

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Embryos, Stem Cells, and Cloning</i>	1. Council of Europe, Bioethics Division (CoE): http://www.coe.int/ 2. European Society of Human Reproduction and Embryology: http://www.eshre.com/	CoE: Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (1998): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=168&CM=8&DF=9/1/04&CL=ENG		
Confederation of Independent States				
<i>General</i>	Interparliamentary Assembly: http://www.iacis.ru/html/index-eng.php			Model Law on the Protection of Human Rights and Dignity in Biomedical Research in the CIS Member States (2005): http://www.iacis.ru/html/index-eng.php?id=54&pag=596&nid=9
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.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
<i>Drugs</i>	1. Agency on Medicines and Medical Technologies 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 of Armenia of January 24, 2002: Procedure for Clinical Trials of New Medications in Armenia		
Austria				
<i>General</i>	1. Forum of Austrian Ethics Committees (German): http://www.ethikkommissionen.at 2. Ministry of Health (German): http://www.bmwf.gv.at	1. University Act (2002): http://www.ris.bka.gv.at/erv/erv_2002_1_120.pdf 2. Hospitals Act (2002): http://www.ris.bka.gv.at/bundesrecht/ (After the word "Suchworte" enter "Krankenanstalten." Then push the "Suche Starten" key. The Hospital Act is seen at "Krankenanstalten- und Kuranstaltengesetz")		Forum of Austrian Ethics Committees: Various guidelines.
<i>Drugs</i>	1. Ministry of Health (German): http://www.bmwf.gv.at 2. Austrian Agency for Health and	Austrian Drug Law (2005) (German): http://www.ris.bka.gv.at/bundesrecht/	Regulation on Leading Ethics Committees: http://www.ris.bka.gv.at/bundesrecht/	Forum of Austrian Ethics Committees: Various guidelines.

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	Food Safety: http://www.ages.at	<u>echt/</u> (Suchworte: “Arzneimittel,” then look for “Arzneimittelgesetz”)	<u>cht/</u> (Suchworte: “Leit- Ethikkommissions-V“)	
Privacy/Data Protection	Austrian Data Protection Commission: http://www.dsk.gv.at/indexe.htm	1. Federal Act Concerning the Protection of Persons (2000): http://www.ris.bka.gv.at/erv/erv_1999_1_165.pdf 2. Privacy/Data Protection laws in Austrian States (German): http://www.dsk.gv.at/landes.htm		
Genetic Research	1. Gene Technology Commission (German): http://www.bmgefj.gv.at/cms/site/search.htm?query=gentechnikkommision 2. Austrian Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	Gene Technology Act No. 510 (1994) (German): http://www.bmgefj.gv.at/cms/site/detail.htm?thema=CH0264&doc=CMS1085735125660	Gene Technology Act (1994) (German): http://www.bmgefj.gv.at/cms/site/detail.htm?thema=CH0264&doc=CMS1085735125660	
Embryos, Stem Cells, and Cloning		1. Reproductive Medicine Act (1992): http://www.ris.bka.gv.at/bundesrecht/ (Suchworte: “Fortpflanzung,” then look for “Fortpflanzungsmedizingesetz”) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		
Belgium				
General	Consultative Bioethics Committee (French): https://portal.health.fgov.be/portal/page?pageid=56,512676&dad=portal&schema=PORTAL	Law Relating to Experimentation on Humans (2004)		1. Opinion No. 13: Regarding Experimentation on Man (2001) 2. Opinion No. 31: Regarding Experimentation Involving Pregnant and Breastfeeding Women (2004)

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<i>Drugs</i>	Medicines Directorate-General (French and Flemish): http://www.afipg.fgov.be/		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)	
<i>Privacy/Data Protection</i>	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/iceri/itl/12privacylaw.php	Decree of February 13, 2001 Implementing the Law of December 8, 1999	
<i>Human Biological Materials</i>	1. Conseil Supérieur de la Santé/Hoge Gezondheidsraad (CSS) (French & 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 Allocation of Organs of Human Origin 3. Act on the Removal and Transplantation of Organs (2006) (French):		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/HOME PAGE MENU/ABOUTUS1 MENU/INSTITUTIONSAPPARENTES1 MENU/HOGEGEZONDHEIDSRAADI MENU/ADVIEZENENAANBEVELINGEN1 MENU/ADVIEZENENAANBEVELINGEN1 DOCS

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		<p>http://www.staatsbladclip.be/lois/2006/08/28/loi-2006022815.html</p> <p>4. 2007 Amendment (French): http://www.staatsbladclip.be/lois/2007/04/13/loi-2007022504.html</p>		/7691_SQ_COMMUNS_2007_FR.PDF
<i>Embryos, Stem Cells, and Cloning</i>	1. Federal Public Service: www.health.fgov.be 2. Federal Commission for Medical and Scientific Research on Embryos in Vitro	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) (French): http://www.staatsbladclip.be/lois/2003/05/28/loi-2003022592.html 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				
<i>Drugs</i>	Ministry of Health	Law on Drugs and Pharmacies, Art. 28		
<i>Privacy/Data Protection</i>		Law on the Protection of Personal Data in Bosnia and Herzegovina (2001): http://www.privacyinternational.org/article.shtml?cmd[347]=x-347-63545		
Bulgaria				
Note: For an overview of human subject protections in Bulgaria, see "National Regulations on Ethics and Research in Bulgaria:" http://ec.europa.eu/research/science-society/pdf/bg_eng_lr.pdf				
<i>General</i>	Ministry of Healthcare: http://www.mh.government.bg/	1. Constitution of the Republic of Bulgaria, Article 29 (1991) 2. Law for Drugs and Pharmacies in Human Medicine (1997)		

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		3. Oviedo Convention on Human Rights and Biomedicine (2001)		
<i>Drugs</i>	1. Ministry of Healthcare: http://www.mh.government.bg/ 2. Bulgarian Drug Agency (BDA): www.bda.bg/	Law for Medicinal Products in Human Medicine (2007), Chapter 4	MOH: Regulation No. 31 on the Rules for GCP (August 12, 2007)	BDA: Guidelines of Good Clinical Practice (1997)
<i>Privacy/Data Protection</i>	Bulgarian Commission for Personal Data Protection: http://www.ceecprivacy.org/main.php?s=2&k=bulgaria	Personal Data Protection Act (2006): http://www.ceecprivacy.org/pdf/law_bulgaria.pdf		
<i>Embryos, Stem Cells, and Cloning</i>	Ministry of Healthcare: http://www.mh.government.bg/	Law Ratifying the Convention for Human Rights (2007)		
Croatia				
<i>Privacy/Data Protection</i>	Croatian Personal Data Protection Agency	Law on Personal Data Protection (2002): http://www.ceecprivacy.org/doc/law_croatia.pdf		
Cyprus				
<i>General</i>		Law No. 31 (III)/2001 (Oviedo Convention on Human Rights and Biomedicine)		
<i>Drugs</i>	1. National Health Authority (Medicines Council): http://pio.gov.cy 2. Ministry of Health, National Bioethics Committee: http://www.moh.gov.cy	Law for Good Clinical Practice (2004)		
<i>Privacy/Data Protection</i>	Commissioner for Personal Data Protection: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/index_en?opendocument	Processing of Personal Data (Protection of the Individual) Law 138(1) 2001: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/\$FILE/138(I)-2001_en.pdf		
Czech Republic				
<i>General</i>	Ministry of Health, Central Ethics Committee (Czech): http://www.mzcr.cz	1. Act No. 20/1996 on the Care for the Health of People 2. Act No. 130/2002 Collection on the Research and Development Support as		

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Drugs	1. Ministry of Health (MOH) (Czech): http://www.mzcr.cz 2. State Institute for Drug Control (SUKL): http://www.sukl.cz/enindex.htm	Amended 1. Act No. 79/1997 Collection, on Pharmaceuticals 2. Amendments to related acts: <ul style="list-style-type: none">• Act No. 149/2000 Collection• Act No. 153/2000 Collection• Act No. 258/2000 Collection• Act No. 102/2001 Collection• Act No. 138/2002 Collection• Act No. 309/2002 Collection• Act No. 320/2002 Collection• Act No. 129/2003 Collection (Issued as Act No. 269/2003 Collection)	MOH: Decree No. 472/2000 Collection, on the Good Clinical Practice and More Detailed Conditions for Clinical Trials on Pharmaceuticals, as Amended	SUKL: KHL-8: Clinical Trial Protocol and Protocol Amendments (1998) KLH-10: Terminology and Principles of Good Clinical Practice (1998) KLH-11: Ethics Committees (1998) KLH-10: Terminology and Principles of Good Clinical Practice (1998) KLH-19: Documentation Required for an Approval of a Clinical Trial on a Human Pharmaceutical (2001) KLH-20: Application for Approval/Notification of a Clinical Trial (2004)
Privacy/Data Protection	Office for Personal Data Protection	Act on the Protection of Personal Data and on Amendment to Some Related Acts (No. 101 of April 4, 2000)		
Embryos, Stem Cells, and Cloning	1. Ministry of Education, Youth, and Sport: www.msmt.cz 2. Research and Development Council, Bioethical Commission: http://www.vyzkum.cz/FrontClanek.aspx?idsekce=15908	Act of 26 April 2006 on Research on Human Embryonic Stem Cells		
Denmark	Note: For an overview of human subject protections in Denmark, see http://www.cvk.im.dk/cvk/site.aspx?p=119 .			
General	1. Danish National Committee on Biomedical Research Ethics (CVK): http://www.cvk.im.dk/cvk/site.aspx?p=119 2. Danish Council of Ethics (DCE): http://www.etiskraad.dk/sw293.asp	1. Act on the Biomedical Research Ethics Committee System (2003): http://www.cvk.im.dk/cvk/site.aspx?p=150 2. Act Amending the Act on the Biomedical Research Ethics Committee System (2006) http://www.cvk.im.dk/cvk/site.aspx?p=152	CVK: 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.im.dk/cvk/site.aspx?p=156	CVK: 1. Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics (2007) 2. Appendices (2007)

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<i>Drugs</i>	Danish Medicines Agency: http://www.dkma.dk	Medicinal Product Act No. 382 (2003)	1. Executive Order No. 935 on Informed Consent from Patients in Biomedical Trials (2000) 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 (2004)	Guideline on Informed Consent from Patients in Biomedical Trials (2000)
<i>Privacy/Data Protection</i>	1. Ministry of Science Technology and Research (VTU) 2. Danish Council of Ethics (DCE): http://www.etiskraad.dk/sw293.asp 3. Danish Data Protection Agency (DPA)	The Act on Processing of Personal Data (Act No. 429) (2007): http://www.datatilsynet.dk/eng/index.html	VTU: Ministerial Order on the Giving of Information to, and the Obtaining of Consent from, Trial Subjects in Biomedical Research Projects (2000)	DCE: Protection of Sensitive Personal Information Other guidelines can be accessed at: http://www.privireal.group.shef.ac.uk/content/dp/denmark.php
<i>Human Biological Materials</i>	Danish National Committee on Biomedical Research Ethics (CVK): http://www.cvk.im.dk/cvk/	Health Law, Chapter 7 (2005) http://147.29.40.90/DELFIN/HTML/A2005/0054630.htm#K7		
<i>Embryos, Stem Cells, and Cloning</i>	Danish Council of Ethics (DCE): http://www.etiskraad.dk/sw293.asp	1. Act on Medically Assisted Procreation (1997) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		DCE: 1. Cloning (2001) 2. The Beginning of Human Life and the Moral Status of the Embryo (2004)
Estonia				
Note: For an overview of human subject protections in Estonia, see "National Regulations on Ethics and Research in Estonia." http://ec.europa.eu/research/science-society/pdf/et_eng_lr.pdf				
<i>General</i>		1. Constitution of the Republic of Estonia, Paragraph 18 (1992) 2. Oviedo Convention on Human Rights and Biomedicine (2001)		
<i>Drugs</i>	1. Minister of Social Affairs (MSA) 2. State Agency of Medicines: http://www.sam.ee/index.aw?set_lang_id=2 3. Estonian Council of Bioethics: http://www.ut.ee/eetikakeskus/download/ethics-committees	Medicinal Products Act (2005): http://www.sam.ee/627	MSA: 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	

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Privacy/Data Protection	Estonian Data Protection Inspectorate: http://www.dp.gov.ee/index.php?id=14	1. Databases Act (1997) 2. Personal Data Protection Act (2003): http://www.legaltext.ee/en/andmebaas/tekst.asp?loc=text&dok=X70030&keel=en&pg=1&ptyvp=RT&ttyp=X&query=data%2BprotectionLink	be Submitted in Order to Obtain Approval (2001)	
Genetic Research	Ethics Committee of the Estonian Genome Project Foundation: http://www.geenivaramu.ee/index.php?lang=eng&sub=72	Human Genes Research Act (RT I 2000, 104, 685) (2000): http://www.geenivaramu.ee/index.php?lang=eng&sub=18&eetika=1&PHPSESSID=ca7dfeabf627e5fba616cc3d4c9b0e24		
Embryos, Stem Cells, and Cloning		Artificial Insemination and Embryo Protection Act (2003)		
Finland				
General	1. Ministry of Social Affairs and Health (MSAH) 2. ETENE Sub-Committee on Medical Research Ethics (TUKIJA): http://www.etene.org/e/tuki/ja/index.shtml 3. National Advisory Board on Research Ethics (TENK): http://pro.tsv.fi/tenk/english1.htm	Medical Research Act No. 295/2004: http://www.finlex.fi/en/laki/kaannokset/1999/en19990488	MSAH: 1. Decree on the National Advisory Board on Health Care Ethics No. 494/1998 2. Decree on Medical Research and Subsidiary Regulations Issued in Pursuance Hereof, No. 898/1999, as amended 313/2004. 3. Decree on the National Research Ethics Council of Finland No. 1347/2002	TUKIJA: Checklist for Researchers and Members of Ethics Committees (2001)
Drugs	1. National Agency for Medicines (NAM): http://www.nam.fi/english/index.html 2. Ministry of Social Affairs and Health (MSAH): http://www.stm.fi	Medicines Act and Decree No. 296/2004	NAM: Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2004 MSAH: Decree on Clinical Trials No. 316/2005	
Privacy/Data Protection	Office of the Data Protection Ombudsman: http://www.tietosuoja.fi/1560.htm	1. Personal Data Act No. 523/1999: http://www.tietosuoja.fi/uploads/hopxtvf.HTM 2. Act on the Amendment of the		

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		Personal Data Act No. 986/2000: http://www.tietosuoja.fi/uploads/p9qzq7zr3xxmm9j.rtf		
<i>Human Biological Materials</i>		Act on the Medical Use of Human Organs and Tissues No. 101/2001: http://www.finlex.fi/pdf/saadkaan/E0010101.PDF		
<i>Genetic Research</i>		Gene Technology Act No. 377/1995		
<i>Embryos, Stem Cells, and Cloning</i>		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002) 2. Medical Research Act No. 295/2004: http://www.finlex.fi/en/laki/kaannokset/1999/en19990488		

France				
<i>General</i>	<p>1. General Health Administration (GHA) (French): http://www.sante.gouv.fr</p> <p>2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr</p> <p>3. National Conference of CPPRB: http://cncp.med.univ-tours.fr/html/index.php</p>	<p>Note: Unless otherwise specified, all French laws that govern human subjects research can be found at the following web site (French): http://www.legifrance.gouv.fr/. From there, go to “Les Codes,” then to “Code de la Santé Publique” (Public Health Code), then to “Nouvelle Partie Législative” (New Legislative Part), and then scroll down to the indicated Article.</p> <p>1. Biomedical Research (Loi Huriet-Sérusclat), Articles L1121-1 to L1126-7 (2004) (French): http://www.legifrance.gouv.fr/</p> <p>2. Decree No. 97-555 Concerning the National Consultative Ethics Committee</p>	<p>GHA:</p> <p>1. Protection of Persons who Participate in Biomedical Research (Public Health Code, Regulatory Section, Additional Book II, Articles R.2001 to R.2053)</p> <p>2. Decision of August 20, 2002</p>	<p>CCNE:</p> <p>Note: Only guidelines issued since 1992 are listed here. The complete list can be found at: http://www.ccne-ethique.fr/english/start.htm, then go to “List of Opinions.”</p> <p>1. Opinion on Ethics Committees (1992)</p> <p>2. Cooperation in the Field of Biomedical Research between French Teams and Teams from Economically Developing Countries. Report (1993)</p> <p>3. Opinion on the Ethics of Research in the Sciences of Human Behaviour. Report (1993)</p> <p>4. Informed Consent of and Information to Persons Accepting Care or Research Procedures (1998)</p> <p>5. Opinion on the Preliminary Draft Revision of the Laws on Bioethics (2001)</p> <p>6. Disparity in Access to Health Care and Participation in Research on a Global</p>

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		for Health and Life Sciences (1997): http://www.ccne-ethique.fr/english/start.htm , then search under "List of Opinions"		Level – Ethical Issues (2003)
Drugs	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr 2. French Health Products Safety Agency (AFSSAPS): http://agmed.sante.gouv.fr/ang/indang.htm	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: http://www.cnil.fr/fileadmin/documents/uk/Decree_20_October_2005_English_version.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-ethique.fr	Donation and Use of the Components and Products of the Human Body, Articles L1211-1 to L1274-3 (2004) (French): http://www.legifrance.gouv.fr/		CCNE: 1. Umbilical Cord Blood Banks for Autologous Use for Research (2002) 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			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)

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<i>Embryos, Stem Cells, and Cloning</i>	National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	1. Bioethics Law (1994) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		CCNE: Commercialisation of Human Stem Cells and Other Cell Line (2006)
Georgia				
Note: 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.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
<i>Drugs</i>	Drug Agency of the Ministry of Health, Labour, and Social Affairs: www.gda.ge	1. Drug and Pharmacy Law No. 659 (1997) 2. Licenses and Approvals Law (2005)	Regulation about the Rules and Conditions of Issuing of the Approval of Clinical Trials Approved #176 (2005)	
Germany				
Note: For an overview of human subject protections in Germany, see http://www.eurecnet.org/bodies/germany/index.html				
<i>General</i>	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. National Ethics Council (NER): http://www.ethikrat.org/_english/index.html 5. Federal Ministry of Health (BMG): http://www.bmg.bund.de/cln_041/nen_600110/EN/Home/homepage_node.param=.html_nnn=true			BÄK: (Model) Professional Code of Conduct, Section 15 (2006) (German): http://www.bundesaerztekammer.de/page.asp?his=1.100.1143
<i>Drugs</i>	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/cln_042/nen_424940/EN/drugs/clinTrials/clintrials-node-en.html_nnn=true 2. Federal Ministry of Education and Research (BMBF): http://www.bmbf.de/en/index.php 3. Paul Ehrlich Institute (PEI) (German): http://www.pei.de/cln_048/DE/home/	Medicinal Products Act, Sections 40-42 (2006): http://www.bmg.bund.de/cln_040/nen_603266/SharedDocs/Download/EN/Health/AMG-pdf.templateId=raw.property=publicationFile.pdf/AMG-pdf.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) 3. Regulation for the Application of Good Clinical Practice of Clinical Medications for Human	

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	<p>de-node.html?_nnn=true</p> <p>4. Federal Ministry of Health (BMG): http://www.bmg.bund.de/cln_041/nn_600110/EN/Home/homepage_node.param=.html_nnn=true</p>		<p>Use (2006)</p> <p>BMBF: Principles and Responsibilities Related to Clinical Studies (2003)</p>	
Privacy/Data Protection	<p>Federal Commissioner for Data Protection and Freedom of Information: http://www.bfdi.bund.de/cln_030/nn_533554/EN/Home/homepage_node.html_nnn=true</p>	<p>Federal Data Protection Act, as Amended (2003): http://www.bfdi.bund.de/cln_029/nn_535764/EN/DataProtectionActs/DataProtectionActs_node.html_nnn=true</p> <p>The 16 German states also have laws about data protection in the non-federal public sector (German): http://www.datenschutz-bayern.de/infoquell/ds-inst/deutschland.html</p>		
Human Biological Materials	<p>1. German Society of Surgery (DGCH) (German): http://www.dgch.de/</p> <p>2. German Medical Association (BÄK): http://www.bundesaerztekammer.de/page.asp?his=4.3569</p> <p>3. German National Ethics Council (NER): http://www.ethikrat.org/_english/index.html</p> <p>4. Central Ethics Commission of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/</p> <p>5. German Institute for Cell and Tissue Replacement (DIZG) (German): http://www.dizg.de</p>	<p>1. Transplantation Law (2007) (German): http://bundesrecht.juris.de/bundesrecht/tpg/gesamt.pdf</p> <p>2. Transfusion Law (2007) (German): http://www.gesetze-im-internet.de/bundesrecht/tfg/gesamt.pdf</p> <p>3. Act of Quality and Security of Human Tissue and Cells (2007) (German): http://www.bmg.bund.de/cln_041/nn_600110/SharedDocs/Gesetzesexte/Arzneimittel/Gewebege setz_templateId=raw_property=publikationFile.pdf/Gewebege setz.pdf</p>	<p>DGCH Rule for the Production of Human Tissues (German): http://www.dgch.de/dgch/aktuelle_s/gewebegegesetz/index.html</p>	<p>BÄK: Organ Transplantation (German): a. http://www.bundesaerztekammer.de/downloads/RiliOrgantrans20070323.pdf b. http://www.bundesaerztekammer.de/downloads/RiliMed.pdf c. http://www.bundesaerztekammer.de/downloads/AnfOrga.pdf</p> <p>More guidelines of the BÄK (German): http://www.bundesaerztekammer.de/page.asp?his=0.7.45&all=true</p> <p>NER: Opinion on Biobanks for Research (2004): http://www.ethikrat.org/_english/publications/Opinion_Biobanks-for-research.pdf</p> <p>ZEKO (German): http://www.zentrale-ethikkommission.de/downloads/Koerperm at.pdf</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
				DIZG: 1. Ethical Code (2000) 2. Common Standards: Tissues and Cell Banking (2004)
<i>Genetic Research</i>	<p>1. German Medical Association (BÄK): http://www.bundesaerztekammer.de/page.asp?his=4.3569</p> <p>2. German Society of Human Genetics (GFHEV): http://www.gfhev.de/en/gfh/</p> <p>3. Paul-Ehrlich-Institut (PEI) (English): http://www.pei.de/cln_048/nm_15903/EN/institute-en/institut-node-en.html?_nnn=true</p>	Law of 20 June 1990 /16.12.1993 to Regulate Matters Related to Gene Technology (2006)		<p>BÄK: Guideline on Gene Transfer (1995) (German) http://www.bundesaerztekammer.de/30/Richtlinien/Richtlin/Gentransferpdf.pdf</p> <p>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)</p> <p>PEI: Gene Therapy Information: http://www.pei.de/cln_048/nm_162568/EN/infos-en/fachkreise-en/genther-fach-en/genther-fach-node-en.html?_nnn=true</p>
<i>Embryos, Stem Cells, and Cloning</i>	<p>1. German National Ethics Council (NER): http://www.ethikrat.org/_english/index.html</p> <p>2. German Research Foundation (DFG): http://www.dfg.de/en/</p> <p>3. Central Ethics Commission of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/</p> <p>4. Central Ethics Committee for Stem-Cell Research (ZES) (English): http://www.rki.de/cln_048/nm_21678/2/EN/Content/Institute/DepartmentsUnits/StemCell/StemCel_node.html?_nnn=true</p>	<p>1. Embryo Protection Act (1990): http://www.bmj.bund.de/enid/Publications/Embryo_Protection_Act_19u.html</p> <p>2. Stem Cell Act (2002): http://www.bmj.bund.de/enid/Publications/Embryo_Protection_Act_19u.html</p>	Implementation Regulation for the Stem Cell Act (German): http://bundesrecht.juris.de/zesv/index.html	<p>NER: 1. On the Import of Human Embryonic Stem Cells (2001): http://www.ethikrat.org/_english/publications/stem_cells/Opinion_Import-HESC.pdf 2. Cloning for Reproductive Purposes and Cloning for the Purposes of Biomedical Research (2004): http://www.ethikrat.org/_english/publications/Opinion_Cloning.pdf 3. Should the Stem Cell Law be Amended? (2007): http://www.ethikrat.org/_english/publications/Opinion_Should_the_Stem_Cell_Law_be_amended.pdf</p> <p>DFG: Opinion on Stem Cell Research (2006) (German): http://www.dfg.de/aktuelles_presse/redenstellungnahmen/2006/download/stammzel</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
				<p>lforschung_deutschland_lang_0610.pdf</p> <p>ZEKO:</p> <ol style="list-style-type: none"> 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
Greece				
<i>Drugs</i>	<ol style="list-style-type: none"> 1. National Organization for Medicines (NOM): http://www.eof.gr/eof_en/cnhome.html 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3 	<ol style="list-style-type: none"> 1. A6/10983/1 (1984) 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. Greek Republic Gazette No. 1973 (2003) 4. Act 3418/2005 Code of Medical Ethics 	<p>NOM:</p> <ol style="list-style-type: none"> 1. Ministerial Decision A6/10983/1/12-20.12.1984 on Clinical Trials and Protection of the Human Being (1984) 2. Ministerial Decision DYG3/89292/31.12.2003 (2003) 	<p>NBC:</p> <ol style="list-style-type: none"> 1. Report on Biomedical Experimentations Involving Human Subjects and Clinical Trials of Medicinal Products (2005): http://www.bioethics.gr/media/pdf/reports/report_ct_en.pdf 2. Code of Medical Ethics (2005)
<i>Privacy/Data Protection</i>		<ol style="list-style-type: none"> 1. Hellenic Data Protection Authority: http://www.dpa.gr/home_eng.htm 	<ol style="list-style-type: none"> 1. Greek Constitution 1975/1986/2001 Article 9.1 2. Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998) 3. Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (As Amended by Laws 2819/2000 and 2915/2000): http://www.dpa.gr/Documents/Eng/2472engl_all.doc 4. Act 3418/2005 Code of Medical Ethics 	
<i>Genetic Research</i>	<ol style="list-style-type: none"> 1. Hellenic Data Protection Authority (HDPA): http://www.dpa.gr/home_eng.htm 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3 	<ol style="list-style-type: none"> 1. Greek Constitution 1975/1986/2001, Article 5.5 2. Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998) 		<p>HDPA:</p> <p>Opinion No. 15/2001</p> <p>NBC:</p> <p>Report on the Collection and Use of Genetic Data</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
	<u>Category_id=3</u>			http://www.bioethics.gr/media/pdf/reports/report_genetic_data_eng.pdf
Embryos, Stem Cells, and Cloning				
<p>1. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3</p> <p>2. National Authority for Medically Assisted Reproduction: http://www.iya.gr</p> <p>1. Act 3089/2002 on Medically Assisted Human Reproduction</p> <p>2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)</p>				
<p>NBC:</p> <p>1. Report on Prenatal and Pre-implantation Diagnostic Tests and the Question of Choice of Embryo: http://www.bioethics.gr/media/pdf/reports/pd_pgd_rep_eng2.pdf</p> <p>2. Report on the Use of Stem Cells in Biomedical Research and Clinical Medicine: http://www.bioethics.gr/media/pdf/reports/stem_cell_report_eng.pdf</p>				
Hungary				
<p>Note: 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</p>				
<i>General</i>	<p>1. Ministry of Health (EüM): http://www.eum.hu/?akt_menu=2&set_lang=2</p> <p>2. Medical Research Council, Scientific and Research Ethics Committee</p>	<p>1. Act CLIV of 1997 on Health Care, Chapter VIII</p> <p>2. 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</p> <p>3. Act LXXXI of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research</p>	<p>EüM:</p> <p>Decree on Biomedical Research on Human Beings 23/2002 (V. 9) (2002)</p>	
<i>Drugs</i>	<p>1. National Institute of Pharmacy: http://www.informed.hu/ogyi/english</p> <p>2. Medical Research Council, Ethics Committee for Clinical Pharmacology</p>	Act XCV of 2005 on Medicinal Products for Human Use	<p>EüM:</p> <p>1. Decree 35/2005 (VIII. 26) of the Minister of Health on Clinical Trials of Medicinal Products for Human Use and Good Clinical Practice</p> <p>2. Regulation (EC) 1901/2006 of the European Parliament and of the Council of 12 December 2006</p>	
<i>Privacy/Data Protection</i>	Parliamentary Commissioner for Data Protection and Freedom of Information	Act LXIII of 1992 on Protection of Personal Data and Disclosure of Data of Public Interest, Amended by the Parliamentary		