.bioethics.gr/media/pdf/biolaw/human/code_of_practice_new_gr.pdf		
Genetic Research	1. Hellenic Data Protection Authority (HDPA) (Greek): http://www.dpa.gr/ 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. Greek Constitution 1975/1986/2001, Article 5.5 2. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 3. Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by Laws 2819/2000 and 2915/2000) (Greek): http://www.dpa.gr/Documents/Eng/2472engl_all.doc 4. Act 3418/2005 Code on Medical Ethics (Greek): http://www.bioethics.gr/media/pdf/biolaw/human/code_of_practice_new_gr.pdf		HDPA: Opinion No. 15/2001 NBC: 1. Recommendation on Banks of Biological Material of Human Origin (Biobanks) in Biomedical Research:" http://www.bioethics.gr/media/pdf/recommendations/biobanks_recom_eng.pdf 2. Recommendation on the Collection and Use of Genetic Data: http://www.bioethics.gr/media/pdf/recommendations/recom_genetic_data_eng.pdf 3. Opinion on Prenatal and Pre-implantation Diagnosis and Embryo Treatment: http://www.bioethics.gr/media/pdf/recommendations/1_pd_pgd_opin_eng2.pdf
Embryos, Stem Cells, and Cloning	1. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3 2. National Authority for Medically Assisted Reproduction (Greek):	1. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998)		NBC: 1. Recommendation on the Use of Stem Cells in Biomedicine and Clinical Medicine: http://www.bioethics.gr/media/pdf/recommendations/recom_stem_cells_eng.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.iya.gr	2. Civil Code (Act 3089/2002, Medically Assisted Reproduction): http://www.bioethics.gr/media/pdf/biolaw/human/assisted_reproduction_gr.pdf 3. Act 3305/2005 Application of Medically Assisted Reproduction: http://www.bioethics.gr/media/pdf/biolaw/human/fertility_clinics_regulation.pdf		2. Recommendation on Human Reproductive Cloning: http://www.bioethics.gr/media/pdf/recommendations/recom_cloning_eng.pdf 3. Opinion on Prenatal and Pre-implantation Diagnosis and Embryo Treatment: http://www.bioethics.gr/media/pdf/recommendations/1_pd_pgd_opin_eng2.pdf
Hungary For an overview of human subject protections in Hungary, see "National Regulations on Ethics and Research in Hungary:" http://ec.europa.eu/research/science-society/pdf/hu_eng_lr.pdf				
General	1. Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Scientific and Research Ethics Committee	1. Fundamental Law of Hungary, Articles II-III 2. Act CLIV of 1997 on Health Care, Chapter VIII 3. Act IV of 1978 on the Criminal Code Title II of Chapter XII. Crimes Against the Order of Medical Interventions and Medical Research and Against Self-Determination Related to Health Issues 4. Act VI. of 2002 on the promulgation of the Oviedo Convention on Human Rights and Biomedicine 5. Act LXXXI of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research	1. Decree No. 235/2009 (X.20.) from the Hungarian Government on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products, and for the Clinical Studies of the Medical Devices (Hungarian): http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900235.KOR&celpara=#xcelparam 2. Decree 23/2002 (V. 9.) of the Minister of Health on Biomedical Research on Human Beings (Hungarian): http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam	
Drugs and Devices	*Drugs*			
	1. National Institute for Quality and Organizational Development in Healthcare and Medicines: http://www.ogyi.hu/main_page/ 2. Medical Research Council, Ethics Committee for Clinical Pharmacology: http://www.ett.hu/kfeb/kfeb.htm	*Clinical Trials:* Act XCV of 2005 on Medicinal Products for Human Use, Section 3: http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=a0500095.tv&dbnum=62	*Clinical Trials:* Decree 35/2005 (VIII. 26) of the Minister of Health on the Clinical Trial and Application of Correct Clinical Practices of Investigational Medicinal Products Intended for Use in	Rules Governing Medicinal Products in the European Union, Volume 10: http://ec.europa.eu/health/documents/eudralex/vol-10/

Country	Key Organizations	Legislation	Regulations	Guidelines
	3. European Union: http://ec.europa.eu/health/index_en.htm	*Non-Interventional Trials:* Act CLIV of 1997 on Health Care, Chapter VIII: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV	Humans: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM&celpara=#xcelparam *Non-Interventional Trials:* Decree 23/2002. (V. 9) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam	
	Devices			
	1. Authority for Medical Devices: http://www.eekh.hu/en/index.php?option=com_content&task=blogcategory&id=14&Itemid=28 2. Medical Research Council, Ethics Committee for Clinical Pharmacology: http://www.ett.hu/kfeb/kfeb.htm	Act CLIV of 1997 on Health Care, Chapter VIII: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV	*Clinical Trials:* Decree 4/2009. (III. 17.) of the Minister of Health on Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900004.EUM&celpara=#xcelparam *Non-Interventional Trials:* 1. Government Decree 235/2009. (X.20.) on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products and for the Clinical Studies of the Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900235.KOR&celpara=#xcelparam 2. Decree 23/2002. (V. 9.) of the Minister of Health on Biomedical Research on Human Beings http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam	
Research Injury	National Institute for Quality and Organizational Development in Healthcare and Medicines: http://www.ogyi.hu/main_page/	Act XCV of 2005 on Medicinal Products for Human Use, Section 3, Paragraph 5: http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=a0500095.tv&dbnum=62		
Privacy/Data Protection	Hungarian National Authority for Data Protection and Freedom of	1. Act CXII of 2011 on Informational Self-		

Country	Key Organizations	Legislation	Regulations	Guidelines
	Information: http://www.naih.hu/general-information.html	Determination and Freedom of Information: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A1100112.TV&celpara=#xcelparam 2. Act XLVII of 1997 on the Handling of Medical and Other Related Data: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700047.TV&celpara=#xcelparam		
Human Biological Materials	Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma	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: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0600080.TV&celpara=#xcelparam	Decree 18/1998 (XII 27) EüM on Implementing Act CLIV of 1997 on Health Care as regards Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam	
Genetic Research		Act XXI of 2008 on the Rules of Protection of Human Genetic Data, of Human Genetic Examinations and Research and of the Operation of Biobanks: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0800021.TV&celpara=#xcelparam		Decree 60/2003. (X. 20.) of the Minister of Health, Social and Family Affairs on the Minimum Professional Requirements Necessary for Providing Health Services: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0300060.ESC&celpara=#xcelparam
Embryos, Stem Cells, and Cloning	1. Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council	1. Act CLIV of 1997 on Health Care, Articles 180-182: http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Hungary/page.aspx/557 2. Act VI of 2002 on the Promulgation of the Convention on Human Rights and Medicine and the Additional Protocol on Cloning: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200006.TV&celpara=#xcelparam	Decree 30/1998. (VI. 24.) of the Minister of Welfare on Regulations on Specific Procedures for Human Reproduction: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800030.NM&celpara=#xcelparam	Decree 18/1998. (XII. 27.) of the Minister of Health on Implementing Act CLIV of 1997 on Health Care as Regards Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam

Country	Key Organizations	Legislation	Regulations	Guidelines
Iceland				
General	1. Ministry of Welfare (MOW): http://ministryofhealth.is 2. National Bioethics Committee (NBC): www.visindasidanefnd.is (Select "English" in the upper-right hand corner.)	1. Act on the Rights of Patients No. 74/1997, Article 10 (2009): http://eng.velferdarraduneyti.is/acts-of-Parliament/nr/20100 2. Oviedo Convention on Human Rights and Biomedicine (2004)	MOW: Regulation on Scientific Research in the Biomedical field, No. 286 (2008) http://eng.heilbrigdisraduneyti.is/laws-and-regulations/Regulations//nr/2847	NBC: 1. Research Projects 2. Withdrawal
Drugs and Devices	*Drugs*			
	1. Icelandic Medicines Agency (MCA): http://www.imca.is/ 2. National Bioethics Committee (NBC): www.visindasidanefnd.is	Medicinal Products Act No. 93/1994 (2013): http://eng.heilbrigdisraduneyti.is/laws-and-regulations/laws//nr/3128	MCA: Regulation on Clinical Trials of Medicinal Products in Humans No. 443/2004 (2010): http://eng.heilbrigdisraduneyti.is/media/Reglugerdir-enska/Regulation_on_clinical_trials_of_medicinal_products_in_humans_No443-2004.pdf	
	Devices			
	Ministry of Welfare: http://eng.heilbrigdisraduneyti.is/	Act on Medical Devices No 16/2001 (2011): http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/687	Regulation on Medical Devices No. 934/2010 (2010): http://eng.velferdarraduneyti.is/media/Reglugerdir-enska/Regulation-on-Medical-Devices-No-934-2010.pdf 2. Regulation on Active Implantable Medical Devices No. 320/2011 (Icelandic): http://www.stjornartidindi.is/Advert.aspx?ID=c50d676c-4651-46c2-83b5-ad946f3deeaa 3. Regulation on In Vitro Diagnostic Medical Devices No. 936/2011 (Icelandic): http://stjornartidindi.is/Advert.aspx?ID=f20b3e4e-ab25-44d3-8e32-e5f42a7b02f0	
Research Injury	Icelandic Medicines Control Agency (MCA): http://www.imca.is/	1. Act on Patient Insurance No. 111/2000 (2011): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act_on_Patient_Insurance_as_amended.pdf 2. Act on Health Insurance No. 112/2008 (2012): http://eng.velferdarraduneyti.is/media/acrobat-	Regulation on Clinical Trials of Medicinal Products in Humans No 443/2004 (2010): http://eng.heilbrigdisraduneyti.is/media/Reglugerdir-enska/Regulation_on_clinical_trials_of_medicinal_products_in_humans_No443-2004.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
		enskar_sidur/Act_on_Health_Insurance_No_112_2008.pdf		
Privacy/Data Protection	Data Protection Authority: http://www.personuvernd.is/information-in-english/	Act on the Protection of Privacy as Regards the Processing of Personal Data, No. 77/2000 (2011): http://www.personuvernd.is/information-in-english/	Government Regulation on a Health Sector Database No. 32 (2000): http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/670	
Human Biological Materials	1. Ministry of Welfare: http://ministryofhealth.is 2. National Bioethics Committee (NBC): www.visindasidanefnd.is	Biobanks Act No. 110/2000 (2009): 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
Embryos, Stem Cells, and Cloning		1. 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 (2004) 2. Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No. 55/1996 (2010): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act_No_55_1996_on_Artificial_Fertilisation_etc_as_amended.pdf	Regulation on Artificial Fertilization No 144/2009 (Icelandic): http://stjornartidindi.is/Advert.aspx?ID=9442c80d-2b63-4a43-9526-41d03d9b2495	
Ireland				
General	Irish Council for Bioethics (ICB): http://www.bioethics.ie			Operational Procedures for Research Ethics Committees: Guidance 2004: http://www.bioethics.ie/uploads/docs/guide.pdf
Drugs and Devices	*Drugs*			
	Irish Medicines Board: http://www.imb.ie/	European Communities (Clinical Trials on Medicinal Products for Human Use) Amendment 2004 (S.I. No. 878 of 2004): http://www.dohc.ie/legislation/statutory_instruments/?year=2004&number=878	1. European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004): http://www.dohc.ie/legislation/statutory_instruments/?year=2004&number=190 2. European Communities (Clinical Trials on Medicinal Products for Human Use)	IMB: Guide to Clinical Trials (2004)

Country	Key Organizations	Legislation	Regulations	Guidelines
			(Amendment No. 2) Regulations 2006 (S.I. 374 of 2006): http://www.dohc.ie/legislation/statutory_instruments/?year=2006&number=374	
	Devices			
	Irish Medicines Board: http://www.imb.ie/EN/Medical-Devices.aspx			Various: http://www.imb.ie/EN/Medical-Devices/PreMarket-Activities/Clinical-Investigations.aspx
Research Injury	Irish Medicines Board: http://www.imb.ie/		European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, Section 13(6)(k) and Schedule 1, Part 2, Paragraph 4 (S.I. No. 190 of 2004): http://www.dohc.ie/legislation/statutory_instruments/?year=2004&number=190	
Privacy/Data Protection	Data Protection Commissioner: http://www.dataprotection.ie/docs/Home/4.htm	Data Protection Act (1988), as amended (2003): http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html		
Human Biological Materials	1. Irish Medicines Board: http://www.imb.ie/EN/Blood-Tissues--Cells~.aspx 2. Irish Council for Bioethics: http://www.bioethics.ie			Human Biological Material: Recommendations for Collection, Use, and Storage in Research (2005): http://www.bioethics.ie/pdfs/BioEthics_fin.pdf
Genetic Research	Irish Medicines Board: http://www.imb.ie/			Guidelines for Pharmacogenetic Research (2006): http://www.imb.ie/images/uploaded/documents/AUT-G0003_Guidelines_for_pharmacogenetic_research_v1.pdf
Italy				
General	1. National Federation of Ethics Committees (FNACE) (Italian): http://www.unich.it/fnace/ 2. National Monitoring Center for Clinical Trials (OSS): http://oss-sper-clin.agenziafarmaco.it/ 3. National Bioethics Committee (NBC): http://www.governo.it/bioetica/eng/index.html 4. Ministry of Health (Italian): http://www.ministerosalute.it	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 Reference for the Establishment and the Functioning of Ethics Committees (May 12, 2006)	NBC: Opinion of the National Bioethics Committee on the European Protocol on Biomedical Research (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	*Drugs*			
	1. National Monitoring Center for Clinical Trials: http://oss-sper-clin.agenziafarmaco.it/ 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) 2. Legislative Decree No. 211: 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 (2003): http://ricerca-clinica.agenziafarmaco.it/en/node/26 3. Legislative Decree No. 200: Transposition of Directive 2005/28 EC Laying down Principles and Detailed Guidelines as Regards Investigational Medical Products for Human Use, as well as the Requirements for Authorizing of Manufacturing or Importing of such Products (2007) (Italian): http://www.aifa.gov.it/allegati/dlgs_200-6nov2007.pdf	Italy has numerous regulations that govern drug research: http://ricerca-clinica.agenziafarmaco.it/en/node/26 The following are the most important: 1. Ministerial Decree 21 December 2007: Directions for Submitting the Request for Authorisation of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authority, for Communicating Substantial Amendments, for Declaring the End of the Trial and for the Request of an Opinion to the Ethics Committee 2. Ministerial Decree 31 March 2008: Definition of the Minimum Requirements that Contract Research Organisations (CROs) Shall Satisfy in Order to Work within Clinical Trials on Medicinal Products	
	Devices			
	Ministry of Health, Directorate General for Medicines and Medical Devices (Italian): http://www.ministerosalute.it		Ministerial Decree 2 of August 2005: Procedures for the Presentation of Documentation to Notify about Clinical Investigations with Medical Devices: http://www.salute.gov.it/dispositivi/paginainterna.jsp?id=1523&menu=clinical&lingua=english	Administrative Procedures Concerning the Conduction of Clinical Investigations with CE-Marked Medical Devices (2007): http://www.salute.gov.it/imgs/C_17_pagineAree_1033_listaFile_itemName_0_file.pdf
Research Injury	Ministry of Health, Employment, and Social Policies		Ministerial Decree 14 of July 2009: Minimum Requirements for Insurance Policies which	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Safeguard Participants to Clinical Trials of Medicinal Products: http://ricerca-clinica.agenziafarmaco.it/it/node/3	
Privacy/Data Protection	Italian Data Protection Independent Authority (Italian): http://www.garanteprivacy.it/garante/navig/jsp/index.jsp?solotesto=N	Italian Personal Data Protection Code, Legislative Decree No. 196 of June 30, 2003: http://www.garanteprivacy.it/garante/navig/jsp/index.jsp?folderpath=Normativa%2FItaliana%2FIl+Codice+in+materia+di+protezione+dei+dati+personali	1. Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000): http://ricerca-clinica.agenziafarmaco.it/it/node/506 2. Regulation for the Implementation of Articles No. 20 and 21 of the Legislative Decree No. 196 of June 30, 2003 3. Ministerial Decree No. 277 (2007)	
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/			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/0478.1106653420.pdf SIGU: Guidelines for Genetic Biobanks (2004): http://www.biobanknetwork.org/documents/GUIDELINES.pdf
Embryos, Stem Cells, and Cloning		Regulation of Medically Assisted Reproduction, Law No. 40, Article 13 (2004): http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Italy/page.aspx/167		

Latvia For an overview of human subject protections in Latvia, see "National Regulations on Ethics and Research in Latvia:" http://ec.europa.eu/research/science-society/pdf/lv_eng_lr.pdf				
General			Statutes of Central Medical Ethics Committees (1998) (Latvian): http://www.likumi.lv/doc.php?id=46597	
Drugs and Devices	*Drugs*			
	1. State Agency of Medicines: http://www.vza.gov.lv/index.php?setlang	1. Pharmaceutical Law, Section 26 (2009)	Cabinet Regulation No. 289: Regulations on Conducting	

Country	Key Organizations	Legislation	Regulations	Guidelines
	=en&large= 2. Central Medical Ethics Committee	http://www.vza.gov.lv/index.php?id=355&sa=355&top=333 2. Law on the Rights of Patients, Section 11 (2010) http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Law_On_the_Rights_of_Patients.doc	Clinical Trials and Non-interventional studies and Labelling of Investigational Medicinal Products, and Procedure for Conducting Inspections on Compliance with the Requirements of Good Clinical Practice: http://www.zva.gov.lv/doc_upl/MK_not_289_English_02062010.pdf	
	Devices			
	State Agency of Medicines: http://www.vza.gov.lv/index.php?setlang=en&large=	Medical Treatment Law, Section 34 (2009): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Medical_Treatment_Law.doc	Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for Human Use (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._891_-_Procedures_for_the_Clinical_Trial_of_Medical_Devices.doc	
Research Injury	State Agency of Medicines: http://www.vza.gov.lv/index.php?setlang=en&large=		*Drugs:* Cabinet Regulation No. 289: Regulations on Conducting Clinical Trials and Non-Interventional studies and Labeling of Investigational Medicinal Products, and Procedure for Conducting Inspections on Compliance with the Requirements of Good Clinical Practice, Sections 22, 31.6, 54.10, 55.9, and 61.14 (2010): http://www.zva.gov.lv/doc_upl/MK_not_289_English_02062010.pdf *Devices:* Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for Human Use, Sections 42.7 and 62.5 (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._891_-_Procedures_for_the_Clinical_Trial_	

Country	Key Organizations	Legislation	Regulations	Guidelines
			of_Medical_Devices.doc	
Privacy/Data Protection	1. Data State Inspectorate: http://www.dvi.gov.lv/eng/ 2. Central Medical Ethics Committee	1. Personal Data Protection Law (2010): http://www.dvi.gov.lv/eng/legislation/pdp/ 2. Law on the Rights of Patients, Section 10 (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Law_On_the_Rights_of_Patients.doc		
Human Biological Materials	Central Medical Ethics Committee	Law on the Protection of Dead Human Beings and Use of Human Organs and Tissue (2008): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/On_the_Protection_of_the_Body_of_Deceased_Human_Beings_and_the_Use_of_Human_Tissues_and_Organs_in_Medicine.doc	Cabinet Regulation No. 208: Procedures for Banking, Storage and Utilisation of Human Tissues and Organs (2008): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._208_-_Bankingx_Storage_and_Utilisation_of_Human_Tissues_and_Organs.doc	
Genetic Research	1. Ministry of Health: http://www.vm.gov.lv/index.php?setlang=en 2. Data State Inspectorate: http://www.dvi.gov.lv/eng/ 3. Central Medical Ethics Committee	1. Human Genome Research Law (2005): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Human_Genome_Research_Law.doc 2. Law on the Development and Use of the National DNA Database (2006): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Development_and_Use_of_the_National_DNA_Database.doc	Regulation of the Cabinet of Ministers: "Procedures for Genetic Research" (2004)	
Embryos, Stem Cells, and Cloning	1. Ministry of Health: http://www.vm.gov.lv/index.php?setlang=en 2. Central Medical Ethics Committee	Sexual and Reproductive Health Law, Sections 15-20 (2004): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Sexual_and_Reproductive_Health_Law.doc	Cabinet Regulation No. 716: Order of Medically-Assisted Procreation, Donor Registry, and Donor Bank (2003) (Latvian) http://www.likumi.lv/doc.php?id=82281&from=off	
Lithuania For an overview of human subject protections in Lithuania, see "National Regulations on Ethics and Research in Lithuania:" http://ec.europa.eu/research/science-society/pdf/lt_eng_lr.pdf http://www.eurecnet.org/information/lithuania.html				
General	1. Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG 2. Lithuanian Bioethics Committee (LBEC):	1. Oviedo Convention on Human Rights and Biomedicine (2002): http://conventions.coe.int/treaty/en/t	Government of the Republic of Lithuania: Decree Nr. 1458 on State Fees (2013)	LBEC: Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://bioetika.sam.lt/index.php?-1073108465	reaties/html/164.htm 2. Law on Ethics of Biomedical Research (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446	MOH: 1. Decree No. 677 on the Procedure for the Estimation and Covering of Expenses Incurred by Research Subjects (2011) 2. Decree No. V-405 on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage, and Providing Information on Biomedical Research (2010) LBEC: 1. Decree No. V-14 on the Requirements for the Biomedical Research Protocol, Patient Information Sheet, and Informed Consent Form, and for the CV of Investigator (2010). 2. The Decree No.V-28 on Biomedical Research on Health Data (2011)	Research of the LBEC (2010)
Drugs and Devices	*Drugs*			
	1. State Medicines Control Agency (SMCA): http://www.vvkt.lt/lit/English 2. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1073108465 3. Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Law on Ethics of Biomedical Research (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446 2. Law on Pharmacy (2013): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=452860	MOH: 1. Decree No. 435 on the Procedure for Issuing Favorable Opinion to Conduct Clinical Trial on Medicinal Product, Approval for Clinical Trial on Medicinal Product, Conducting and Controlling Clinical Trials (2011) 2. Decree No. 320 on the Rules of Good Clinical Practice (2006) LBEC: 1. Decree No. V-11 on the Documents Required by the Lithuanian Bioethics Committee to be Presented by the Sponsor of Biomedical Research and (or) by the Principal Investigator in Order to be Authorized to Conduct a Clinical Trial on Medicinal	LBEC: Guidelines to Advertise clinical trials, adopted by the Group of Experts on Biomedical Research of the LBEC (2007) SMCA: Detailed Guidance No. 1A-396 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)

Country	Key Organizations	Legislation	Regulations	Guidelines
			Products, and on the Procedure on the Submission of the Documents to be presented to the Lithuanian Bioethics Committee (2004) 2. Decree No. V-10 on the Procedure for Issuing a Favorable Opinion for Substantial Amendment (2008)	
	Devices			
	1. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1073108465 2. State Health Care Accreditation Agency Under the Ministry of Health (SHCA): http://www.vaspvt.gov.lt/en	Law on Ethics of Biomedical Research (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446	MOH: Decree No. V-2 on the Procedure to Issue Approvals to Conduct Biomedical Research (2011) SHCA: Decree No. T1-1064 on the Procedure to Issue Recommendation to Conduct Clinical Trial on Medical Device (2010)	
Research Injury	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	Law on Ethics of Biomedical Research (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446	MOH: Decree No. 745 on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor (2012)	
Privacy/Data Protection	State Data Protection Inspectorate: https://www.ada.lt/go.php/lit/English	Law on Legal Protection of Personal Data (2011): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=400103		
Human Biological Materials	1. Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG 2. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1073108465	Law on Ethics of Biomedical Research (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446	LBEC: Decree No.V-28 on Biomedical Research on Health Data (2011)	
Embryos, Stem Cells, and Cloning	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Law on Ethics of Biomedical Research (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446 2. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to	MOH: 1. Decree No. V-660 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	

Country	Key Organizations	Legislation	Regulations	Guidelines
		the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002): http://conventions.coe.int/Treaty/EN/Treaties/Html/168.htm	Stem Cells throughout the Territory of the Republic of Lithuania (2007) 2. Decree No. V-659 on the Procedure for Importing of the Stem Cells Taken from the Umbilical Cord or Placenta after the Birth of a Child and the Samples Taken for Genetic Research into the Territory of the Republic of Lithuania and Exporting Therefrom (2007)	
Luxembourg				
General		Hospitals Act of 1998, Article 25 (French): http://www.legilux.public.lu/leg/a/archives/2011/0103/a103.pdf#page=2		
Drugs and Devices	1. Ministry of Health (French): http://www.ms.public.lu and http://www.sante.lu 2. National Committee on Ethics in Research (CNER) (French): http://www.cne.lu 3. Division of Pharmacy and Medicines (French) http://www.ms.public.lu/fr/direction/divisions-services/pharmacie-medicaments/index.html		Grand-Ducal Decree of 30th of May, 2005 on Good Clinical Practice (French): http://www.legilux.public.lu/leg/a/archives/2005/0084/2005A15161.html	
Privacy/Data Protection	National Commission for Data Protection (French and German): http://www.cnpd.public.lu/fr/index.html	1. Law of August 2, 2002 on the Protection of Persons with Regard to the Processing of Personal Data as amended by a law of July 27, 2007: http://www.cnpd.public.lu/fr/legislation/droit-lux/doc_loi02082002_en.pdf	Grand-Ducal Decree of October 2nd, 1992 on the Use of Personal Medical Data in IT Processing (French): http://www.legilux.public.lu/leg/a/archives/1992/0074/a074.pdf#page=12	
Macedonia Note: All websites and documents are in Macedonian				
Drugs and Devices	*Drugs*			
	1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Drug Register: https://lekovi.zdravstvo.gov.mk/	1.Law on Medicinal Products and Medical Devices, Items 12 and 13 (2007): https://lekovi.zdravstvo.gov.mk/documents/2 2. Law on Changing and	1. Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents, Items 25 and 26 (2009) https://lekovi.zdravstvo.gov.mk/docu	1. Guideline for the Clinical Trial Applicant in Accordance with the Law on Medicinal Products and Medical Devices 2. Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal

Country	Key Organizations	Legislation	Regulations	Guidelines
		Amending the Law on Medicinal Products and Medical Devices, Items 10 and 11 (2010): https://lekovi.zdravstvo.gov.mk/documents/2 3. Law on Addenda to the Law on Medicines and Medical Devices, Items 8 and 9 (2011): https://lekovi.zdravstvo.gov.mk/documents/2 4. Law On Amendments And Modifications To The Law On Medicines And Medical Devices, Items 6 and 7: https://lekovi.zdravstvo.gov.mk/documents/2 5. Law on Amendments and Modifications to the Law on Medicines and Medical Devices, Items 4 and 5 (2011): https://lekovi.zdravstvo.gov.mk/documents/2 6. Law on Amendments and Modifications to the Law on Medicines and Medical Devices, Items 2 and 3 (2012): https://lekovi.zdravstvo.gov.mk/documents/2	ments/1/1 2. Rulebook for the Changes in the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents, Item 24 (2010) (Macedonian): https://lekovi.zdravstvo.gov.mk/documents/1/1 3. Rulebook for the Changes in the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents, Item 23 (2012) (Macedonian): https://lekovi.zdravstvo.gov.mk/documents/1/1 4. Regulation on the Manner of Reporting, Contents of the Reporting Form for Adverse Reactions to Medicinal Products and the Manner of Organisation of Pharmaco-vigilance System, Items 38 and 39: https://lekovi.zdravstvo.gov.mk/documents/1/1	Products and the Documentation Contents and GCP Guidelines (2012): https://lekovi.zdravstvo.gov.mk/documents/1/1
	Devices			
	1. Macedonian Drug Agency http://moh.gov.mk/index.php?category=39 2. Macedonian Drug Agency: http://www.reglek.com.mk/	Same as above.	Same as above.	Same as above.
Research Injury	1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Macedonian Drug Agency http://www.reglek.com.mk/	Law on Medicinal Products and Medical Devices (2007): http://www.reglek.com.mk/dokumenti/18_zakon_za_lekovi.doc	Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and Documentation Contents, Items 25 and 26 (2009): https://lekovi.zdravstvo.gov.mk/documents/1/1	
Privacy/Data	Directorate for Personal Data	1. Law on Personal Data		

Country	Key Organizations	Legislation	Regulations	Guidelines
Protection	Protection (Macedonian): www.dzlp.mk	Protection (2005): http://dzlp.mk/sites/default/files/Dokumenti/DOMASNI%20PROPISI/ZZLP_precisten_2012.pdf 2. Law On Amendments And Modifications To The Law on Personal Data Protection (2008): http://www.dzlp.mk/sites/default/files/ZZLP%20izmeni%202008_0.pdf 3. Law On Amendments And Modifications To The Law on Personal Data Protection (2010): http://www.dzlp.mk/sites/default/files/Izmeni%20na%20ZZLP%202010_0.pdf 4. Law On Amendments To The Law on Personal Data Protection (2011): http://dzlp.mk/sites/default/files/ZZLP_DOPOLNUVANJE_2011.pdf		
Human Biological Materials	1. Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/ 2. Health Insurance Fund of Republic of Macedonia: http://www.fzo.org.mk	1. Law on Health Protection http://www.fzo.org.mk/WBStorage/Files/ZAKON%20ZA%20ZDRAVSTVENATA%20ZASTITA%2043%20od%2029.03.2012.pdf 2. Law on Taking and Transplanting of Human Body Organs: http://mz.gov.mk/wp-content/uploads/2012/12/Zemanje-i-presaduvanje-na-delovi-od-coveckoto-telo-precisten.pdf Sub-Law Acts : http://www.fzo.org.mk/default.asp?ItemID=6541AC10FFC3C5498F0887C57131D996 3. Law on Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, With Additional Protocol on the Prohibition of Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and		Regulation on Criteria Relating to Space, Personnel and Equipment for Collection, Transplantation and Exchange of Organs and Tissues, the Necessary Space, Equipment and Staff Required to be Provided by the Health Institution for the Collection, Transfer, Exchange and Storage of Organs and Tissues from Human Body for Treatment Purposes (2012): http://mz.gov.mk/wp-content/uploads/2012/12/ZA_POBLISKITE_KRITERIUMI_VO_ODNOS_NA_PROSTOROT_KADAROT_I_OPREMATA_ZA_ZEMAWE_PRESADUVAWE_I_RAZMENUVAWE_NA_ORGANITE_I_TKIVATA_ZA_POTREBNIOT_PR.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
		Tissues of Human Origin: http://www.pravo.org.mk/download.php?id=5543		
Genetic Research	Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/	Law on Patients Rights Protection, Article 21: Action on Human Genome: http://www.miahealth.mk/dokumentacija/80_648801981.pdf		
Embryos, Stem Cells, and Cloning	Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/	Law on Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, With Additional Protocol on the Prohibition of Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin: http://www.pravo.org.mk/download.php?id=5543		
Malta 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: https://ehealth.gov.mt/HealthPortal/others/regulatory_councils/health_ethics_committee/health_ethics_committee.aspx			
Drugs and Devices	*Drugs*			
	Medicines Authority: http://medicinesauthority.gov.mt/	1. Medicines Act, 2003: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8924&l=1 2. Subsidiary Legislation, 458.43, Clinical Trials Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11281&l=1 3. Subsidiary Legislation, 458.47, Good Clinical Practice and Requirements for Manufacturing or Import		Guidance Notes on Good Clinical Practice (2010): http://medicinesauthority.gov.mt/clinicaltrials.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
		Authorisation of Investigational Medicinal Products (Human Use) Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11285&l=1		
	Devices			
	1. Medicines Authority: http://medicinesauthority.gov.mt/ 2. Malta Competition and Consumer Affairs Authority, Technical Regulations Division, Regulatory Affairs Directorate: http://www.mccaa.org.mt/en/regulatory-affairs-directorate	1. Product Safety Act, 2001: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8893&l=1 2. Subsidiary Legislation, 427.44, Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10781&l=1 3. Subsidiary Legislation, 427.16, *In Vitro* Diagnostic .Medical Devices Regulations, 2003 http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10756&l=1 4. Subsidiary Legislation, 427.10, Active Implantable Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10753&l=1		
Privacy/Data Protection	Office of the Information and Data Protection Commissioner: http://idpc.gov.mt/index.aspx	Data Protection Act, 2002: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8906&l=1		
Moldova 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.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf Note: All websites and documents are in Moldovian.				
General	National Committee of Bioethics of the Ministry of Health: http://www.ms.gov.md/	Oviedo Convention on Human Rights and Biomedicine (2002)		
Drugs and Devices	1. National Committee of Ethics for Clinical Study of Drugs and New Methods of Treatment of the Ministry	Moldova Republic Law on Medicines of December 17, 1997, Articles 11 and 12: http://lex.justice.md/index.php?actio	MOH: 1. Ordnance No. 10: On Performance of Clinical Trials in	

Country	Key Organizations	Legislation	Regulations	Guidelines
	of Health (MOH): http://www.ms.gov.md/ 2. Medicines Agency: http://www.amed.md/	n=view&view=doc&lang=1&id=311586 Law No. 263 of 27.10.2005 on Rights and Responsibilities of Patient. Articles 9, 10, 11, 12, 13 and 14: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=313060	the Republic of Moldova (2002) 2. Order No. 22 of 12.01.2006 "Regarding Modification of the Order No. 10 on Performance of Clinical Trials"	
Research Injury	Ministry of Health (MOH): http://www.ms.gov.md/	1. Annex No.1 to the Oder No.10 from 14.01.2002 of the Ministry of Health, Sections 5.8 and 8: http://www.amed.md/ordine_MS.html 2. Law No. 411-XIII of 28.03.1995 "Regarding Health Protection"		
Privacy/Data Protection	National Center for Personal Data Protection of the Republic of Moldova: http://www.datepersonale.md/en/start/	1. Law No.133 of 08.07.2011 on the Protection of Personal Data: http://lex.justice.md/md/340495/ 2. Law No. 982 of 11.05.2000 on Access to Information: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311759	Decision of Government No. 1123 of 14.12.2010: On the Approval of the Requirements for the Assurance of Personal Data Security at their Processing within the Information Systems of Personal Data: http://www.datepersonale.md/file/hotariri/cerinte_securitate%20eng_101228.pdf	
Human Biological Materials	1. Ministry of Health (MOH): http://www.ms.gov.md/ 2. Transplant Agency http://lex.justice.md/md/334622	Law No. 42 of 06.03.2008 on Transplantation of Organs, Tissues and Human Cells: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=327709	MOH: Ordnance No. 10: On Performance of Clinical Trials in the Republic of Moldova (2002)	
Embryos, Stem Cells, and Cloning	1. Ministry of Health (MOH): http://www.ms.gov.md/en/ 2. National Commission on Biological Security http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=303353	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being, on the Prohibition of Cloning Human Beings (2002) 2. Law No. 42 of 06.03.2008 on Transplantation of Organs, Tissues and Human Cells: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=327709		

Country	Key Organizations	Legislation	Regulations	Guidelines
Montenegro				
Drugs and Devices	Ministry of Health of Montenegro: www.mz.cg.yu	Law for Drugs and Pharmacies of Montenegro, Articles 37-39		
Research Injury	Medicines and Medical Devices Agency: http://calims.me/	Law on Medicinal Products, Article 48		
Netherlands				
General	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl	1. Population Screening Act (1996): http://www.gr.nl/en/about-us/council/committees-standing-committees/ciebvo 2. Medical Research Involving Human Subjects Act (2006 version - minor changes implemented in 2012 have not yet been translated to English): http://www.ccmo-online.nl/hipe/uploads/downloads_catw/Medical%20Research%20involving%20Human%20Subjects%20Act%20March%2001%202006.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) 5. Research Contract Review Guideline (2009)	Manual for the Review of Medical Research Involving Human Subjects (2002)
Drugs and Devices	1. Ministry of Health, Welfare, and Sport (MHWS): http://www.government.nl/ministries/vws#ref-minvws 2. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl 3. Medicines Evaluation Board (MEB): http://www.cbg-meb.nl/cbg/en/default.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
Research Injury	Ministry of Health, Welfare and Sport: http://www.government.nl/ministries/vws#ref-minvws	Medical Research Involving Human Subjects Act, Article 7 (2006): http://www.ccmo-online.nl/hipe/uploads/downloads_catw/Medical%20Research%20involving%20Human%20Subjects%20Act%20March%2001%202006.pdf	Regulation on Mandatory Insurance Regarding Medical Research Involving Human Subjects (2003): http://www.ccmo-online.nl/hipe/uploads/downloads/Verzekeringsbesluit_2003-ENG.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/Pages/home.aspx	Personal Data Protection Act (2004) (Dutch): http://www.cbpweb.nl/downloads_wetten/WBP.PDF		FMWV: 1. Code for Adequate Secondary Use of Data (2004): http://www.federa.org/sites/default/files/bijlagen/coreon/code_of_conduct_for_medical_research_1.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
				2. Explanatory Report Accompanying the Code: http://www.federa.org/sites/default/files/bijlagen/coreon/explanatory_report1.pdf
Human Biological Materials	Federation of Biomedical Scientific Societies (Dutch): http://www.federa.org/	Civil Code, Article 467 (1994) (Dutch): http://www.dutchcivillaw.com/legislation/dcctitle7777.htm		Code for Proper Secondary Use of Human Tissue in the Netherlands (2002): http://www.federa.org/sites/default/files/bijlagen/coreon/codeproperseconderyuseofhumantissue1_0.pdf
Genetic Research	1. Ministry of Housing, Spatial Planning, and Environment (VROM): http://english.verkeerenwaterstaat.nl/english/ 2. Dutch Health Care Inspectorate (IGZ): http://www.igz.nl/ 3. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/	Medical Research Involving Human Subjects Act (2006): http://www.ccmo-online.nl/hipe/uploads/downloads_catw/Medical%20Research%20involving%20Human%20Subjects%20Act%20March%2001%202006.pdf		VROM, IGZ, and CCMO: Guidelines for Researchers and Sponsors with Regard to the Assessment by Official Bodies of Clinical Research Involving Gene Therapeutics in the Netherlands (2007): http://bggo.rivm.nl/Documenten/Documenten%20IM/Guidelines%20gene%20therapy%20applications.pdf
Embryos, Stem Cells, and Cloning	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl	1. Foetal Tissue Act (2001) (Dutch): http://wetten.overheid.nl/BWBR0012983/ 2. Embryos Act (2002) (Dutch): http://wetten.overheid.nl/BWBR0013797/		
Norway				
General	1. National Committee for Medical and Health Research Ethics (NEM): http://www.etikkom.no/en/In-English/Committee-for-Medical-and-Health-Research/ 2. National Committee for Research Ethics in the Social Sciences and the Humanities (NESH): http://www.etikkom.no/en/In-English/ 3. National Committee for Research Ethics in Science and Technology (NENT): http://www.etikkom.no/English/NENT	1. Oviedo Convention on Human Rights and Biomedicine (2006) 2. Law regarding Ethics and Integrity in Research (2006): http://www.ub.uio.no/ujur/ulovdata/lov-20060630-056-eng.pdf 3. Act on Health Care Research (2008) (Norwegian): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&		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 and Devices	*Drugs*			
	Norwegian Medicines Agency:		Regulation Relating to Clinical	1. Guidelines for the Regulations

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	http://www.regjeringen.no/en/dep/hod/About-the-Ministry/Subordinate-institutions/The-Norwegian-Medicines-Agency.html?id=279753		Trials on Medicinal Products for Human Use (2003)	Concerning Clinical Trials of Human Drugs (1999) 2. Guidance to the Regulation (2004) (Norwegian): www.legemiddelverket.no/upload/78182/Endelig%20veiledning%202004.doc
	Devices			
	Ministry of Health and Care Services: http://www.regjeringen.no/en/dep/hod/Subjects/Pharmaceutical-products/medical-devices.html?id=86835			Guidelines on Notification for Clinical Investigation of Medical Devices in Norway (2005): http://www.helsedirektoratet.no/vp/multimedia/archive/00014/Guidelines_on_Notifi_14826a.doc
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2007)		
Privacy/Data Protection	Data Inspectorate: http://www.datatilsynet.no/templates/Page____194.aspx	Personal Data Act No. 31 (2000): http://www.datatilsynet.no.htest.osl.basefarm.net/upload/Dokumenter/regelverk/lov_forskrift/lov-20000414-031-eng.pdf	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	
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	1. 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 2. Act Relating to the Application of Biotechnology in Human Medicine, etc. (December 5, 2003, No. 100) 3. Act on Health Care Research (2008) (Norwegian): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&	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:	Act Relating to the Application of Biotechnology in Human Medicine, etc. (December 5, 2003, No. 100): http://www.odin.no/hod/english/doc		

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.bion.no/index_eng.shtml 3. Regional Committees for Medical Research Ethics (REK): http://www.etikkom.no/English/NEM/REK	/legislation/acts/048051-990012/dok-bn.html		
Embryos, Stem Cells, and Cloning	Directorate for Health and Social Affairs: http://www.helsedirektoratet.no/portal/page?_pageid=134,112387&_dad=portal&_schema=PORTAL&language=english	1. 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) 2. Norwegian Law on the Human-Medical Use of Biotechnology, Chapter 3: http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Norway/page.aspx/168		
Poland 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. Polish Chamber of Physicians and Dentists (NIL): http://www.nil.org.pl/xml/nil/wladze/nil_eng	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)	NIL: Code of Medical Ethics, Chapter II (2003)
Drugs and Devices	*Drugs*			
	Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/english/index.htm	1. Pharmaceutical Law, Chapter 2a (2008): www.gif.gov.pl/?aid=173 2. Law of 20/04/2004 on Amendment of the Pharmaceutical Law, Law on the Profession of Medical Doctor, and Regulations Introducing the Pharmaceutical Law, Law on Medical Devices, and Law on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws No. 92,	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) 3. March 11, 2005 Order of the Minister of Health Concerning Detailed Requirements of Good Clinical Practice (2005)	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Item 882)		
	Devices			
	Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products: http://www.urpl.gov.pl/english/index.htm	Act on Medical Devices	Various (Polish): http://www.urpl.gov.pl/	
Research Injury		Pharmaceutical Law, Chapter 36b(2)(6) (2008): www.gif.gov.pl/?aid=173	1. Order of the Minister of Finance Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2004) 2. Order of the Minister of Finance Amending the Regulation Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (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 3. July 1, 2005 Act Regarding Sampling, Storage and Transplanting of Cells, Tissues and Organs		

Portugal				
General	National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/	Oviedo Convention on Human Rights and Biomedicine (2001)		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 and Devices	*Drugs*			
	1. National Institute of Pharmacy and	1. Approval of the Applicable	Decree-Law No. 102/2007 of	

Country	Key Organizations	Legislation	Regulations	Guidelines
	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	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_FARMACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/portaria_57-2005.pdf	April 2	
	Devices			
	National Institute of Pharmacy and Medicines: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS	Various: http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_V/TITULO_V_CAPITULO_II		Various: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS/NOTAS_INFORMATIVAS
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
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: http://www.portugal.gov.pt/en/the-ministries/ministry-of-health.aspx	Law 12/2005		
Embryos, Stem Cells, and Cloning	National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/	Oviedo Convention on Human Rights and Biomedicine, Additional Protocol on Prohibition of Human Cloning (2001) 2. Portuguese Law on Assisted Reproductive Technologies, Articles 7 and 9 (2006) http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-		1. Opinion 15/CNECV/95 on Embryo Research (1995) 2. Opinion 47/CNECV/2005 on Stem Cell Research (2005): http://www.cnecv.gov.pt/NR/rdonlyres/F13B34FD-F9F7-4C9D-96DC-419999D9B693/0/47CNECV2005.pdf 3. Opinion 48/CNECV/2006 on Human Cloning (2006): http://www.cnecv.gov.pt/NR/rdonlyres/770EA390-9326-4FF9-B28D-

Country	Key Organizations	Legislation	Regulations	Guidelines
		documentation/Portugal/page.aspx/473		D70A7E9AD961/0/p048_en.pdf
Romania 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/	Oviedo Convention on Human Rights and Biomedicine (2001)	Ordinance No. 57/16.08.2002 (2002)	
Drugs and Devices	1. Ministry of Health (MOH) (Romanian): http://www.ms.ro/ 2. National Medicines Agency: http://www.anm.ro/en/home.html		MOH: 1. Order 904/25Jul2006 on Approval of Rules Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use -- Transposition of 2001/20/EC Directive 2. Order 905/25Jul2006 on Approval of the Principles and Guidelines for Good Manufacturing Practice in Respect of Medicinal Products for Human Use and Investigational Medicinal Products for Human Use -- Transposition of the 2003/94/CE Directive *Access:* http://www.anm.ro/en/html/legislation_minister_orders.html	MOH: Guideline for Clinical Trials in Pediatric Populations (CPMP/ICH/2711/99) (1999)
Research Injury	National Medicines Agency: http://www.anm.ro/en/home.html	Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
Privacy/Data Protection	National Supervisory Authority for Personal Data Processing: http://www.dataprotection.ro/index.jsp?page=documents&lang=en	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: http://www.dataprotection.ro/servlet/ViewDocument?id=174		
Human Biological Materials	Ministry of Health (MOH) (Romanian): http://www.ms.ro/	Law No. 95/2006 Regarding the Reform in Health Field. Title	Directive 2010/53/EU of the European Parliament and of the	

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		VI. Performing of Sampling and Transplant of Organs, Tissues and Human Origin Cells with Therapeutic Purpose: http://www.transplant.ro/Lege/TitlulVI_Legea_95_2006.html	Council of 7 July 2010 on Standards of Quality and Safety of Human Organs Intended for Transplantation: http://europa.eu/legislation_summaries/public_health/threats_to_health/sp0008_ro.htm	
Embryos, Stem Cells, and Cloning		1. 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 (2001) 2. Law No. 301 from 2004 Penal Code – Chapter IV – Crimes and Felonies Regarding Genetic Manipulation: http://www.codpenal.ro/legislatie/document/lege-301-din-2004-codul-penal-capitol-4-crime-si-delicte-privind-manipularea-genetica-1260-63259.html		
Russia				
General	1. Ministry of Healthcare of the Russian Federation: http://www.rosminzdrav.ru 2. Federal Service on Surveillance in Healthcare (Roszdravnadzor): (Russian): http://www.roszdravnadzor.ru/	1. Constitution of the Russian Federation, Article 21 (1993): http://www.constitution.ru/en/10003000-03.htm 2. Federal Law #FZ 323 "On Foundations of Protection of Citizen's Health in the Russian Federation" (2011) (Russian): http://www.rosminzdrav.ru/docs/laws/104		
Drugs and Devices	Council of Ethics of the Ministry of Healthcare of the Russian Federation: http://www.roszdravnadzor.ru/etika/et/norm	Federal Law #61FZ "On circulation of Medicines" (2011): http://www.consultpharma.ru/index.php?option=com_content&view=article&id=152:61fz&catid=31:drugs&Itemid=36&lang=en	MOH: 1. Ministry of Health Order No. 753n (August 26, 2010) "On Assertion of Order of Organization and Carrying out of Ethical Review…" (Russian): http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=104353 2. Ministry of Health Order No.	

Country	Key Organizations	Legislation	Regulations	Guidelines
			774n (August 31, 2010) "On Council of Ethics" (Russian): http://www.businesspravo.ru/Docum/DocumShow_DocumID_171302.html GOST: Good Clinical Practice. GOST-R 52379-2005 (September 27, 2005)	
Research Injury		Federal Law #61FZ "On Circulation of Medicines" (2011), Art. 38-44: http://www.consultpharma.ru/index.php?option=com_content&view=article&id=152:61fz&catid=31:drugs&Itemid=36&lang=en		
Privacy/Data Protection		1. Federal Law of the Russian Federation on Information, Information Technologies, and Protection of Information (2006) 2. Federal Law of the Russian Federation No. 152-FZ on Personal Data (2006): http://www.hunton.com/files/tbl_s47Details/FileUpload265/1625/Privacy_Russia_White_Paper.pdf		
Genetic	Inter-Departmental Commission on Genetic-Engineering Activity	Federal Law of July 5, 1996, N OF 8'-FZ "About the State Control in the Area of Genetic-Engineering Activity" (With changes of July 12, 2000)	Order of the Ministry of Education and Science of the Russian Federation #154 (2005): "Statute of the Inter-Departmental Commission on Genetic-Engineering Activity" (Russian): http://www.zakonprost.ru/content/base/part/438157	
Embryos, Stem Cells, and Cloning		Federal Law #30-FZ "On Introduction of Change in Art. 1 of the Federal Law "On Temporary Ban on Human Cloning" (2010) (Russian): http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=98895;fld=134;dst=100008;rnd=0.5044818258109531		
San Marino				

Country	Key Organizations	Legislation	Regulations	Guidelines
General		Oviedo Convention on Human Rights and Biomedicine (1998)		
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1999)		
Serbia				
Drugs and Devices	1. Ministry of Health (MOH): http://www.zdravlje.gov.rs/ 2. Serbian Drug Agency http://www.alims.gov.rs/eng/	Law on Medicines and Medical Devices, Official Gazette of RS No. 30/2010 and 107/2012: http://www.alims.gov.rs/ciril/files/2012/11/zakon-30-2010-107-2012.pdf	MOH: Regulation on Content of Requests and Documents for Approval of Clinical Trials and Procedures for Conducting Clinical Trials, Official Gazette of RS, 64/2011, 31 August 2011: http://www.alims.gov.rs/ciril/files/2012/06/p-klinicka-64-2011.pdf	
Research Injury	1. Ministry of Health (MOH): http://www.alims.gov.rs/eng/ 2. Serbian Drug Agency http://www.alims.gov.rs	Law on Medicines and Medical Devices, Article 72 (Serbian): http://www.alims.gov.rs/ciril/files/2012/11/zakon-30-2010-107-2012.pdf	MOH: Regulation on Content of Requests and Documents for Approval of Clinical Trials and Procedures for Conducting Clinical Trials, Official Gazette of RS, 64/2011, 31 August 2011	
Privacy/Data Protection	Commissioner for Information of Public Importance and Personal Data Protection: http://www.poverenik.rs/en/the-commissioners-authority-di.html	Law on the Protection of Personal Data, Official Gazette 97/08, 104/09, 68/20 and 107/12: http://www.poverenik.rs/images/stories/dokumentacija-nova/zakon-o-zastiti-podataka-o-licnosti_en.pdf		
Embryos, Stem Cells, and Cloning		Law on Organ Transplantation, Official Gazette No. 72/2009 (Serbian): http://www.rfzo.rs/download/zakoni/Zakon_transplantacija.pdf		
Slovakia For an overview of human subject protections in Slovakia, see "National Regulations on Ethics and Research in Slovak Republic:" ec.europa.eu/research/science-society/pdf/sk_eng_lr.pdf				
General	1. Ministry of Health (Slovak): http://www.health.gov.sk/ 2. Institute of Medical Ethics and Bioethics: http://www.bioethics.sk/	1. Act No. 576/2004 Coll on Health Care, as amended by Acts No. 350/2005, 282/2006, 662/2007, 345/2009 Coll.: http://www.privireal.org/content/rec/documents/Slovakia_ActNo576_H		

Country	Key Organizations	Legislation	Regulations	Guidelines
		ealthcare_2004.pdf 2. Oviedo Convention on Human Rights and Biomedicine (1998) 3. Additional Protocol on Biomedical Research (2005)		
Drugs and Devices	State Institute for Drug Control: http://www.sukl.sk/en	Act No. 140/1998 Coll. on Drugs and Medical Devices, as amended by Acts No. 9/2004 and 542/2006, 489/2008, and 402/2009 Coll.	Ministerial Regulation No. 239/2004 Coll. on Requirements for Clinical Trials and Good Clinical Practice, as amended by Ministerial Regulation No. 148/2009 Coll.	
Research Injury		Law 277/1994 on Health Care, Section 44		
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 by Act No. 90/2005 Coll.: http://www.privireal.org/content/dp/documents/SlovakiaAct428_2002%20_2005_PersonalData.pdf		
Human Biological Materials		1. Act No. 576/2004 Coll. on Health Care, Sections 35-39. 2. Act No. 489/2008 Coll. on Drugs and Medical Devices, Section 18 (29b).	Governmental Regulation No. 20/2007 Coll. on Tissue and Cell Collection	
Embryos, Stem Cells, and Cloning		1. Act No. 576/2004 Coll. on Health Care, Section 26.10.a. 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 (1998)		
Slovenia 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	National Medical Ethics Committee (NMEC)	1. Oviedo Convention on Human Rights and Biomedicine (1998) 2. Additional Protocol on Biomedical Research (2006)		Slovenian Code of Medical Deontology, Articles 47-50 (1992)
Drugs and Devices	*Drugs*			

Country	Key Organizations	Legislation	Regulations	Guidelines
	1. National Medical Ethics Committee (NMEC) 2. Agency for Medicinal Products and Medical Devices (Slovenian): http://www.jazmp.si/index.php?id=56	Bylaw on Clinical Trials, Official Gazette, No. 54/06	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	
	Devices			
	Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/index.php?id=56			Various: http://www.jazmp.si/index.php?id=115
Research Injury		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1999) 2. Additional Protocol Concerning Biomedical Research, Article 13, CETS No. 195 (2007)		
Privacy/Data Protection	Inspectorate for Personal Data Protection (Slovenian): http://www.ip-rs.si/	1. Personal Data Protection Act No. 59 (1999) 2. Act Amending the Personal Data Protection Act No. 57/2001		
Human Biological Materials	1. National Medical Ethics Committee (NMEC) 2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/index.php?id=56		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		1. 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 (2002) 2. Law on Biomedically Assisted Fertilization No. 70 (2000)		

Country	Key Organizations	Legislation	Regulations	Guidelines
Spain For an overview of human subject protections in Spain, see "National Information – Spain": http://www.eurecnet.org/information/spain.html				
General	1. Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US 2. Coordinating Center for Ethical Committees on Clinical Research (Spanish): http://www.msc.es/profesionales/farmacia/ceic/home.htm 3. Institute of Health Carlos III, Ministry of Science and Innovation http://www.isciii.es/htdocs/en/index.jsp	1. Oviedo Convention on Human Rights and Biomedicine (1999): http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/ETS164Spanish.pdf 2. Law 14/2007 on Biomedical Research: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Drugs and Devices Note: Many of the Spanish autonomous communities have their own laws and regulations pertaining to drug research.	*Drugs* Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/investigacionClinica/medicamentos/home.htm	1. Royal Decree 223/2004: Regulation of Medication Clinical Trials: http://www.aemps.gob.es/en/legislacion/espana/investigacionClinica/docs/rcl_2004_325.pdf 2. Law 29/2006, of Guarantees and Rational Use of Medicines and Sanitary Products (Spanish): http://www.aemps.gob.es/en/legislacion/espana/laAEMPS/docs/general/rcl_2006_1483.pdf 3. Royal Decree 1015/2009: Drug Availability for Special Purposes (Spanish): http://www.boe.es/boe/dias/2009/07/20/pdfs/BOE-A-2009-12002.pdf 4. Royal Decree 577/2013, Regulating Pharmacovigilance in Human Use Medicines: http://www.boe.es/diario_boe/txt.php?id=BOE-A-2013-8191 5. Law 10/2013, Incorporating into Spanish Laws Certain EU Directives About Monitoring and Preventing Commercialization of Counterfeit Medicines (Spanish): http://www.boe.es/diario_boe/txt.php?id=BOE-A-2013-8083	1. Order SCO/256/2007 That Establishes the Principles and Detailed Directives on Good Clinical Practice, and the Requirements to Approve the Manufacture and Import of Research Medications for Human Use (Spanish): http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rcl_2007_270.pdf 2. Order SCO/362/2008 that Modifies Order SCO/256/2007 (Spanish): http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rcl_2008_410.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Devices			
	Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/investigacionClinica/productosSanitarios/home.htm	Royal Decree 1591/2009, Regulating Sanitary Devices: http://www.ont.es/infesp/Legislacin/RD_1591_2009.pdf	Various (Spanish): http://www.aemps.es/actividad/pschb/implantables1.htm#circulares	
Research Injury	Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/home.htm	Royal Decree 223/2004: Regulation of Medication Clinical Trials, Article 8: http://www.aemps.gob.es/en/legislacion/espana/investigacionClinica/docs/rcl_2004_325.pdf Law 14/2007 on Biomedical Research, Article 18: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Privacy/Data Protection Note: Many of the Spanish autonomous communities have their own laws and regulations on privacy/data protection.	Spanish Data Protection Authority (Spanish): https://www.agpd.es/portalweb/index-ides-idphp.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. Law 14/2007 on Biomedical Research, Title I, Article 5: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf	1. Royal Decree 1720/2007 (Spanish): https://www.agpd.es/portalwebAGPD/canaldocumentacion/legislacion/estatal/common/pdfs/RD_1720_2007.pdf 2. Royal Decree of 19 January 2008 (Spanish): https://www.agpd.es/portalwebAGPD/canaldocumentacion/legislacion/estatal/common/pdfs/RD_1720_2007.pdf	
Human Biological Materials	Ministry of Health and Consumption: http://www.msc.es/en/home.htm	1. Royal Decree 1301/2006 of November 10 Regarding the Use of Cells and Human Tissue: http://www.ont.es/legislacion/ficherosPDF/RD1301.pdf 2. Royal Decree 2070/1999 of December 30, Regarding Activities of Collection and Clinical Use of Human Organs for Organ Transplants and Tissues 3. Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglis	Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples (2006) (Spanish): http://www.boe.es/boe/dias/2006/02/07/pdfs/A04626-04636.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
		h.pdf 4. Royal Decree 1716/2011 on Biobanks: http://www.comitedebioetica.es/normativa/docs/RD%201716_2011_de%20autorizacion%20y%20funcionamiento%20de%20los%20biobancos.pdf		
Genetic	Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US	Law 14/2007 of July 3 on Biomedical Research, Title I, Articles 6-9; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Embryos, Stem Cells, and Cloning	Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US	1. 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 (2000) 2. Law 14/2006 on Methods of Assisted Human Reproduction, Chapters IV and V: http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Spain/page.aspx/170 3. Law 14/2007 of July 3 on Biomedical Research, Title III: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Sweden For an overview of human subject protections in Sweden, see "CODEX: Rules and Guidelines for Research:" http://www.codex.uu.se/en/index.shtml				
General	1. Central Ethical Review Board (CEPN): http://www.epn.se/start/startpage.aspx 2. 2. Swedish Research Council (SRC): http://www.vr.se/english	Law No. 460 on the Ethical Review of Research Involving Humans (2003): http://www.epn.se/media/45159/the_etical_review_act.pdf	CEPN: 1. Ordinance No. 615 Concerning the Ethical Vetting of Research Involving Humans (2003): http://www.epn.se/media/45162/2003_615.pdf 2. Statute No. 2007:1069 Containing Instructions for Regional Ethical Review Boards	CEPN: Information for Research Participants SRC: 1. Guidelines for the Ethical Evaluation of Medical Research on Humans (2003) 2. Policy Statement Regarding the Assessment of Scientific Studies in which Patients or Healthy Subjects are to

Country	Key Organizations	Legislation	Regulations	Guidelines
			(2007): http://www.epn.se/media/45228/1069.pdf 3. Statute No. 2007:1068 Containing Instructions for the Central Ethical Review Boards (2007): http://www.epn.se/media/45225/1068.pdf SRC: Regulations and General Counsel VRFS 2012:1 on Ethical Vetting of Human Subjects Research: http://www.epn.se/media/48216/vrfs_2012_1.pdf	Undergo Invasive Operations (2003) 3. Good Research Practice: http://www.cm.se/webbshop_vr/pdfer/2011_03.pdf
Drugs and Devices	*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	MPA Regulations on Clinical Trials in Humans -- LVFS 2011:19 (Swedish): http://www.lakemedelsverket.se/upload/lvfs/LVFS_2011_19.pdf	
	Devices			
	Medical Products Agency: http://www.lakemedelsverket.se/english/product/Medical-devices/Clinical-Investigations/	1. Swedish Medical Devices Act (SFS 1993:584) 2. Medical Devices Ordinance (SFS1993:876)	1. Swedish Implementation of Directive 90/385/EEC -- LVFS 2001:5 2. Swedish Implementation of Directive 93/42/EEC -- LVFS 2003:11 with Amendment LVFS 2004:11	
Privacy/Data Protection	1. Swedish Data Inspection Board: http://www.datainspektionen.se/in-english/ 2. Swedish Research Council (SRC): http://www.vr.se/english	SFS 2009:400 - Public Access to Information and Secrecy Act: http://www.notisum.se/rnp/sls/lag/20090400.htm	SFS 2009:641 - Public Access to Information and Secrecy Ordinance: http://www.notisum.se/rnp/sls/lag/20090641.htm	Swedish Data Inspection Board Report 2004:2: http://www.datainspektionen.se/Documents/rapport-biobanker.pdf SRC: Policy Document: Handling Personal Data (Swedish): http://www.vr.se/download/18.6b2f98a910b3e260ae28000342/Personuppgifter_7.pdf
Human Biological Materials	1. National Board of Health and Welfare (SOS): http://www.socialstyrelsen.se/english 2. Swedish Research Council (SRC): http://www.vr.se/english	1. Biobanks in Medical Care Act No. 297 (2002): http://www.biobanksverige.se/getDocument.aspx?id=339 2. Regulation No. 746 (2002):	SOS: Consolidated regulations (Swedish): http://www.socialstyrelsen.se/sosfs/2002-11/Sidor/2002-11.aspx	SRC: Research Ethics Guidelines for Using Biobanks (Swedish) (2003) http://www.vr.se/download/18.6b2f98a910b3e260ae28000350/Riktlinjer_Biobanker_11.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
	3. Swedish National Biobank Program: http://www.biobanks.se/	http://www.notisum.se/rnp/sls/lag/20020746.htm		
Genetic Research	1. Ministry of Health and Social Affairs: http://www.sweden.gov.se/sb/d/2061 2. National Board of Health and Welfare: http://www.socialstyrelsen.se/english	Act on Genetic Integrity (2006:351) (Swedish): http://www.notisum.se/rnp/sls/lag/20060351.htm	Drug Administration Regulations and Guidelines (LVFS 2004:10) on the Intentional Release of Clinical Trials of Medicinal Products Containing or Consisting of Genetically Modified Organisms: http://www.lakemedelsverket.se/upload/lvfs/LVFS_2004-10.pdf	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) (Swedish): 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 2. Regulations and Guidelines for the Use of Tissues and Cells in Healthcare and Clinical Research - SOSFS 2009:32: http://www.socialstyrelsen.se/sosfs/2009-32/Documents/2009_32.pdf	SRC: Guidelines for Ethical Vetting of Human Stem Cell Research (Swedish): http://www.vr.se/download/18.6b2f98a910b3e260ae28000362/human_stamcellsforskning_16.pdf
Switzerland				
General	1. Federal Office of Public Health (BAG): http://www.bag.admin.ch/index.html?lang=en 2. National Advisory Commission on Biomedical Ethics (NEK-CNE): http://www.bag.admin.ch/nek-cne/index.html?lang=en&langId=2 3. Swiss Association of Research Ethics Committees: www.swissethics.ch	Swiss Federal Constitution, Article 118b (2010): http://www.admin.ch/opc/en/classified-compilation/19995395/index.html#a118b Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG BAG: Federal Act on Research Involving Human Beings (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3215.pdf	1. Ordinance on Clinical Trial (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3407.pdf 2. Ordinance on Research Involving Human Beings, with the Exception of Clinical Trials (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3381.pdf 3. Ordinance on the Organization of the Federal Act on Research Involving Human Beings (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3455.pdf	SAMS: 1. Guidelines on Human Research (1997) 2. Memorandum Concerning Research on Human Beings (2009)
Drugs and Devices	*Drugs*			

Country	Key Organizations	Legislation	Regulations	Guidelines
	1. Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en 2. Federal Office of Public Health (BAG): http://www.bag.admin.ch/index.html?lang=en	Swissmedic: Federal Law on Medicinal Products and Medical Devices, RS 812.21 (2002) (French): http://www.admin.ch/ch/f/rs/c812_21.html BAG: Federal Act on Research Involving Human Beings (2014) (French): http://www.admin.ch/opc/fr/federal-gazette/2011/6823.pdf	1. Ordinance on Clinical Trial (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3407.pdf 2. Ordinance on Research Involving Human Beings, with the Exception of Clinical Trials (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3381.pdf 3. Ordinance on the Organization of the Federal Act on Research Involving Human Beings (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3455.pdf	
	Devices			
	Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/produktbereiche/00450/index.html?lang=en	Swissmedic: Federal Law on Medicinal Products and Medical Devices, RS 812.21 (2002) (French): http://www.admin.ch/ch/f/rs/c812_21.html Unofficial English version: http://www.swissmedic.ch/leitfaden/00016/index.html?lang=en&download=NHzLpZeg7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCDdIR,gmym162epYbg2c_JjKbNoKSn6A-- BAG: Federal Act on Research Involving Human Beings (2014) (French): http://www.admin.ch/opc/fr/federal-gazette/2011/6823.pdf	1. Ordinance on Clinical Trial (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3407.pdf 2. Ordinance on Research Involving Human Beings, with the Exception of Clinical Trials (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3381.pdf 3. Ordinance on the Organization of the Federal Act on Research Involving Human Beings (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3455.pdf	Guide to the Regulation of Medical Devices: http://www.swissmedic.ch/php/modules/leitfaden/leitfaden.html?lang=en
Research Injury	1. Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en 2. Federal Office of Public Health (BAG): http://www.bag.admin.ch/index.html?lang=en	BAG: Federal Act on Research Involving Human Beings, Articles 19 and 20 (2014) (French): http://www.admin.ch/opc/fr/federal-gazette/2011/6823.pdf	1. Ordinance on Clinical Trials, Articles 10-14 (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3407.pdf 2. Ordinance on Research Involving Human Beings, with the Exception of Clinical Trials, Art. 12-13 (2014) (French): http://www.admin.ch/opc/fr/official-	Swissmedic: 1. Requirements for Insurance Policies for Clinical Trials on Therapeutic Products Involving Human Subjects (2007): 2. Requirements for Insurance Policies for Clinical Trials on Therapeutic Products Involving Human Subjects 3. Insurance Certificate for the Attention of the Swiss Ethics Commissions (2007)

Country	Key Organizations	Legislation	Regulations	Guidelines
			compilation/2013/3381.pdf	
Privacy/Data Protection Note: Most Swiss cantons have enacted laws regarding data collection in the public sector.	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. Federal Act on Research Involving Human Beings (2014) (French): http://www.admin.ch/opc/fr/federal-gazette/2011/6823.pdf 3. Federal Act on Research Involving Human Beings, Articles 57-60 (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3215.pdf	1. Ordinance on Clinical Trials, Article 18 (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3407.pdf 2. Ordinance on Research Involving Human Beings, with the Exception of Clinical Trials, Articles 12-13 (2014) (French) http://www.admin.ch/opc/fr/official-compilation/2013/3381.pdf	
Human Biological Materials	1. Federal Office of Public Health (BAG): http://www.bag.admin.ch/index.html?lang=en 2. Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/	BAG: Federal Act on Research Involving Human Beings (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3215.pdf	1. Ordinance on Clinical Trials, Articles 22 and 35 (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3407.pdf 2. Ordinance on Research on Human Beings, with the Exception of Clinical Trials (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3381.pdf 3. Ordinance of 14 February 2007 on Human Genetic Testing, RS 810.122.1 (French): http://www.admin.ch/ch/f/rs/810_122_1/index.html	SAMS: Biobanks: Obtainment, Preservation and Utilization of Human Biological Material (2006): http://www.samw.ch/dms/en/Ethics/Guidelines/Currently-valid-guidelines/e_RL_Biobanken.pdf
Genetic Research		1. Swiss Federal Constitution, Article 119 (2006) (French): http://www.admin.ch/ch/f/rs/101/a119.html 2. Federal Act on Research Involving Human Beings (2014) (French): http://www.admin.ch/opc/fr/federal-gazette/2011/6823.pdf	1. Ordinance on Clinical Trials, Articles 22 and 35 (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3407.pdf 2. Ordinance on Research on Human Beings, with the Exception of Clinical Trials (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3381.pdf 3. Ordinance of 14 February 2007 on Human Genetic Testing, RS 810.122.1 (French): http://www.admin.ch/ch/f/rs/810_122	

Country	Key Organizations	Legislation	Regulations	Guidelines
			_1/index.html	
Embryos, Stem Cells, and Cloning	Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE): http://www.bag.admin.ch/nek-cne/04236/index.html?lang=en	*Embryos in Vivo:* Federal Act on Research Involving Human Beings (2014) (French): http://www.admin.ch/opc/fr/federal-gazette/2011/6823.pdf *Others:* Federal Act of 19 December 2003 on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), RS 810.13 (French): http://www.admin.ch/ch/e/rs/c810_31.html	*Embryos in Vivo:* Ordinance on Clinical Trials (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3407.pdf *Others:* Ordinance of 2 February 2005 on Research involving Embryonic Stem Cells (Stem Cell Research Ordinance, SCRO), RS 810.311 (French): http://www.admin.ch/ch/e/rs/c810_311.html	NEK-CNE: 1. Pre-Implantation Genetic Diagnosis, Opinion No. 10/2005 2. Research Involving Human Embryos and Fetuses. Opinion No. 11/2006 3. Pre-Implantation Genetic Diagnosis II, Opinion No. 14/2007 *Access:* http://www.bag.admin.ch/nek-cne/04229/04232/index.html?lang=en
Turkey				
General	Ministry of Health (Turkish): http://www.saglik.gov.tr/	1. Turkish Constitution, Article 17 2. Health Services Basic Law No. 3359 (1987) 3. Oviedo Convention on Human Rights and Biomedicine (2004)	1. Regulation on Medical Deontology, Article 11 (1960) 2. Bylaw on Patient Rights No. 23420 (1998)	
Drugs and Devices	*Drugs*			
	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr	Turkish Penal Law, Article 90 (2005)	1. Fundamental Law #3359 on Health Services, Supplemental Article 10 (2011): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=1&thelawId=347 2. Regulation on Clinical Trials (2013): http://www.klinikarastirmalar.org.tr/en/document.php?id=291	1. Guideline for Good Clinical Practice (2013) (Turkish): http://www.iegm.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=6&thelawId=421 2. Guidance on the Ethics of Pediatric Clinical Research (2013) (Turkish): http://www.iegm.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=6&thelawId=319 3. Drug Observational Studies Guide (2013): http://www.titck.gov.tr/Folders/TheLaws/Clinical%20Drug%20Research%20Department/GUIDELINE_FOR_OBSERVATIONAL_STUDIES_CONDUCTED_ON_DRUGS__August_2011_PO_96aad43.pdf 4. Guideline for Independent Data Review Committees (2013) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-

Country	Key Organizations	Legislation	Regulations	Guidelines
				TR&thelawtype=6&thelawId=316 5. Guidance on Education Programs Related to GCP and Clinical Trials (2013) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=6&thelawId=429 6. Guidance on Archiving in Clinical Research (2013) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=6&thelawId=429?qqepojzfbzargwzp 7. Guidance on Ethical Committee Submission (2013) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=6&thelawId=456?qqepojzfbzargwzp 8. Guidance on Submission to the Turkey Pharmaceuticals and Medical Devices Agency in Clinical Trials (2013) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=6 9. Guidance on Adverse Event Reaction Reporting in Clinical Trials (2013) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=6&thelawId=461
	Devices			
	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr		Various (Turkish): http://www.klinikarastirmalar.org.tr/en/documents.php?dok_cat=25	
Research Injury	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr	Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2004)		Guidance on Insuring Volunteers in a Clinical Trial (2011): http://www.titck.gov.tr/Folders/TheLaws/Clinical%20Drug%20Research%20Department/GUIDANCE_ON_INSURING_VOLUNTEERS_IN_A_CLINICAL_TRIAL_August__2011_rev_PO__47a0c5b.pdf
Human Biological Materials		1. Law on Procurement, Preservation, Grafting, and Transplantation of Organs and Tissues, No. 2238 (1979)	Regulation on Blood and Blood Products, No. 7314 (1983)	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999) 2. Good Clinical Practice Guidelines for

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Law on Blood and Blood Products, No. 2857 (1983)		Advanced Therapy Medicinal Products (2011): http://www.titck.gov.tr/Folders/TheLaws/Klinik%20Araştırmalar%20Şube%20Müdürlüğü/Ileri%20tedavi%20Kılavuzu%20Eylül%202011_21a9d11.pdf
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			1. Regulation on Centers for Medically Assisted Procreation, No. 19551 (1987) 2. Regulation on Organ and Tissue Transplantation Services (2005) 3. Regulation on Cordon Blood Banks (2005)	1. Circular on Research of Embryonic Stem Cells (2005) 2. Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)
Ukraine All listed documents are in Ukrainian.				
General	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	1. Criminal Code of Ukraine 2001, Article 142 2. Health Care Law, Article 45 (1992)	Order HEC Ukraine from 29.05.2007 No. 342, with Changes from 03.03.2008 No. 147	
Drugs and Devices	Ministry of Health of Ukraine State Expert Center: http://www.dec.gov.ua	1. On Medicines, Articles 7 and 8 No. 123/96BP (1996): http://www.pharma-center.kiev.ua/site/file_uploads//en/new_doc/law_en.doc 2. Ministry of Health Act 23.09/2009 No. 690, with Changes 12.07.2012 No. 523: http://zakon1.rada.gov.ua/laws/show/z1010-09	1. Ukrainian Ministry of Health Order No. 95 About Approval of Documents Related to the Quality Assurance of Medicines (2009): http://www.moz.gov.ua/ua/main/docs/?docID=12796 With changes 03.10.2011 No. 634: http://www.moz.gov.ua/ua/portal/dn_20111003_634.html 2. Ukrainian Ministry of Health Order No. 690 About Approval of Procedure for Conducting Clinical Trials of Medical Products and Expertise of Materials of Clinical Trials and Model Statute of the Ethics Commission (2009) with changes from 12.07.2012 No. 523: http://zakon1.rada.gov.ua/laws/show/z1010-09	MOH Central Ethics Committee: 1. Information Letters on Ethics Questions of Clinical Trials and Implementation of Medicines (2006) 2. Ethics Expertise of Clinical Trials Medicines (2007) 3. Methodological Aspects of Central EC Activity of Ukrainian Ministry of Health (2007) 4. Ethical Aspects of Placebo Controlled Clinical Trials in Patients with MS (2008) 5. Optimization of Local Ethics Committee Activities (2009)
Research Injury		On Medicines, Article 8 No.		

Country	Key Organizations	Legislation	Regulations	Guidelines
		123/96BP (1996): http://www.pharma-center.kiev.ua/site/file_uploads//en/new_doc/law_en.doc		
Privacy/Data Protection	State Service of Ukraine on Personal Data Protection: http://zpd.gov.ua/dszpd/en/index	1. Information Act from the Cabinet of Ministers of the Ukraine (2002) 2. On Protection Personal Data Act, 01.06.2010 with changes from 23.02.2012 http://zakon3.rada.gov.ua/laws/show/2297-17	1. Ministry of Justice of Ukraine Order 30.12.2011 N 3659/5 About Approval Model Procedures for Processing of Personal Data in Databases with Personal Data: http://zakon3.rada.gov.ua/laws/show/z0001-12 2. Cabinet of Ministry of Ukraine Resolution of 25.05.2011 No. 616 On the Approval of the State Register of Personal Data and the Order of Keeping: http://zakon3.rada.gov.ua/laws/show/616-2011-%D0%BF	
Human Biological Materials	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/main/siterubr/		Ukrainian Ministry of Health Order No. 630 About Approval of Procedure for the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007): http://www.moz.gov.ua/ua/main/docs/?docID=8767	
Genetic Research	Academy of Medical Sciences of the Ukraine			Medical and Ethical Guidelines for Genetic Investigations in Humans
Embryos, Stem Cells, and Cloning	1. National Bioethics Committee of the National Academy of Sciences of the Ukraine (NBC) 2. 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 Council of Europe No. 1046, Use of the Human Fetus for the Purpose of Diagnosis, Therapy, Research, Industrial Purchase, and Trading (1986) 2. Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) with Changes from 23.09.2009 No. 690:	NBC: Ethical Regulations and Problems of Embryo-Tissue Storage (Recommendations)

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://zakon1.rada.gov.ua/laws/show/z1206-07	
United Kingdom 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. Health Research Authority (HRA): http://www.hra.nhs.uk/ 3. National Research Ethics Service (NRES): http://www.nres.nhs.uk/ 4. Medical Research Council (MRC): http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm	Department of Health: http://www.dh.gov.uk/health/category/publications/legislation/		DH: 1. Governance Arrangements for NHS Research Ethics Committees (2011): http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474 2. Research Governance Framework for Health and Social Care (2005) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962 NRES: 1. Directory of NRES Guidance: http://www.nres.nhs.uk/applications/guidance/ 2. Integrated Research Application System: https://www.myresearchproject.org.uk/ Medical Research Council: 1. Personal Information in Medical Research (2000) 2. Research Involving Human Participants in Developing Societies (2004) 3. MRC Guidelines for Good Clinical Practice in Clinical Trials (2006) 4. Medical Research Involving Children (2007) 5. Good Research Practice: Principles and Guidelines (2012) *Access:* http://www.mrc.ac.uk/Newspublications/Publications/Ethicsandguidance/index.htm
	Scotland:			
	1. NHSScotland, Chief Scientist Office (CSO): http://www.cso.scot.nhs.uk/Resources/sitemap.htm 2. NHS Research Scotland:	Adults with Incapacity (Scotland) Act 2000, Section 51: http://www.scotland.gov.uk/Topics/Justice/law/awi/legislation	Adults with Incapacity (Ethics Committee) (Scotland) Regulations (2002): http://www.scotland-legislation.hmso.gov.uk/legislation/sc	CSO: 1. Research Governance Framework for Health and Community Care (2006) 2. Governance Arrangements for NHS Research Ethics Committees (2011):

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.cso.scot.nhs.uk/SuppScience/NRS/NRS.html		otland/ssi2002/20020190.htm	http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474
	Wales:			
	National Institute for Health and Social Care, Welch Government: http://wales.gov.uk/topics/health/research/nischr/?lang=en			Governance Arrangements for NHS Research Ethics Committees (2011): http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474
Drugs and Devices	*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.nhs.uk/ 4. Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk/Pages/default.aspx	Medicines Act (1968): http://www.legislation.gov.uk/ukpga/1968/67/contents	MHRA: 1. Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004): http://www.legislation.gov.uk/uksi/2004/1031/contents/made 2. Amendment Regulations (SI 2006/1928) http://www.legislation.gov.uk/uksi/2006/1928/contents/made 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.legislation.gov.uk/uksi/2006/2984/pdfs/uksi_20062984_en.pdf	MHRA: Consultation Letter on the Medicines for Human Use (Clinical Trials) Regulations (2003): https://www.google.com/url?q=http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con007629.pdf&sa=U&ei=A0qAUM_hHs_J0AGu84GwDw&ved=0CBoQFjAH&client=internal-uds-cse&usg=AFQjCNFuVjyMnPXGv46_3pLxM36SSDmGYQ 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) ABPI: Guidelines for Phase I Clinical Trials (2012): http://www.abpi.org.uk/our-work/library/guidelines/Pages/phase-1-trials-2012.aspx
	Devices			
	1. Medicines and Healthcare Products Regulatory Agency (MHRA): http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/index.htm 2. National Research Ethics Service (NRES): http://www.nres.nhs.uk/		Medical Devices Regulations (2002): http://www.opsi.gov.uk/si/si2002/20020618.htm	MHRA: Clinical Trials for Medical Devices: http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/index.htm NRES: Medical Devices Guidance : http://www.nres.nhs.uk/applications/guidance/guidance-and-good-practice/#medical

Country	Key Organizations	Legislation	Regulations	Guidelines
Research Injury	1. Medicines and Healthcare Products Regulatory Agency (MHRA): http://www.mhra.gov.uk 2. Department of Health (DH): http://www.dh.gov.uk/Home/fs/en 3. Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk 4. Association of the British Healthcare Industry (ABHI): http://www.abhi.org.uk/		Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031, Regulation 15(5)(i)(j)(k) and Schedule 3 Part 1, Paragraphs 1(g) and 3(c) (2004): http://www.mhra.gov.uk/HowHowweregul/Devices/index.hth	DH: Research in the NHS: Indemnity and Arrangements (2005): http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4125284.pdf ABPI: Clinical Trial Compensation Guidelines (1994): http://www.abpi.org.uk/our-work/library/guidelines/Pages/ct-compensation.aspx ABHI: Clinical Investigations Compensation Guidelines (1995): http://www.abhi.org.uk/multimedia/groups/clinical-investigations/ci_compensationguidelines.doc
Privacy/Data Collection	*England:*			
	1. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm 2. Information Commissioner's Office: http://www.informationcommissioner.gov.uk/ 3. National Research Ethics Service (NRES): http://www.nres.nhs.uk/ 4. National Information Governance Board for Health and Social Care: http://www.nigb.nhs.uk/	Data Protection Act (1998): http://www.legislation.gov.uk/ukpga/1998/29/contents		MRC: Personal Information in Medical Research (2000) NRES: Ethical Review of Research Databases: http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-databases/ NHS: Security of NHS Patient Data Shared for Research Purposes (2008): http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/links/infosecresearchdata.pdf/view?searchterm=data%20shared%20for%20research
Human Biological Materials	1. Royal College of Physicians (RCP): http://www.rcplondon.ac.uk/ 2. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm 3. Human Tissue Authority (HTA): http://www.hta.gov.uk/	1. Human Tissue Act (2004): http://www.legislation.gov.uk/ukpga/2004/30/contents 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.legislation.gov.uk/uksi/		RCP: Research Based on Archived Information and Samples (1999) MRC: Human Tissue and Biological Samples for Use in Research (2001) + Annex (2004) HTA:

Country	Key Organizations	Legislation	Regulations	Guidelines
		2006/1260/contents/made 3. Statutory Instrument 2006 No. 1659: The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006: http://www.legislation.gov.uk/uksi/2006/1659/contents/made		Codes of Practice: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice.cfm
Genetics Research	1. Human Genetics Commission: http://www.hgc.gov.uk/Client/index.asp?ContentId=1 2. Public Health Genetics Foundation: http://www.phgu.org.uk/index.php			Human Genetics Commission: http://www.hgc.gov.uk/Client/index.asp?ContentId=1
Embryos, Stem Cells, and Cloning	Human Fertilisation and Embryology Authority: http://www.hfea.gov.uk/	Human Fertilisation and Embryology Act (1990): http://www.legislation.gov.uk/ukpga/1990/37/contents The HFE Act (2008): http://www.hfea.gov.uk/134.html	Human Fertilisation and Embryology Regulation and Chronology: http://www.hfea.gov.uk/1319.html	