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				
Drugs	1. National Organization for Medicines (NOM): http://www.eof.gr/eof_en/enhome.html 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	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	NOM: 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)	NBC: 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)
Privacy/Data Protection	1. Hellenic Data Protection Authority: http://www.dpa.gr/home_eng.htm	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		
Genetic Research	1. Hellenic Data Protection Authority (HDPA): http://www.dpa.gr/home_eng.htm 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?ca	1. Greek Constitution 1975/1986/2001, Article 5.5 2. Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998)		HDPA: Opinion No. 15/2001 NBC: Report on the Collection and Use of Genetic Data

Country	Key Organizations	Legislation	Regulations	Guidelines
	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		

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Country	Key Organizations	Legislation	Regulations	Guidelines
	vClinica/docs/contactosCCAA-agosto06.pdf	2. Law 29/2006 of July 26 on Assurances and Rational Use of Medications and Health Products		
Privacy/Data Protection	Spanish Data Protection Authority (Spanish): https://www.agpd.es/index.php	1. Organic Law 15/1999 of December 13 on the Protection of Personal Data: https://www.agpd.es/upload/Ley%20Org%E1nica%2015-99_ingles.pdf 2. Royal Decree 994/99 Regarding Databases with Personal Information		
Human Biological Materials	Ministry of Health and Consumption (MOH): http://www.msc.es/en/home.htm	1. Royal Decree 411/1996, of March 1, By Which Activities Regarding the Use of Human Tissues are Regulated (1996) (Spanish): http://europa.eu.int/comm/research/biosociety/pdf/spanish_act411.pdf 2. Royal Decree 2070/1999 of December 30, Regarding Activities of Collection and Clinical Use of Human Organs for Organ Transplants and Tissues	1. Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples (2006)	
Embryos, Stem Cells, and Cloning		1. Assisted Reproduction Techniques (1988) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		
Srpska				
Drugs	Ministry of Health and Social Welfare, Agency for Medicines	Law on Drugs and Pharmacies of the Republic of Srpska	Regulation on Conducting Clinical Trials (2005)	Guidelines of Good Clinical Practice
Sweden Note: For an overview of human subject protections in Sweden, see "CODEX: Rules and Guidelines for Research:" http://www.codex.uu.se/codex_eng/codex/index.html				
General	1. Central Ethical Review Board (CEPN): http://www.epn.se/eng/start/index.aspx	Law No. 460 on the Ethical Review of Research Involving Humans (2003): http://www.epn.se/eng/start/200	CEPN: 1. Ordinance No. 615 Concerning the Ethical Vetting of Research Involving Humans (2003):	CEPN: Information for Research Participants SRC:

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Swedish Research Council (SRC): http://www.vr.se/english	3_460.aspx	http://www.epn.se/eng/start/2003_615.aspx 2. Statute No. 616 Containing Instructions for Regional Ethical Review Boards (2003): http://www.epn.se/eng/start/2003_616.aspx 3. Statute No. 617 Containing Instructions for the Central Ethical Review Boards (2003): http://www.epn.se/eng/start/2003_617.aspx	1. Ethical Guidelines of Epidemiological Research (1994) 2. Guidelines for Good Medical Research (1996) 3. Guidelines for the Ethical Evaluation of Medical Research on Humans (2003) 4. Policy Statement Regarding the Assessment of Scientific Studies in which Patients or Healthy Subjects are to Undergo Invasive Operations (2003)
Drugs	Medical Products Agency: http://www.lakemedelsverket.se/Tpl/StartPage____395.aspx	Pharmaceuticals Act No. 1992: 859 (Swedish): http://www.notisum.se/rnp/SLS/LAG/19920859.HTM	1. Medical Products Agency's Provisions and Guidelines on the Clinical Trials of Medicinal Products (1999) 2. Medical Product Agency's Provisions and Guidelines on Clinical Trials of Medicinal Products for Human Use, Code of Statutes No. 6 (2003)	
Privacy/Data Protection	Swedish Data Inspection Board: http://www.datainspektionen.se/in_english/start.shtml	Personal Data Act No. 204 (2002): http://www.datainspektionen.se/pdf/ovrigt/pul-eng.pdf		
Human Biological Materials	1. National Board of Health and Welfare (SOS) 2. Swedish Research Council (SRC): http://www.vr.se/english 3. Swedish National Biobank Program: http://www.biobanks.se/	Biobanks in Medical Care Act No. 297 (2002): http://www.sweden.gov.se/content/1/c6/02/31/26/f69e36fd.pdf	SOS: 1. Regulation No. 746 (2002) 2. SOSFS No. 11 (2002) 3. SOSFS No. 2 (2004)	SRC: Research Ethics Guidelines for Using Biobanks (2003)
Genetic Research	1. Ministry of Health and Social Affairs: http://www.sweden.gov.se/sb/d/2061 2. National Board of Health and Welfare	Act on Genetic Integrity (2006:351): http://www.notisum.se/rnp/sls/lag/20060351.htm		Genetics and Gene Technology in the Health Care: State of the Art and Guidelines for Ethical Considerations (1999)
Embryos, Stem Cells, and Cloning		Act on Genetic Integrity (2006:351): http://www.notisum.se/rnp/sls/lag/20060351.htm	Legal Regulation of Stem Cell Research 2002:119: http://www.regeringen.se/sb/d/108/a/2717	
Switzerland				
General	1. Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/		Many of the Swiss cantons have implemented regulations regarding human subject research	SAMS: Guidelines on Human Research (1997)

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

Country	Key Organizations	Legislation	Regulations	Guidelines
Turkey Note: For an overview of human subject protections in Turkey, see "National Regulations on Ethics and Research in Turkey:" http://ec.europa.eu/research/science-society/pdf/tr_eng_lr.pdf				
General	Ministry of Health	1. Turkish Constitution, Article 17 2. Health Services Basic Law No. 3359 (1987) 3. Oviedo Convention on Human Rights and Biomedicine, Articles 15-18 (1999)	1. Regulation on Medical Deontology, Article 11 (1960) 2. Regulation on Medical Research (1993) 3. Bylaw on Patient Rights No. 23420 (1998)	
Drugs	Ministry of Health	Turkish Penal Law, Article 90 (2005)	1. Bylaw on the Clinical Trials Conducted by Medical Products Used in Humans (1995) 2. Bylaw on the Evaluation and Monitoring of the Safety of Medical Products (2005)	1. Guideline of Good Clinical Practice (1995) 2. Guideline of Compassionate Use of Experimental Drugs (2006)
Human Biological Materials		1. Law on Procurement, Preservation, Grafting, and Transplantation of Organs and Tissues, No. 2238 (1979) 2. Law on Blood and Blood Products, No. 2857 (1983)	Regulation on Blood and Blood Products, No. 7314 (1983)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999)
Genetic Research			Regulation on Centers for Diagnosis and Genetic Diseases, No. 23368 (1998)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14 (1999)
Embryos, Stem Cells, and Cloning			Regulation on Centers for Medically Assisted Procreation, No. 19551 (1987)	1. Circular on Research of Embryonic Stem Cells (2005) 2. Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)
Ukraine Note: For an overview of human subject protections in the Ukraine, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 10: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
General	1. Ethical Commission with the Higher Education Committee (EC-HEC)		EC-HEC: Order of this Committee for Requirements of Ethical Review of All Dissertation Theses on Science, Degree in Biology, Medicine, and Veterinary Medicine (2005)	
Drugs	1. State Pharmacological Center: http://www.pharma-center.kiev.ua/old/index_a.html 2. Ukrainian Ministry of Health,	On Medicines, Articles 7 and 8 No. 123/96BP (1996): http://www.pharma-center.kiev.ua/view/ua/zakon	1. Ukrainian Ministry of Health Decree No. 373 About Approval of Documents Related to the Standardization, Registration and	Central Ethics Committee: On Ethics Questions of Clinical Trials and Implementation of Medicines (2006)

Country	Key Organizations	Legislation	Regulations	Guidelines
	Central Ethics Committee: http://www.moz.gov.ua/en/main/siterubr/		Conduct of Clinical Trials of Study Drugs 42-7.0:2005 (2005) 2. Ukrainian Ministry of Health Order No. 66 About Approval of Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials and Model Regulations of the Ethics Committee (2006): http://www.pharma-center.kiev.ua/old/orders/Order_66.doc	
Privacy/Data Protection		Information Act from the Cabinet of Ministers of the Ukraine (1992)		
Human Biological Materials	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/main/siterubr/		Order of Ministry of Health: For the Improvement of Ukrainian Regulations and Harmonization of Legislation for European Transplantation Standards in Organs, Tissues, and Cell Procurement and Transplantations No. 650 (2006)	
Genetic Research	Academy of Medical Sciences of the Ukraine			Medical and Ethical Guidelines for Genetic Investigations in Humans
Embryos, Stem Cells, and Cloning	National Bioethics Committee of the National Academy of Sciences of the Ukraine (NBC) Ukrainian Ministry of Health: http://www.moz.gov.ua/en/main/siterubr/	1. About the Ban of Human Reproductive Cloning (2004) 2. About Organs and Other Human Materials Transplantology No. 1007-XIV (2007)	1. Recommendation No. 1046, Use of the Human Fetus for the Purpose of Diagnosis, Therapy, Research, Industrial Purchase, and Trading (1986) 2. Order of the Ministry of Health: For Adoption of the Regulations Concerning the Investigations of Human Stem Cells, Clinical Trials for Cells, and Tissue Transplantations (2006)	NBC: Ethical Regulations and Problems of Embryo-Tissue Storage (Recommendations)
United Kingdom Note: Unless otherwise noted, all laws, regulations, and guidelines listed for England apply to the entire United Kingdom.				
General	*England:*			
	1. Department of Health (DH): http://www.dh.gov.uk/Home/fs/en 2. National Research Ethics Service	Mental Capacity Act 2005, Sections 30-34 (England and Wales):		DH: 1. Research Governance Framework for Health and Social Care (2005)

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

Country	Key Organizations	Legislation	Regulations	Guidelines
				Committees in Medical Research with Human Participants (2007) ESRC: Research Ethics Framework
	Northern Ireland:			
	Northern Ireland Health and Personal Social Services: http://www.dhsspsni.gov.uk/			Research Governance Framework for Health and Social Care (2002)
	Scotland:			
	NHSScotland, Chief Scientist Office: http://www.show.scot.nhs.uk/cso/	Adults with Incapacity (Scotland) Act 2000, Section 51: http://www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm	Adults with Incapacity (Ethics Committee) (Scotland) Regulations (2002): http://www.scotland-legislation.hmso.gov.uk/legislation/scotland/ssi2002/20020190.htm	Research Governance Framework for Health and Community Care (2006)
	Wales:			
	Wales Office of Research and Development for Health and Social Care: http://www.word.wales.gov.uk/			Research Governance Framework for Health and Social Care in Wales (2001)
Drugs	1. Medicines and Healthcare Products Regulatory Agency (MHRA): http://www.mhra.gov.uk 2. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm 3. National Research Ethics Service (NRES): http://www.nres.npsa.nhs.uk/index.htm	Medicines Act (1968)	MHRA: 1. The Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004): http://www.uk-legislation.hmso.gov.uk/si/si2004/20041031.htm 2. Amendment Regulations (SI 2006/1928) http://www.opsi.gov.uk/si/si2006/20061928.htm 3. Amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 and Adults with Incapacity (Scotland) Act 2000 to Facilitate Clinical Research in Emergency Settings (SI 2006/2984): http://www.opsi.gov.uk/si/si2006/20062984.htm	MHRA: Consultation Letter on the Medicines for Human Use (Clinical Trials) Regulations (2003) MRC: 1. MRC Guidelines for Good Clinical Practice in Clinical Trials (1998) 2. MRC Policy on Antiretroviral Therapy for People Infected with HIV and Involved in AIDS Research in Developing Countries (2003) NRES: Memorandum of Understanding between MHRA, COREC, and GTAC (2006) http://www.nres.npsa.nhs.uk/docs/guidance/MoU.pdf
Privacy/Data Collection	*England:*			
	1. Information Commissioner Office: http://www.informationcommissioner	Data Protection Act (1998): http://www.opsi.gov.uk/acts/acts		MRC: Personal Information in Medical Research

Country	Key Organizations	Legislation	Regulations	Guidelines
	.gov.uk/ 2. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm	1998/19980029.htm A number of Statutory Instruments have been developed to implement the Data Protection Act: http://www.dca.gov.uk/ccpd/dpsubleg.htm		(2003)
	Scotland:			
	NHSScotland: http://www.show.scot.nhs.uk/			Protecting Patient Confidentiality (2002)
Human Biological Materials	1. Royal College of Physicians (RCP): http://www.rcplondon.ac.uk/index.asp 2. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm 3. Department of Health (DH): http://www.dh.gov.uk/Home/fs/en 4. Human Tissue Authority (HTA): http://www.hta.gov.uk/	1. Human Tissue Act (2004): http://www.opsi.gov.uk/acts/acts2004/20040030.htm 2. Statutory Instrument 2006 No. 1260: The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006: http://www.opsi.gov.uk/si/si2006/20061260.htm 3. Statutory Instrument 2006 No. 1659: The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006: http://www.opsi.gov.uk/si/si2006/20061659.htm		RCP: Research Based on Archived Information and Samples (1999) MRC: Human Tissue and Biological Samples for Use in Research (2001) DH: The Use of Human Organs and Tissue: An Interim Statement (2003): http://www.nres.npsa.nhs.uk/docs/guidance/MoU.pdf HTA: Codes of Practice 2006
Genetics Research	1. Advisory Committee on Genetic Testing (ACGT): http://www.advisorybodies.doh.gov.uk/genetics/acgt/ 2. Public Health Genetics Unit: http://www.phgu.org.uk/index.php			ACGT: Advice to Research Ethics Committees (1998)
Embryos, Stem Cells, and Cloning	Human Fertilisation and Embryology Authority: http://www.hfea.gov.uk/	Human Fertilisation and Embryology Act (1990): http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm	Human Fertilisation and Embryology (Research Purposes) Regulation (2001)	

Country	Key Organizations	Legislation	Regulations	Guidelines
ASIA/PACIFIC/MIDDLE EAST				
Australia				
General	National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/ethics/human/ahec/index.htm	National Health and Medical Research Council Act (1992): http://scaleplus.law.gov.au/html/pasteact/0/379/top.htm		1. Human Research Ethics Handbook – Commentary on the National Statement on Ethical Conduct in Research Involving Humans (2001) 2. Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) 3. Australian Code for the Responsible Conduct of Research (2007) 4. National Statement on Ethical Conduct in Human Research (2007)
Drugs	Therapeutic Goods Administration: http://www.tga.gov.au/ct/index.htm	Therapeutic Goods Act (1989): http://www.comlaw.gov.au/comlaw/Legislation/ActCompilation1.nsf/0/697A52AA408416B4CA256FBF000F43EC?OpenDocument	Therapeutic Goods Regulations (1991)	Human Research Ethics Committees and the Therapeutic Goods Administration (2001)
Privacy/Data Protection	*Federal:*			
	Office of the Privacy Commissioner: http://www.privacy.gov.au/	Privacy Act No. 119 (1998), Incorporating Amendments up to Act No. 49 (2004): http://www.privacy.gov.au/publications/privacy88_030504.doc		
	New South Wales:			
		Privacy and Personal Information Protection Act (2005): http://www.austlii.edu.au/au/legis/nsw/consol_act/papipa1998464/index.html		
	Victoria:			
		Information Privacy Act No. 98 (2000): http://www.dms.dpc.vic.gov.au/Domino/Web_Notes/LDMS/PubLawToday.nsf?OpenDatabase Select "Acts," then the letter "I," then "Information Privacy Act."		

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	National Health and Medical Research Council, Australian Health Ethics Committee (AHEC): http://www.nhmrc.gov.au/ethics/human/ahec/index.htm			AHEC: National Statement on Ethical Conduct in Human Research (2007): Chapter 3.2 Databanks Chapter 3.4 Human Tissue Samples Chapter 4.1 Women Who are Pregnant and the Human Foetus
Genetic Research	National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/ethics/human/ahec/index.htm	Genetic Privacy and Non-Discrimination Act (1998): http://www.aph.gov.au/parlinfo/billsnet/98021.pdf		AHEC: 1. Essentially Yours: The Protection of Human Genetic Information in Australia (2003) 2. National Statement on Ethical Conduct in Human Research, Chapter 3.5 Human Genetics (2007)
Embryos, Stem Cells, and Cloning	1. National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/ethics/human/ahec/index.htm 2. National Health and Medical Research Council Embryo Research Licensing Committee	1. Prohibition of Human Cloning for Reproduction Act (2002): http://www.austlii.edu.au/au/legis/cth/consol_act/pohcfra2002465/ 2. Research Involving Human Embryos Act (2006): http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/03F95E485D04231DCA2572F80003B1C3/$file/ResearchInvolvingHumanEmbryosAct2002_WD02.pdf	Research Involving Human Embryos Regulations (2003): http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/all/search/5D4B2F1A72744D3DCA257340000A1339	AHEC: 1. National Statement on Ethical Conduct in Human Research (2007): Chapter 3.6 Human Stem Cells 2. Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2007)
Bangladesh				
General	Bangladesh Medical Research Council, Ethics Review Committee			
Drugs	Bangladesh Directorate of Drug Administration: http://www.ddabd.org	1. The Drugs Act (1964) 2. Drugs (Control) Ordinance 1982, Ordinance No. VIII: http://www.ddabd.org/ordinance_1982.htm		
Human Biological Materials	Bangladesh Medical Research Council, Ethics Review Committee			Guidelines for Transfer of Human Biological Materials Abroad for Research Purposes (2004)
China, People's Republic of				
General	1. Ministry of Health (MOH) (Mandarin): http://www.moh.gov.cn/ 2. Chinese Association for Science	Law on Practicing Doctors (June 26, 1998), Articles 26 and 37		MOH: Guidelines on Ethical Review of Biomedical Research Involving Human

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

Country	Key Organizations	Legislation	Regulations	Guidelines
	Committee on Human Research: http://www.icmr.nic.in/human_ethics.htm			
Genetic Research	1. Department of Biotechnology (DBT): http://dbtindia.nic.in/ 2. Indian Council of Medical Research (ICMR), Central Ethics Committee on Human Research: http://www.icmr.nic.in/human_ethics.htm	Environmental Protection Act		DBT: 1. Recombinant DNA Safety Guidelines (1990) 2. Ethical Policies on the Human Genome, Genetic Research, and Services (2002) ICMR: Ethical Guidelines for Biomedical Research on Human Subjects: Statement of Specific Principles for Human Genetics and Genomics Research (2006)
Embryos, Stem Cells, and Cloning	Indian Council of Medical Research (ICMR), Central Ethics Committee on Human Research: http://www.icmr.nic.in/human_ethics.htm			National Guidelines for Stem Cell Research and Therapy (2006)
Indonesia				
Drugs	Ministry of Health, National Institute of Health Research and Development	Indonesian Health Act No. 23 (1992)	Regulation No. 39/19 on Health Research and Development (1995)	Guidelines for Ethics in Health Research and Development (2002)
Iran				
General	Ministry of Health and Medical Education, Office for the Study of Humanistic and Islamic Science in Medicine and Medical Ethics: http://www.mohme.gov.ir/		Protection Code for Human Subjects in Medical Research (1999)	
Israel				
General	Ministry of Health: http://www.health.gov.il/english/		Public Health Regulations (Medical Experiments Involving Human Subjects) (1999) (Hebrew): http://www.health.gov.il/pages/default.asp?maincat=11&catid=301&pageid=2203	
Drugs	Ministry of Health, Pharmaceutical Administration: http://www.health.gov.il/english/Pages_E/default.asp?maincat=10	Public Health Order (1940)	1. Public Health Regulations (Clinical Studies in Human Subjects) – 1980 (Hebrew): http://www.health.gov.il/download/forms/a365_si12r_81.pdf	Guidelines for Clinical Trials in Human Subjects (2006) (English): http://www.health.gov.il/Download/pages/GuidelinesforClinicalTrials.doc

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

Country	Key Organizations	Legislation	Regulations	Guidelines
Privacy/Data Protection	Several ministries have been designated to oversee this issue, including: 1. Ministry of Health, Labor, and Welfare 2. Ministry of Economy, Trade, and Industry 3. Ministry of Internal Affairs and Communications	Personal Information Protection Act (2003)		
Genetic Research	1. Ministry of Education, Culture, Sports, Science, and Technology (MEXT) 2. Ministry of Health, Labor, and Welfare (MHLW) 3. Ministry of Economy, Trade, and Industry (METI)			MEXT, MHLW, and METI: Ethics Guidelines for Human Genome/Gene Analysis Research (2005) MEXT and MHLW: Guidelines for Clinical Research in Gene Therapy (2004)
Jordan				
Drugs	Jordan Food and Drug Administration: http://www.jfda.jo/en/default/	1. Narcotic and Psychotropic Law No. 11 (1988) 2. Clinical Trial Law No. 67 (2001) 3. Pharmacy and Drug Law No. 80 (2001)		
Kazakhstan Note: For an overview of human subject protections in Kazakhstan, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 5: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
General	Bioethics Commission			Guidelines on Ethics in Health Research. (2007)
Drugs	Ministry of Health, Committee of Pharmacy (Kazakh): http://www.mz.gov.kz/	Drug Law (13.01.2004 No. 522-2), Articles 19 and 20 (2004) (Kazakh): http://www.zakon.kz/	1. Order 14.02.2005 No. 53 Instruction on the Conduct of Clinical Trials in Kazakhstan (2005) 2. Order 25.06.2007 # 442 Rules on Preclinical, Medico-Biological Experiments, and Clinical Trials in Kazakhstan (2007)	Guidelines on Clinical Trials in Kazakhstan (2003)
Privacy/Data protection	Ministry of Health (Kazakh): http://www.mz.gov.kz/	Law on the Health Care System (4.06.2003 # 430-II) (2003) (Kazakh): http://www.zakon.kz/		

Country	Key Organizations	Legislation	Regulations	Guidelines
Korea				
Drugs	Korea Food and Drug Administration: www.kfda.go.kr/	Pharmaceutical Affairs Law (1999)	Regulation for Evaluation on Safety and Efficacy of Drugs (2002)	
Privacy/Data Protection	1. Ministry of Government Administration and Home Affairs 2. Ministry of Health and Welfare	Act on the Protection of Personal Information Maintained by Public Agencies No. 4734 (1994)		
Genetic Research	Ministry of Health and Welfare: http://english.mohw.go.kr/	Bioethics and Safety Act, Chapters 4 -6 (2004): http://www.ruhr-uni-bochum.de/kbe/BioethicsBiosafetyAct-SouthKorea-v1.0.pdf		Guidelines for Research Involving Recombinant DNA Molecules (1997)
Embryos, Stem Cells, and Cloning	1. Ministry of Health and Welfare: http://english.mohw.go.kr/ 2. Ministry of Science and Technology	Bioethics and Safety Act, Chapter 3 (2004): http://www.ruhr-uni-bochum.de/kbe/BioethicsBiosafetyAct-SouthKorea-v1.0.pdf		
Kuwait				
General	Ministry of Health, Kuwait Institute for Medical Specialization: http://www.kims.org.kw/			Ethical Guidelines for Biomedical Research: http://www.kims.org.kw/Ethical%202.doc
Nepal				
General	Nepal Health Research Council: http://www.nhrc.org.np/			National Ethical Guidelines for Health Research in Nepal (2001): http://www.nhrc.org.np/guidelines/nhrc_ethicalguidelines_2001.pdf
Drugs	Nepal Health Research Council: http://www.nhrc.org.np/			National Guidelines on Clinical Trials with the Use of Pharmaceutical Products (2005): https://webapps.sph.harvard.edu/live/gremap/files/np_pharmaceutical_trial_guidelines.pdf
New Zealand				
General	1. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ 2. National Ethics Advisory Committee (NEAC): http://www.neac.health.govt.nz/ 3. Ministry of Health (MOH): http://www.moh.govt.nz/ 4. Health and Disability	1. Health Research Council Act 1990, Sections 24 and 25 2. New Zealand Bill of Rights Act, Article 10 (1990) 3. Health and Disability Commissioner Act 1994 4. New Zealand Public Health and Disability Act 2000, Section 16	HDC: The Code of Health and Disability Services Consumers' Rights (the Code of Rights) (2004): http://www.hdc.org.nz/	HRC: 1. Guidelines for Researchers on Health Research Involving Māori (1998) 2. Guidelines on Ethics in Health Research (2005) NEAC: 1. Goals, Objectives, and Desired Outcomes of an Ethical Review System

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

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

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

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

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

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

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

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			4. Regulation of Resolution CNS 292/99 on Research with Foreign Cooperation (2002) (Portuguese): http://www.conselho.saude.gov.br/docs/Resolucoes/Reso292.doc 5. Resolution 346/2005: On Multicenter Research (2005) (Portuguese): http://www.conselho.saude.gov.br/docs/Resolucoes/Reso346.doc	
Drugs	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Healthcare Surveillance Agency (Portuguese): http://www.anvisa.gov.br		CNS: Resolution 251/1997: On Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests (Portuguese) (1997): http://conselho.saude.gov.br/docs/Resolucoes/CNS_Reso251_English.doc	
Human Biological Materials	National Commission on Research Ethics (CONEP) (Portuguese): http://www.conselho.saude.gov.br/comissao/eticapesq.htm		CONEP: CNS Resolution 347/05 Approval Guidelines for Ethical Analysis of Research Projects Involving Storage of Materials or Use of Materials Stored by Previous Research: http://conselho.saude.gov.br/docs/Reso347.doc	CONEP: Approval Guidelines for Ethical Analysis of Research Projects Involving Storage of Materials or Use of Materials Stored by Previous Research: Resolution 347/05 (2005)
Genetic Research	1. National Commission on Research Ethics (CONEP) (Portuguese): http://www.conselho.saude.gov.br/comissao/eticapesq.htm 2. National Biosafety Technical Commission (CTNBio) (Portuguese): http://www.ctnbio.gov.br	Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/3671.html	CONEP: Resolution 304/2004 : On Research on Human Genetics (2004) (Portuguese): http://www.conselho.saude.gov.br/docs/Reso%20340.doc CTNBio: Decree No. 5,591, of November 22, 2005: http://www.ctnbio.gov.br/index.php/content/view/3670.html	CONEP: Approval Guidelines for Ethical Analysis and Conduct of Research Projects in the Special Thematic Area of Human Genetics: Resolution 340/04 (2004)
Embryos, Stem Cells, and Cloning	National Biosafety Technical Commission (Portuguese):	Biosafety Law 11.105/05 (2005):	CTNBio: Decree No. 5,591, of November	

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	http://www.ctnbio.gov.br	http://www.ctnbio.gov.br/index.php/content/view/3671.html	22, 2005: http://www.ctnbio.gov.br/index.php/content/view/3670.html	
Chile				
General	Ministry of Health (Spanish): http://www.minsal.cl	Law No. 26.027 (2005)	1. Supreme Decree No. 42 (1986) 2. Supreme Decree No. 1.935 (1993) 3. General Technical Rule No. 2 of the Ministry of Health (1993) 4. Exemption Resolution No. 134 (1994) 5. Supreme Decree No. 494 (1999) 6. Exemption Resolution No. 1.856 (1999) 7. Resolution No. 2.085 of the Ministry of Health (2001)	
Drugs	Ministry of Health (Spanish): http://www.minsal.cl		Technical Rule No. 57: Regulation of the Conduct of Clinical Trials that Use Pharmaceutical Products in Human Beings (2001)	Ethical Guidelines for Clinical Trials with Pharmaceutical and Biological Products (2001)
Privacy/Data Protection		Law for the Protection of Private Life No. 19.628 (1999)		
Genetic Research		Law No. 26.027 (2005)		
Colombia				
General	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430 (1993)	
Drugs	National Institute of Drug and Food Surveillance (Spanish): http://www.invima.gov.co/			
Privacy/Data Protection		Constitution, Article 15 (2003)		
Human Biological Materials	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter VI (1993)	
Genetic Research	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No.	

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			008430, Title III, Chapter II (1993)	
Costa Rica				
General	1. National Council on Health Research (CONIS) Network of Scientific Ethics Committees 2. Social Security Fund (CCSS), Research and Bioethics Subarea 3. Ministry of Health: http://www.ministeriodesalud.go.cr/	Law 5395, General Health Law, Articles 64-68 (1973) (Spanish): http://www.ministeriodesalud.go.cr/leyes/leygeneraldesalud.pdf	CONIS: Executive Decree No. 31078-S (2003): http://www.ministeriodesalud.go.cr/reglamentos/31078-s.pdf CCSS: Regulation of Clinical Investigation in the Assistance Services of the Social Security Fund (2005)	CONIS: 1. Ethical and Legal Principles 2. Duties and Responsibilities of the National Council on Health Research, of Investigators, and of the Sponsor 3. Structure and Functioning of the Committee Network 4. Design of the Research Protocol 5. Requirements for the Submission of a Research Protocol 6. Informed Consent 7. Approval and Follow-up of a Research Project 8. Sanctions
Drugs	1. National Council on Health Research (CONIS) Network of Scientific Ethics Committees (Spanish): http://www.ministeriodesalud.go.cr/comconis.htm 2. Ministry of Health (Spanish): www.ministeriodesalud.go.cr			CONIS: 1. Guidelines for Good Clinical Practice (1996) 2. Protocol for Clinical Trials
Human Biological Materials	National Council on Health Research Network (CONIS) of Scientific Ethics Committees (Spanish): http://www.ministeriodesalud.go.cr/comconis.htm			Informed Consent, Research that Requires Biobanks
Jamaica				
General	Ministry of Health: http://www.moh.gov.jm			Ministry of Health Guidelines for the Conduct of Research on Human Subjects (2002)
Mexico				
General	Secretariat of Health (Spanish): http://www.salud.gob.mx/	General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2005)	Regulation of the General Health Law in the Area of Health Research (1986)	
Drugs	General Directorship of Medicines and Health Technologies		Regulation of the General Health Law in the Area of Health Research, Title Three (1986)	
Privacy/Data Protection		See listing at (Spanish): http://profesor.uia.mx/aveleyra/c		

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		omunica/privacidad/leyes2.htm		
Human Biological Materials	Secretariat of Health (Spanish): http://www.salud.gob.mx/	General Health Law, Title XIV, Articles 313-350 (2005)	Regulation of the General Health Law in the Area of Health Research, Title II, Chapter VI (1986)	
Genetic Research	Secretariat of Health (Spanish): http://www.salud.gob.mx/		Regulation of the General Health Law in the Area of Health Research, Title III, Chapter II (1986)	
Panama				
General	National Research Bioethics Committee (Spanish): http://www.gorgas.gob.pa/index.php?option=com_content&task=view&id=15&Itemid=43		Ministry of Health Resolution No. 390 Adopting the Operational Guide for Research Bioethics, Official Gazette 24,938 (2003) (Spanish): http://www.gorgas.gob.pa/images/Gaceta%20N°%2024%20938%20%20Resolucion390.doc	Informed Consent (2006) (Spanish): http://www.gorgas.gob.pa/images/bioetica/Elementos%20del%20Consentimiento%20Informado.pdf
Human Biological Materials		Law 52 of 1995, Official Gazette 22,929		
Embryos, Stem Cells, and Cloning		Law 3 of 2004, Official Gazette 24,969		
Peru				
General	1. National Institute of Health (Spanish): http://www.ins.gob.pe/ 2. National Network of Research Ethics Committees: http://www.ins.gob.pe/gxpsites/hgxpp001.aspx?2,13,59,O,S,0,MNU;C;1;14;20;5;MNU;,	General Health Law No. 26842, Article 28 (1997) (Spanish)		
Drugs	National Institute of Health (Spanish): http://www.ins.gob.pe/gxpsites/hgxpp001.aspx?2,13,326,O,S,0,MNU;E;1;14;20;10;MNU;,		1. Supreme Decree No. 017-2006-SA: Regulation on Clinical Trials in Peru (2006) 2. Supreme Decree No. 006-2007-SA: Modification of the Regulation on Clinical Trials in Peru (2007)	
Uruguay				
Human Biological Materials	Ministry of Public Health (Spanish): http://www.msp.gub.uy/index_1.html		Circular No. 40/95 Establishing Rules Regarding the Donation of Organs and Tissues for Scientific and Therapeutic Purposes (1995)	

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Venezuela				
General	1. National Fund on Science and Technology, Commission on Bioethics and Biosecurity (FONACIT) (Spanish): http://www.fonacit.gov.ve/bioetica.asp 2. Venezuelan Institute of Scientific Research, Bioethics Commission (IVIC) (Spanish): http://www.ivic.ve/bioetica/	Constitution, Article 46 (Spanish)	Resolution No. 48 (1998)	FONACIT: Code on Bioethics and Biosecurity (2002) IVIC: 1. Annex 1: General Ethical Issues in Research Involving Living Persons 2. Annex 2: Necessity of Establishing a Clear and Precise Study Protocol Before Starting Research 3. Informed Consent
Drugs	National Institute of Hygiene "Rafael Rangel" (Spanish): http://www.inhrr.gov.ve	Medicines Act, Articles 72 and 73		
Genetic Research	Venezuelan Institute of Scientific Research, Bioethics Commission (Spanish): http://www.ivic.ve/bioetica/			1. Contract for Accessing Genetic Resources (2003) (Spanish): http://www.ivic.ve/bioetica/contrato.pdf 2. Revised Outline of the International Declaration of Human Genetic Data (2003): http://www.ivic.ve/bioetica/chapter3.pdf

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AFRICA				
Botswana				
General	Ministry of Health, Research and Development Committee: http://www.moh.gov.bw/	Anthropological Research Act 45 (1967)		1. Guide – Consent Form (2005): https://webapps.sph.harvard.edu/live/gremap/files/bw_consent_form.pdf 2. Guidelines for the Review of Research Proposals (2005)
Drugs	Ministry of Health, Drug Regulatory Unit: http://www.moh.gov.bw/		Drugs and Related Substances Regulations (1993)	
Ethiopia				
General	Ethiopian Science and Technology Commission, Health Department: http://www.estc.gov.et/	Proclamation 60/1999, Section 21		National Health Research Ethics Review Guideline, Fourth Edition (2005): http://www.estc.gov.et/Ethics%20Guideline.pdf
Human Biological Materials	Ethiopian Science and Technology Commission, Health Department: http://www.estc.gov.et/			National Health Research Ethics Review Guideline, Fourth Edition, Section 8 (2005)
Kenya				
General	1. National Council for Science and Technology (NCST) 2. Ministry of Health (MOH): http://www.health.go.ke/index.html	Science and Technology Act (2001)	NCST: Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (2004): https://webapps.sph.harvard.edu/live/gremap/files/ke_NCST_guidelines.pdf MOH: Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005): https://webapps.sph.harvard.edu/live/gremap/files/ke_HIV_vaccine_guidelines.pdf	
Drugs	Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/	Pharmacy and Poisons Act, Chapter 244 (2001)		
Human Biological Materials	Ministry of Health (MOH): http://www.health.go.ke/index.html		Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, page 44 (2005)	

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Malawi				
General	1. National Research Council of Malawi (NRCM) 2. National Health Sciences Research Committee (NHSRC) 3. College of Medicine Research and Ethics Committee (COMREC) 4. Ministry of Health	1. Presidential Decree on 30th March 1974 2. Malawi Government Gazette, June 11, 1976, General Notice No. 398	NRCM: Procedures and Guidelines for the Conduct of Research in Malawi (2002)	NHSRC: 1. Operational Guidelines (2001) 2. Summary Guidelines for Writing Research Proposals (2001) COMREC: Research Guidelines (2004): http://www.medcol.mw/comrec/res.guidelines.php
Drugs	Pharmacy, Medicines, and Poisons Board of Malawi	Pharmacy, Medicines, and Poisons Act, Act 15 of 1988)		
Genetic Research	National Research Council of Malawi (NRCM)		Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002)	
Nigeria				
General	National Health Research Ethics Committee: http://nhrec.net/	National Health Bill 2004		National Code of Health Research Ethics (2006)
Drugs	National Agency for Food, Drug Administration and Control (NAFDAC): http://www.nafdacnigeria.org/	Decree No. 15 of 1993		Guidelines, Procedures, and Protocols for Clinical Trials (1993)
South Africa				
General	1. Department of Health (DH): http://www.doh.gov.za 2. Medical Research Council of South Africa (MRC): http://www.mrc.ac.za 3. National Health Research Ethics Council	National Health Act No. 61, Chapter 9 (2003): http://www.doh.gov.za/docs/legislation-f.html		DH: Ethics in Health Research: Principles, Structures, and Processes (2004): http://www.doh.gov.za/docs/policy-f.html MRC: http://www.sahealthinfo.org/ethics/index.htm 1. Guidelines on Ethics in Medical Research: General Principles (2002) 2. Guidelines on Ethics in the Use of Biohazards and Radiation (2003) 3. Guidelines on Ethics in HIV Vaccine Trials (2003)
Drugs	Medicines Control Council: http://www.mccza.com		Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2000): http://www.doh.gov.za/docs/policy/trials/trials_contents.html	

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Genetic Research	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za			MRC: Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.sahealthinfo.org/ethics/book2.htm
Embryos, Stem Cells, and Cloning	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za			MRC: Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.sahealthinfo.org/ethics/book2.htm
Tanzania				
General	1. Ministry of Health (MOH) 2. National Institute for Medical Research (NIMR), National Health Research Ethics Committee (NHREC): http://www.nimr.or.tz/index.php?option=com_content&task=view&id=26&Itemid=34 3. Tanzania Commission for Science and Technology (COSTECH): www.costech.or.tz	1. National Institute for Medical Research, Act of Parliament No. 23, of 1979 2. Tanzania Commission for Science and Technology, Act No. 7 of 1986 3. Amendment of NIMR Act 1997, Tanzania Government Gazette, No. 675	NIMR: 1. Coordination of Health Research in Tanzania 2. Coordination of Formation of Institutional Health Research Committees to Formally Approve for Local Health Research 3. Coordination of Research in Tanzania	NHREC: 1. Guidelines on Ethics for Health Research in Tanzania (2001): https://webapps.sph.harvard.edu/live/gremap/files/tz_health_research_ethics.pdf 2. Brochure for Health Researchers in Tanzania (2006) COSTECH: COSTECH Guidelines on Research Permits and Clearance (2006)
Drugs	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003): http://www.tfda.or.tz/tfdaact.pdf		
Uganda				
General	Uganda National Council on Science and Technology (UNCST): http://www.uncst.go.ug/			National Guidelines for Research Involving Humans as Research Participants (2007)
Drugs	National Drug Authority: http://www.nda.or.ug/	National Drug Authority Statute (1993)		
Zimbabwe				
General	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw	1. Government Notice Act (1974) 2. Research Act (1986)		1. Guidelines for Researchers and Ethics Review Committees in Zimbabwe (2004): http://www.mrcz.org.zw/docs/MRCZ%20guidelines%20for%20researchers%202004.pdf 2. Conducting Health Research in Zimbabwe: What Researchers Need to Know (2004): http://www.mrcz.org.zw/docs/conducting_health_research_in_zim.pdf

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Drugs	Medicines Control Authority of Zimbabwe	Medicines and Allied Substances Control Act, Chapter 15:03 (1997)	1. Medicines and Allied Substances Control Act, General Regulations (1991) 2. Statutory Instrument 150 of 1991	Guidelines for Good Clinical Practice
Human Biological Materials	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw			Ethical Guidelines on the Collection of Blood Samples for Research (1999): http://www.mrcz.org.zw/docs/blood%20collection%20guidelines%201999.pdf