第5回臨床研究専門委員会	資料　3
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各国・地域の臨床研究に関する法制について

International Compilation of Human Research Protections

2008 Edition

Compiled By:
Office for Human Research Protections
U.S. Department of Health and Human Services

PURPOSE

This Compilation lists the approximately 900 laws, regulations, and guidelines that govern human subjects research in 84 countries, as well as from a number of international and regional organizations. This Compilation was developed for IRBs/Ethics Committees, researchers, sponsors, and others who are involved in international research. Its purpose is to help these groups familiarize themselves with the laws, regulations, and guidelines where the research will be conducted, to assure those standards are followed appropriately.

This year's Compilation features a new section on research standards for Embryos, Stem Cells, and Cloning. The 2008 Edition includes the laws, regulations, and/or guidelines for four new countries: Georgia, Kazakhstan, Kuwait, and Turkey. In addition, Montenegro declared its independence from Serbia in 2006, so that country is now listed separately. Finally, the Compilation includes numerous updates to the 2007 Edition.

ORGANIZATION

The Table of Contents is found on page 3. Under each country, the rows categorize the standards as:

1. General, i.e., applicable to most or all types of human subjects research
2. Drugs
3. Privacy/Data Protection
4. Human Biological Materials
5. Genetic
6. Embryos, Stem Cells, and Cloning

These six categories overlap, so it is necessary to review all standards to obtain a complete understanding of the country's requirements.

The standards are then organized into four columns:

1. Key Organizations – include those groups that issue regulations or guidelines, or serve in a national oversight role for human subjects research
2. Legislation – includes statutes, statutory instruments, legislative decrees, and constitutional provisions, if any, that relate to human subject protections.
3. Regulations – refer to instruments that are created and issued under the name of governmental administrative bodies.
4. Guidelines – refer to non-binding instruments.

The year of the document's initial approval or most recent modification is indicated in parenthesis (when that information is available), unless the date is part of the document's actual title. For example, Law 46/2006 indicates the law was enacted in 2006.

HOW TO ACCESS A DESIRED DOCUMENT

Documents can be accessed in several ways:

1. For laws, the web address (URL) is listed whenever available.
2. For regulations and guidelines, desired documents can be accessed in several ways:
    a. Go to the website of the agency listed in the Key Organizations column and look for the sub-page labeled "guidance," "regulations," or similar terms.
    b. Go to the website of the corresponding agency and e-mail a request for the document.
    c. Perform a web search on the document title.
    d. For non-English language standards, the URL is listed if available.
3. The local research ethics committee also should be able to provide information about applicable laws, regulations, and guidelines.

In most cases the documents are available in English. Sometimes the English translation is a non-official version. When the link is to a non-English language website or document, the language is indicated in parenthesis, e.g., (Spanish).

TOPICS NOT COVERED

In order to focus its scope, the Compilation does not include:

1. Laws that represent enabling legislation, i.e., authorize an agency to promulgate human subjects regulations, but do not direct the content of those regulations.
2. Laws, regulations, or guidelines specific to clinical bioethics, medical devices, adverse event reporting, insurance requirements, clinical trial inspection procedures, assisted reproduction, human tissue engineering, or informed consent in clinical practice.
3. Ethics codes of academic, medical, or other professional organizations.
4. Working papers, drafts, or discussion papers.

Updates and Broken Links

Updates and broken links should be reported to the attention of Edward E. Bartlett, PhD, Office for Human Research Protections, International Activities Program, at: edward.bartlett@hhs.gov .

Disclaimer

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new laws, regulations, and guidelines are issued on a continuing basis, this Compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to human subject protections. While reasonable efforts have been made to assure the accuracy and completeness of the information provided, researchers and other individuals should check with local authorities and/or research ethics committees before starting research activities.

TABLE OF CONTENTS

Region:

Country:

Country	Key Organizations	Legislation	Regulations	Guidelines
INTERNATIONAL				
General	1. Office of the United Nations High Commissioner for Human Rights (OHCHR): http://www.ohchr.org/english/ 2. UNAIDS: http://www.unaids.org/en/default.asp 3. Council for International Organization of Medical Sciences (CIOMS): http://www.cioms.ch/ 4. World Medical Association (WMA): http://www.wma.net/e/ 5. United Nations Educational, Scientific, and Cultural Organization (UNESCO): http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html			OHCHR: International Covenant on Civil and Political Rights, Article 7 (1976) UNAIDS: Ethical Considerations in HIV Preventive Vaccine Research (2000) CIOMS: 1. International Guidelines for Ethical Review of Epidemiological Studies (1991) 2. International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) WMA: Declaration of Helsinki (2004) UNESCO: Universal Declaration on Bioethics and Human Rights (2005)
Drugs	1. World Health Organization (WHO): http://www.who.int/en/ 2. International Conference on Harmonization (ICH): http://www.ich.org/			WHO: 1. Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation (2002) 2. Operational Guidance: Information Needed to Support Clinical Trials of Herbal Products (2005) ICH: E6 Good Clinical Practice: Consolidated Guidance (1996)
Privacy/Data Protection	World Medical Association: http://www.wma.net/e/index.htm			Declaration on Ethical Considerations Regarding Health Databases (2002)
Human Biological Materials	1. World Health Organization: http://www.who.int/en/ 2. International Air Transport Association (IATA): http://www.iata.org/ 3. International Society for Biological and Environmental Repositories (ISBER): http://www.isber.org			WHO: Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research (2003) IATA:

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				Infectious Substances and Diagnostic Specimens Shipping Guidelines (2005) ISBER: Best Practices for Repositories I: Collection, Storage and Retrieval of Human Biological Materials for Research (2005)
Genetic Research	1. UNESCO Bioethics Program: http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html 2. Human Genome Organization (HUGO): http://www.hugo-international.org/			UNESCO: 1. Universal Declaration on the Human Genome and Human Rights (1997) 2. International Declaration on Human Genetic Data (2003) HUGO: 1. Statement on DNA Sampling: Control and Access (1998) 2. Statement on Gene Therapy Research (2001) 3. Statement on Human Genomic Databases (2002)

Country	Key Organizations	Legislation	Regulations	Guidelines
NORTH AMERICA				
Canada				
General	*National:*			
	1. Royal Commission on Aboriginal People (RCAP) 2. National Defence 3. Correctional Service of Canada 4. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/english/ 5. National Council on Ethics in Human Research: http://www.ncehr-cnerh.org/english/home.php			RCAP: Ethical Guidelines for Research (1993): http://www.pre.ethics.gc.ca/english/pdf/RCAP_Guidelines_1993.pdf National Defence: Research Involving Human Subjects (1998): http://www.admfincs.forces.gc.ca/admfincs/subjects/daod/5061/0_e.asp Correctional Service of Canada: Commissioner's Directive - Research: DCOO9 (2004): http://www.csc-scc.gc.ca/text/plcy/cdshtm/009-cde_e.shtml PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2005)
	Newfoundland and Labrador:			
	Health Research Ethics Authority: http://www.hrea.ca/	Bill 23: An Act to Establish a Health Research Ethics Authority for the Province of Newfoundland and Labrador (2006): http://www.hoa.gov.nl.ca/hoa/bills/Bill0623.htm		
	Northwest Territories:			
	Aurora Research Institute: http://www.nwtresearch.com/	Scientist Act (1988): http://www.canlii.org/nt/laws		
	Nunavut:			
	Nunavut Research Institute	Nunavut Scientists Act (1988)		
	Quebec:			
	1. Quebec Minister of Health and Social Services, Ethics Unit (MSSS) (French):	1. Civil Code of Quebec, S.Q., c. 64: Articles 11, 20, 21, 22, 24, and 25 (1991):	MSSS: 1.Terms of Reference for the Research Ethics Boards	FRSQ: Research Ethics and Scientific Integrity Guidelines (2003)

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://ethique.msss.gouv.qc.ca/site/accueil.phtml 2. Fund for Health Research of Quebec (FRSQ): http://www.frsq.gouv.qc.ca/en/ethique/ethique.shtml 3. Fund for Research on Society and Culture (FQRSC) (French): http://www.fqrsc.gouv.qc.ca/fonds/ethique/index.html 4. Commission de l'éthique de la Science et de la Technologie (CEST): http://www.ethique.gouv.qc.ca 5. Comité d'éthique de Santé Publique : http://msssa4.msss.gouv.qc.ca/fr/sujets/ethiqSP.nsf/vsite?OpenView	http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/CCQ/CCQ_A.html 2. An Act Respecting Health Services and Social Services, R.S.Q., c. S-4.2: Articles 19.1 and 19.2: http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/S_4_2/S4_2_A.html	Designated or Instituted in Accordance to Article 21 of the Civil Code of Quebec (1998) (French): http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml 2. Ministerial Action Plan on Research Ethics and Scientific Integrity (1998) (French): http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml 3. Contribution of Private Companies within the Framework of Research Activities Derived from Research Grants (2003) (French): http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml 4. Ethics Review and Continuous Ethics Review of Multi-center Projects Mechanism (2007) (French) 5. Memorandum 1: Clarification Regarding Subject-Matter and Territorial Jurisdictions of Research Ethics Boards (2007) (French) http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml 6. Memorandum 2: Clarification Regarding the Concept of Continuous Monitoring of Project Ethics (2007) (French) http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml 7. Memorandum 3: Clarification Regarding the REB Review of Relevant Parts of the Budget and the Sponsor-Institution-Researcher Agreement (2007) (French) http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Yukon Territory:			
	Government of Yukon, Department of Tourism and Culture	Yukon Scientists and Explorers Act (2000): http://www.canlii.org/yk/laws/sta/200/20041124/whole.html		
Drugs	Health Canada, Therapeutic Products Directorate: http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_e.html		1. Good Clinical Practice Consolidated Guideline (1997) 2. Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials) (2004)	
Privacy/Data Protection	*National:*			
	1. Office of the Privacy Commissioner of Canada (OPC): http://www.privcom.gc.ca/index_e.asp 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/english/	1. Privacy Act, Sections 7-8 (1983): http://www.privcom.gc.ca/legislation/02_07_01_e.asp 2. Personal Information Protection and Electronic Documents Act, Articles 5 and 7 (2001): http://www.privcom.gc.ca/legislation/02_06_01_e.asp Note: Each of the Canadian provinces and territories has enacted privacy legislation.	OPC: SOR/2001-6, SOR/2001-7, and SOR/2001-8 (December 13, 2000)	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 3: Privacy and Confidentiality (2004)
Human Biological Materials	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/english/			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 10: Human Tissue (2004)
Genetic Research	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/english/ 2. Canadian Biotechnology Advisory Committee (CBAC): http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/Home 3. Biologics and Genetic Therapies Directorate: http://www.hc-sc.gc.ca/hpfb-dgpsa/bgtd-dpbtg/aboutus_e.html			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 8: Human Genetic Research (2004) CBAC: Genetic Research and Privacy (2004)
	Quebec:			
	RMGA Network of Applied Genetic Medicine			1. Statement of Principles: Human Genome Research (2000) http://www.rmga.qc.ca/en/index.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
				2. Statement of Principles on the Ethical Conduct of Human Research Involving Populations (2003) http://www.rmga.qc.ca/en/index.htm
Embryos, Stem Cells, and Cloning	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/english/ 2. Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 9: Research Involving Human Gametes, Embryos, or Foetuses (2004) CIHR: Updated Guidelines for Human Pluripotent Stem Cell Research (2007): http://www.cihr-irsc.gc.ca/e/34460.html
United States				
General	The U.S. Federal Policy for the Protection of Human Subjects consists of four subparts. All of the Common Rule departments and agencies subscribe to subpart A (2005). Some of the departments and agencies also subscribe to additional subparts: 1. Subpart B: Additional Protections for Pregnant Women, Human Fetuses, and Neonates (2001) 2. Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (1978) 3. Subpart D: Additional Protections for Children Involved as Subjects in Research (1991) Each department's or agency's participation in the various subparts is indicated below in parenthesis: • Agency for International Development: www.usaid.gov/ (Subpart A) • Central Intelligence Agency: www.odci.gov/ (Subparts A, B, C, and D) • Consumer Product Safety	Department of Defense: United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects Department of Education: 1. Protection of Pupil Rights Amendment (1974) 2. Family Educational Rights and Privacy Act (1974) Department of Health and Human Services: Public Health Service Act (1993): http://www.hhs.gov/ohrp/humansubjects/guidance/statute.htm	Agency for International Development: • 22 CFR 225 Central Intelligence Agency: • Executive Order 12333 Consumer Product Safety Commission: • 16 CFR 1028 Department of Agriculture: • 7 CFR 1c Department of Commerce: • 15 CFR 27 Department of Defense: • 32 CFR 219 • DoD Directive 3216.02 (2002) *Army:* • AR 70-25 • AR 40-38 *Navy:* • SECNAVINST 3900.39 series • BUMED Instruction 3900.6 series *Air Force:* • AFI 40-402 (2000) *OUSD(P&R):* • USUHS Instruction 3201	Office for Human Research Protections: http://www.hhs.gov/ohrp/policy/index.html#topics

Country	Key Organizations	Legislation	Regulations	Guidelines
	Commission: www.cpsc.gov/ (Subpart A) • Department of Agriculture: www.usda.gov/wps/portal/usdahome/ (Subpart A) • Department of Commerce: www.commerce.gov/ (Subpart A) • Department of Defense: www.dtic.mil/biosys/org/regulatory.html (Subpart A) • Department of Education: www.ed.gov/ (Subparts A and D) • Department of Energy: www.energy.gov/engine/content.do/ (Subpart A) • Department of Health and Human Services: www.hhs.gov/ohrp/ (Subparts A, B, C, and D) • Department of Homeland Security: www.dhs.gov/ (Subpart A) • Department of Housing and Urban Development: www.hud.gov/ (Subpart A) • Department of Justice: www.usdoj.gov/ (Subpart A) • Department of Transportation: www.dot.gov/ (Subpart A) • Department of Veterans Affairs (Subpart A) 1. Office of Research Oversight (ORO): www1.va.gov/oro/ 2. Office of Research and Development: www.research.va.gov • Environmental Protection Agency: www.epa.gov/ (Subpart A) • National Aeronautics and Space Administration:		*DTRA:* • DTRA Directive 3216.1 • DTRA Instruction 3216.2 Department of Education: • 34 CFR 97 subparts A (1991) and D (1997) • 34 CFR 98 (1984) • 34 CFR 99 (2000) • 34 CFR 350.4(c) (1991) • 34 CFR 356.3(c) (1991) Department of Energy: • 10 CFR 745 (1991) • Order 1300.3 • Order 481.1 Department of Health and Human Services: • 45 CFR 46 Department of Homeland Security: • Public Law 108-458, Section 8306 Department of Housing and Urban Development: • 24 CFR 60 Department of Justice: • 28 CFR 22 (1976) • 28 CFR 46 (1991) • 28 CFR 512 (1994) Department of Transportation: 49 CFR 11 Department of Veterans Affairs: • 38 CFR 16 (1991) • 38 CFR 17.85 (1998) Environmental Protection Agency: • 40 CFR 26 National Aeronautics and Space Administration: • 14 CFR 1230 National Science Foundation: • 45 CFR 690	

Country	Key Organizations	Legislation	Regulations	Guidelines
	www.nasa.gov/home/index.html?skipIntro=1 (Subpart A) • National Science Foundation: www.nsf.gov (Subpart A)			
Drugs	Food and Drug Administration: www.fda.gov	1. Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (2004): http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm 2. Public Health Service Act, 42 USC Section 262 (1944): http://www.fda.gov/opacom/laws/phsvcact/phsvcact.htm	1. 21 CFR 50 (1980) 2. 21 CFR 312 (1987) 3. 21 CFR 56 (2001)	Various: www.fda.gov/oc/ohrt/irbs/default.htm Guidances and Information Sheets on Good Clinical Practice in FDA-Regulated Clinical Trials: www.fda.gov/oc/gcp
Privacy/Data Protection	1. Department of Health and Human Services, Office for Civil Rights (OCR): http://www.hhs.gov/ocr/hipaa/ 2. Department of Health and Human Services, National Institutes of Health (NIH): http://privacyruleandresearch.nih.gov/	Health Insurance Portability and Accountability Act (1996): http://www.hhs.gov/ocr/hipaa/privrulepd.pdf	OCR: Privacy Rule (2002)	OCR: Standards for Privacy of Individually Identifiable Health Information (2003) NIH: Health Services Research and the HIPAA Privacy Rule (2005)
Human Biological Materials	Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/			1. Issues to Consider in the Research Use of Stored Data or Tissues (1997) 2. Guidance on Research Involving Coded Private Information or Biological Specimens (2004)
Genetic Research	National Institutes of Health, Office of Biotechnology Activities: http://www4.od.nih.gov/oba/	Research on Transplantation of Fetal Tissue, Public Law 103-43		NIH Guidelines for Research Involving Recombinant DNA Molecules (2002)
Embryos, Stem Cells, and Cloning	1. National Institutes of Health 2. Food and Drug Administration, Center for Biologics Evaluation and Research: http://www.fda.gov/cber/index.html 3. Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/ 4. National Research Council: http://www.nationalacademies.org/nrc/	Research on Transplantation of Fetal Tissue. Public Law 103-43	NIH: Approval Process for the Use of Human Pluripotent Stem Cells in NIH-Supported Research (2000)	FDA: Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products. October 14, 1993. 58 FR 53248. OHRP: Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles (2002) NRC: 1. Guidelines for Human Embryonic Stem

Country	Key Organizations	Legislation	Regulations	Guidelines
				Cell Research (2005): http://www.nap.edu/catalog.php?record_id=11278 2. 2007 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research: http://books.nap.edu/catalog.php?record_id=11871

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EUROPE				
European-wide				
General	1. Council of Europe, Bioethics Division (CoE): http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/ 2. European Group on Ethics in Science and New Technologies (EGE): http://europa.eu.int/comm/european_group_ethics/index_en.htm	CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=1&DF=10/24/2007&CL=ENG 2. Additional Protocol on Biomedical Research (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG		EGE: Ethical Aspects of Clinical Research in Developing Countries (2003): http://ec.europa.eu/european_group_ethics/docs/avis17_en.pdf
Drugs	1. European Commission, Enterprise Directorate-General, Pharmaceuticals Unit (EC): http://europa.eu.int/comm/enterprise/pharmaceuticals/index_en.htm 2. European Medicines Agency (EMEA): http://www.emea.eu.int Note: Directives of the European Commission take effect when the EU member countries enact implementing laws or regulations.	EC: 1. Directive 2001/20/EC: http://europa.eu/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf 2. Directive 2005/28/EC: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_091/l_09120050409en00130019.pdf	EC: 1. Detailed Guidance on the European Clinical Trials Database (EUDRACT Database) (2004) 2. Detailed Guidance on the Application Format and Documentation to be Submitted in an Application for an Ethics Committee Opinion on the Clinical Trial on Medicinal Products for Human Use (2004) 3. Detailed Guidance for the Request for Authorisation of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authorities, Notification of Substantial Amendments and Declaration of the End of the Trial (2004)	EMEA: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997) EC: Notice to Applicants: Questions & Answers, Clinical Trial Documents (2005)
Privacy/Data Protection	1. European Commission (EC): http://europa.eu.int/ 2. Council of Europe, Bioethics Division (CoE): http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/	EC: Data Protection Directive 95/46/EC of the European Parliament and of the Council (1995): http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&num		

Country	Key Organizations	Legislation	Regulations	Guidelines
		doc=31995L0046&model=guichett CoE: 1. Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1985) 2. Recommendation No. R (97) 5 on the Protection of Medical Data (1997)		
Human Biological Samples	1. European Commission (EC): http://europa.eu.int/ 2. Council of Europe, Bioethics Division (CoE): http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/ 3. European Group on Ethics in Science and New Technologies (EGE): http://europa.eu.int/comm/european_group_ethics/index_en.htm 4. European Medicines Agency (EMEA): http://www.emea.eu.int	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://europa.eu/eur-lex/pri/en/oj/dat/2004/l_102/l_102200404 07en00480058.pdf CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=1&DF=10/24/2007&CL=ENG 2. Recommendation Rec (2006)4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin (2006)		EGE: Ethical Aspects of Human Tissue Banking (1998) EMEA: Concept Paper on the Development of a Guideline on Biobanks Issues Relevant to Pharmacogenetics (2005)
Genetic Research	Council of Europe: http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14 (1999): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=1&DF=10/24/2007&CL=ENG		Recommendation No. R (92) on Genetic Testing and Screening for Health Care Purposes (1992)

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	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				
General	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				
Drugs	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				
General	1. Forum of Austrian Ethics Committees (German): http://www.ethikkommissionen.at 2. Ministry of Health (German): http://www.bmgf.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.
Drugs	1. Ministry of Health (German): http://www.bmgf.gv.at 2. Austrian Agency for Health and	Austrian Drug Law (2005) (German): http://www.ris.bka.gv.at/bundesr	Regulation on Leading Ethics Committees: http://www.ris.bka.gv.at/bundesre	Forum of Austrian Ethics Committees: Various guidelines.

Country	Key Organizations	Legislation	Regulations	Guidelines
	Food Safety: http://www.ages.at	echt/ (Suchworte: "Arzneimittel," then look for "Arzneimittelgesetz")	cht/ (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.bmgfj.gv.at/cms/site/search.htm?query=gentechnikkommission 2. Austrian Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	Gene Technology Act No. 510 (1994) (German): http://www.bmgf.gv.at/cms/site/detail.htm?thema=CH0264&doc=CMS1085735125660	Gene Technology Act (1994) (German): http://www.bmgfj.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)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs	Medicines Directorate-General (French and Flemish): http://www.afigp.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)	
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 & 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/HOMEPAGE_MENU/ABOUTUS1_MENU/INSTITUTIONSAPPARENTEES1_MENU/HOGEGEZONDHEIDSRAAD1_MENU/ADVIEZENENAANBEVELINGEN1_MENU/ADVIEZENENAANBEVELINGEN1_DOCS

Country	Key Organizations	Legislation	Regulations	Guidelines
		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		/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	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				
Drugs	Ministry of Health	Law on Drugs and Pharmacies, Art. 28		
Privacy/Data Protection		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				
General	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)		

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Oviedo Convention on Human Rights and Biomedicine (2001)		
Drugs	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)
Privacy/Data Protection	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		
Embryos, Stem Cells, and Cloning	Ministry of Healthcare: http://www.mh.government.bg/	Law Ratifying the Convention for Human Rights (2007)		
Croatia				
Privacy/Data Protection	Croatian Personal Data Protection Agency	Law on Personal Data Protection (2002): http://www.ceecprivacy.org/doc/law_croatia.pdf		
Cyprus				
General		Law No. 31 (III)/2001 (Oviedo Convention on Human Rights and Biomedicine)		
Drugs	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)		
Privacy/Data Protection	Commissioner for Personal Data Protection: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/index_en/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				
General	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		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Amended		
Drugs	1. Ministry of Health (MOH) (Czech): http://www.mzcr.cz 2. State Institute for Drug Control (SUKL): http://www.sukl.cz/enindex.htm	1. Act No. 79/1997 Collection, on Pharmaceuticals 2. Amendments to related acts: • 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)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs	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)
Privacy/Data Protection	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
Human Biological Materials	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		
Embryos, Stem Cells, and Cloning	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				
General		1. Constitution of the Republic of Estonia, Paragraph 18 (1992) 2. Oviedo Convention on Human Rights and Biomedicine (2001)		
Drugs	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	

Country	Key Organizations	Legislation	Regulations	Guidelines
			be Submitted in Order to Obtain Approval (2001)	
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&ptyyp=RT&tyyp=X&query=data%2BprotectionLink		
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=ca7dfeabf627e5fba616cc3d4e9b0e24		
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/tukija/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		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Personal Data Act No. 986/2000: http://www.tietosuoja.fi/uploads/p9qzq7zr3xxmm9j.rtf		
Human Biological Materials		Act on the Medical Use of Human Organs and Tissues No. 101/2001: http://www.finlex.fi/pdf/saadkaan/E0010101.PDF		
Genetic Research		Gene Technology Act No. 377/1995		
Embryos, Stem Cells, and Cloning		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				
General	1. General Health Administration (GHA) (French): http://www.sante.gouv.fr 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr 3. National Conference of CPPRB: http://cncp.med.univ-tours.fr/html/index.php	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. 1. Biomedical Research (Loi Huriet-Sérusclat), Articles L1121-1 to L1126-7 (2004) (French): http://www.legifrance.gouv.fr/ 2. Decree No. 97-555 Concerning the National Consultative Ethics Committee	GHA: 1. Protection of Persons who Participate in Biomedical Research (Public Health Code, Regulatory Section, Additional Book II, Articles R.2001 to R.2053) 2. Decision of August 20, 2002	CCNE: 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." 1. Opinion on Ethics Committees (1992) 2. Cooperation in the Field of Biomedical Research between French Teams and Teams from Economically Developing Countries. Report (1993) 3. Opinion on the Ethics of Research in the Sciences of Human Behaviour. Report (1993) 4. Informed Consent of and Information to Persons Accepting Care or Research Procedures (1998) 5. Opinion on the Preliminary Draft Revision of the Laws on Bioethics (2001) 6. Disparity in Access to Health Care and Participation in Research on a Global

Country	Key Organizations	Legislation	Regulations	Guidelines
		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)

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	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				
Drugs	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				
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. National Ethics Council (NER): http://www.ethikrat.org/_english/index.html 5. Federal Ministry of Health (BMG): http://www.bmg.bund.de/cln_041/nn_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
Drugs	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/cln_042/nn_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/nn_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	

Country	Key Organizations	Legislation	Regulations	Guidelines
	de-node.html?__nnn=true 4. Federal Ministry of Health (BMG): http://www.bmg.bund.de/cln_041/nn_600110/EN/Home/homepage__node,param=.html__nnn=true		Use (2006) BMBF: Principles and Responsibilities Related to Clinical Studies (2003)	
Privacy/Data Protection	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	Federal Data Protection Act, as Amended (2003): http://www.bfdi.bund.de/cln_029/nn_535764/EN/DataProtectionActs/DataProtectionActs__node.html__nnn=true The 16 German states also have laws about data protection in the non-federal public sector (German): http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html		
Human Biological Materials	1. German Society of Surgery (DGCH) (German): http://www.dgch.de/ 2. German Medical Association (BÄK): http://www.bundesaerztekammer.de/page.asp?his=4.3569 3. German National Ethics Council (NER): http://www.ethikrat.org/_english/index.html 4. Central Ethics Commission of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/ 5. German Institute for Cell and Tissue Replacement (DIZG) (German): http://www.dizg.de	1. Transplantation Law (2007) (German): http://bundesrecht.juris.de/bundesrecht/tpg/gesamt.pdf 2. Transfusion Law (2007) (German): http://www.gesetze-im-internet.de/bundesrecht/tfg/gesamt.pdf 3. Act of Quality and Security of Human Tissue and Cells (2007) (German): http://www.bmg.bund.de/cln_041/nn_600110/SharedDocs/Gesetzestexte/Arzneimittel/Gewebegesetz,templateId=raw,property=publicationFile.pdf/Gewebegesetz.pdf	DGCH Rule for the Production of Human Tissues (German): http://www.dgch.de/dgch/aktuelles/gewebegesetz/index.html	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 More guidelines of the BÄK (German): http://www.bundesaerztekammer.de/page.asp?his=0.7.45&all=true NER: Opinion on Biobanks for Research (2004): http://www.ethikrat.org/_english/publications/Opinion_Biobanks-for-research.pdf ZEKO (German): http://www.zentrale-ethikkommission.de/downloads/Koerpermat.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
				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/cln_048/nn_159030/EN/institute-en/institut-node-en.html?__nnn=true	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/30/Richtlinien/Richtidx/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: Gene Therapy Information: http://www.pei.de/cln_048/nn_162568/EN/infos-en/fachkreise-en/genther-fach-en/genther-fach-node-en.html?__nnn=true
Embryos, Stem Cells, and Cloning	1. German National Ethics Council (NER): http://www.ethikrat.org/_english/index.html 2. German Research Foundation (DFG): http://www.dfg.de/en/ 3. Central Ethics Commission of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/ 4. Central Ethics Committee for Stem-Cell Research (ZES) (English): http://www.rki.de/cln_048/nn_216782/EN/Content/Institute/DepartmentsUnits/StemCell/StemCel__node.html?__nnn=true	1. Embryo Protection Act (1990): http://www.bmj.bund.de/enid/Publications/Embryo_Protection_Act_19u.html 2. Stem Cell Act (2002): http://www.bmj.bund.de/enid/Publications/Embryo_Protection_Act_19u.html	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/_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 DFG: Opinion on Stem Cell Research (2006) (German): http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/2006/download/stammzel

Country	Key Organizations	Legislation	Regulations	Guidelines
				lforschung_deutschland_lang_0610.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
Greece				
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	tegory_id=3			http://www.bioethics.gr/media/pdf/reports/report_genetic_data_eng.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: http://www.iya.gr	1. Act 3089/2002 on Medically Assisted Human Reproduction 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		NBC: 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 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
Hungary 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				
General	1. Ministry of Health (EüM): http://www.eum.hu/?akt_menu=2&set_lang=2 2. Medical Research Council, Scientific and Research Ethics Committee	1. Act CLIV of 1997 on Health Care, Chapter VIII 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 3. Act LXXXI of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research	EüM: Decree on Biomedical Research on Human Beings 23/2002 (V. 9) (2002)	
Drugs	1. National Institute of Pharmacy: http://www.informed.hu/ogyi/english 2. Medical Research Council, Ethics Committee for Clinical Pharmacology	Act XCV of 2005 on Medicinal Products for Human Use	EüM: 1. Decree 35/2005 (VIII. 26) of the Minister of Health on Clinical Trials of Medicinal Products for Human Use and Good Clinical Practice 2. Regulation (EC) 1901/2006 of the European Parliament and of the Council of 12 December 2006	
Privacy/Data Protection	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		

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