

International Compilation of Human Research Protections

2009 Edition

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

PURPOSE

This Compilation lists the approximately 1,100 laws, regulations, and guidelines that govern human subjects research in 92 countries, as well as standards 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.

The 2009 Edition includes numerous additions and updates to the 2008 Edition, and features the laws, regulations, and/or guidelines for 7 new countries: Burma (also known as Myanmar), Egypt, the Gambia, San Marino, South Korea, the Sudan, and Vietnam.

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 (Note: Further information can be found at the website of Privacy Laws and Business: <http://www.privacylaws.com/>)
4. Human Biological Materials
5. Genetic (Note: Further information can be found in the HumGen International database at <http://www.humgen.umontreal.ca/int/>)
6. Embryos, Stem Cells, and Cloning

These six categories often overlap, so it may be necessary to review all standards to obtain a full understanding of the country's requirements.

The information is 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. Note that the English translation of a non-English document may not be an official translation.

HOW TO ACCESS A DESIRED DOCUMENT

Documents can be accessed in one of five ways:

1. Link to the listed web address (URL), when provided.
2. Perform a web search on the document title.
3. 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.
4. Go to the website of the corresponding agency and e-mail a request for the document.
5. Request the local research ethics committee to provide the document.

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, regulations, or guidelines specific to clinical bioethics, medical devices, adverse event reporting, insurance requirements, product liability, clinical trial inspection procedures, human tissue engineering, intellectual property, or informed consent in clinical practice.
2. Enabling legislation, i.e., laws that authorize an agency to promulgate human subjects regulations, but do not direct the content of those regulations.
3. Ethics codes of academic, medical, or other professional organizations.
4. Working papers, drafts, commentaries, 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 standards 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.

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Country	Key Organizations	Legislation	Regulations	Guidelines
INTERNATIONAL				
<i>General</i>	1. Office of the United Nations High Commissioner for Human Rights (OHCHR): http://www.ohchr.org/english/ 2. Council for International Organization of Medical Sciences (CIOMS): http://www.cioms.ch/ 3. UNAIDS: http://www.unaids.org/en/default.asp 4. World Health Organization (WHO) 5. World Medical Association (WMA): http://www.wma.net/e/ 6. 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) CIOMS: 1. International Guidelines for Ethical Review of Epidemiological Studies (1991) 2. International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) 3. International Ethical Guidelines for Biomedical Research Involving Human Subjects (An Islamic Perspective) (2004) UNAIDS: Ethical Considerations in HIV Preventive Vaccine Research (2000) WHO: Operational Guidelines for Ethics Committees that Review Biomedical Research (2000): http://whqlibdoc.who.int/hq/2000/TDR_PRD_ETHICS_2000.1.pdf WMA: Declaration of Helsinki (2008) UNESCO: Universal Declaration on Bioethics and Human Rights (2005)
<i>Drugs</i>	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)

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Privacy/Data Protection</i>	World Medical Association: http://www.wma.net/e/index.htm			Declaration on Ethical Considerations Regarding Health Databases (2002)
<i>Human Biological Materials</i>	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): http://www.who.int/reproductive-health/hrp/tissue.pdf IATA: 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)
<i>Genetic Research</i>	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 the Principled Conduct of Genetic Research (1996) 2. Statement on DNA Sampling: Control and Access (1998) 3. Statement on Gene Therapy Research (2001) 4. Statement on Human Genomic Databases (2002)
<i>Embryos, Stem Cells, and Cloning</i>	International Society for Stem Cell Research: http://www.isscr.org/			Guidelines for the Conduct of Human Embryonic Stem Cell Research (2006): http://www.isscr.org/guidelines/ISSCRhESCguidelines2006.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
NORTH AMERICA				
Canada				
<i>General</i>	<i>National:</i> 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)
	<i>Newfoundland and Labrador:</i> 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.assembly.nl.ca/legislation/sr/annualstatutes/2006/HO1-2.c06.htm		
	<i>Northwest Territories:</i>			
Aurora Research Institute: http://www.nwtresearch.com/		Scientist Act (1988): http://www.canlii.org/nt/laws		
	<i>Nunavut:</i>			
Nunavut Research Institute		Nunavut Scientists Act (1988)		
	<i>Quebec:</i>			
1. Quebec Minister of Health and Social Services, Ethics Unit (MSSS)		1. Civil Code of Quebec, S.Q., c. 64: Articles 11, 20, 21, 22, 24,	MSSS: All of the following regulations	FRSQ: Research Ethics and Scientific Integrity

Country	Key Organizations	Legislation	Regulations	Guidelines
	<p>(French): 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.fqrsq.gouv.qc.ca/fr/accueil.php 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</p>	<p>and 25 (1991): 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_42/S4_2_A.html</p>	<p>can be found at: http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml 1. Terms of Reference for the Research Ethics Boards Designated or Instituted in Accordance to Article 21 of the Civil Code of Quebec (1998) (French) 2. Ministerial Action Plan on Research Ethics and Scientific Integrity (1998) (French): 3. Contribution of Private Companies within the Framework of Research Activities Derived from Research Grants (2003) (French) 4. Memorandum 1: Clarification Regarding Subject-Matter and Territorial Jurisdictions of Research Ethics Boards (2007) (French) 5. Memorandum 2: Clarification Regarding the Concept of Continuous Monitoring of Project Ethics (2007) (French) 6. Memorandum 3: Clarification Regarding the REB Review of Relevant Parts of the Budget and the Sponsor-Institution-Researcher Agreement (2007) (French) 7. Terms of Reference for Eligible Operating Expenses of Research Ethics Boards (2007) (French) 8. Mechanism for the Ethical Review and Ongoing Oversight of Multicentre Projects (2008) (French) English translation: http://www.muhc.ca/research/ethics/34</p>	<p>Guidelines (2003)</p>
	<p><i>Yukon Territory:</i> Government of Yukon, Department of Tourism and Culture</p>	<p>Yukon Scientists and Explorers Act (2000): http://www.canlii.org/yk/laws/sta/200/20041124/whole.html</p>		

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<i>Drugs</i>	Health Canada, Therapeutic Products Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php		1. Good Clinical Practice Consolidated Guideline (1997) 2. Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials) (2004)	
<i>Privacy/Data Protection</i>	<i>National:</i> 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/ 3. Canadian Institutes of Health Research (CIHR)	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 also 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 (2005) CIHR: CIHR Best Practices for Protecting Privacy in Health Research (2005): http://www.cih-irsc.gc.ca/e/documents/pbp_sept2005_e.pdf
<i>Human Biological Materials</i>	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 (2005)
<i>Genetic Research</i>	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/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 8: Human Genetic Research (2005) CBAC: Genetic Research and Privacy (2004)
	<i>Quebec:</i> RMGA Network of Applied Genetic Medicine (French): https://rmga.ca/			1. Statement of Principles: Human Genome Research (2000) 2. Statement of Principles on the Ethical Conduct of Human Research Involving Populations (2003)
<i>Embryos, Stem Cells, and Cloning</i>	1. Interagency Advisory Panel on Research Ethics (PRE):	Assisted Human Reproduction Act (2004): http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php	Assisted Human Reproduction (Section 8 Consent) Regulations	PRE: Tri-Council Policy Statement: Ethical

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	http://www.pre.ethics.gc.ca/english/ 2. Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html	sc.gc.ca/hl-vs/reprod/hc-sc/legislation/index_e.html	(2007)	Conduct for Research Involving Humans, Section 9: Research Involving Human Gametes, Embryos, or Foetuses (2005) CIHR: Updated Guidelines for Human Pluripotent Stem Cell Research (2007): http://www.cihr-irsc.gc.ca/e/34460.html
United States				
<p>Note: All of the following departments and agencies subscribe to the Common Rule, which is subpart A (last updated in 2005) of the relevant section of the Code of Federal Regulations. As indicated below, some departments and agencies subscribe to additional subparts:</p> <ul style="list-style-type: none"> • Subpart B: Additional Protections for Pregnant Women, Human Fetuses, and Neonates (2001) • Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (1978) • Subpart D: Additional Protections for Children Involved as Subjects in Research (1991) 				
<i>General</i>	Agency for International Development: www.usaid.gov/		22 CFR 225, Subpart A	Protection of Human Subjects in Research Supported by USAID: A Mandatory Reference for ADS Chapter 200 (2006): http://www.usaid.gov/policy/ads/200/200mbe.pdf
	Central Intelligence Agency: www.odci.gov/		Executive Order 12333, Subparts A, B, C, and D	
	Consumer Product Safety Commission: www.cpsc.gov/		16 CFR 1028, Subpart A	
	Department of Agriculture: www.usda.gov/wps/portal/usdahome/		7 CFR 1c, Subpart A	
	Department of Commerce: www.commerce.gov/		15 CFR 27, Subpart A	
	Department of Defense, Regulatory Affairs: www.dtic.mil/biosys/org/regulatory.html	United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects	1. 32 CFR 219, Subpart A 2. DoD Directive 3216.02 (2002) <i>Army:</i> 1. AR 70-25 2. AR 40-38 <i>Navy:</i> SECNAVINST 3900.39 series <i>Air Force:</i> AFI 40-402 (2005) <i>Office of the Under Secretary of Defense for Personnel and</i>	

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			<i>Readiness:</i> USUHS Instruction 3201 <i>Defense Threat Reduction Agency:</i> 1. DTRA Directive 3216.1 2. DTRA Instruction 3216.2	
	Department of Education: www.ed.gov/	1. Protection of Pupil Rights Amendment (1974) 2. Family Educational Rights and Privacy Act (1974)	1. 34 CFR 97 subparts A (1991) and D (1997) 2. 34 CFR 98 (1984) 3. 34 CFR 99 (2000) 4. 34 CFR 350.4(c) (1991) 5. 34 CFR 356.3(c) (1991)	
	Department of Energy: www.energy.gov/engine/content.do/		1. 10 CFR 745 (1991), Subpart A 2. Order 1300.3 3. Order 481.1	
	Department of Health and Human Services, Office for Human Research Protections: www.hhs.gov/ohrp/	Public Health Service Act (1993): http://www.hhs.gov/ohrp/human_subjects/guidance/statute.htm	45 CFR 46, Subparts A, B, C, and D	Various: http://www.hhs.gov/ohrp/policy/index.html#topics
	Department of Homeland Security: www.dhs.gov/	Public Law 108-458, Section 8306		
	Department of Housing and Urban Development: www.hud.gov/		24 CFR 60, Subpart A	
	Department of Justice: www.usdoj.gov/		1. 28 CFR 22 (1976) 2. 28 CFR 46 (1991), Subpart A 3. 28 CFR 512 (1994)	
	Department of Transportation: www.dot.gov/		49 CFR 11, Subpart A	
	Department of Veterans Affairs 1. Office of Research Oversight (ORO): www1.va.gov/oro/ 2. Office of Research and Development: www.research.va.gov		1. 38 FR 16 (1991), Subpart A 2. 38 CFR 17.85 (1998)	
	Environmental Protection Agency: www.epa.gov/		40 CFR 26 1. Subpart A: Common Rule 2. Subpart B: Prohibition of Intentional Exposure Research Conducted or Supported by EPA in Children and Pregnant or Nursing Women (2006) 3. Subpart C: Additional	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Protections for Observational Research Conducted or Supported by EPA in Pregnant Women and Fetuses (2006) 4. Subpart D: Additional Protections for Observational Research Conducted or Supported by EPA in Children (2006) 5. Subpart K: Regulation of Third-Party Intentional Exposure Research for Pesticides in Non-Pregnant, Non-Nursing Adults (2006) 6. Subpart L: Prohibition of Third-Party Intentional Exposure Research for Pesticides in Children and Pregnant or Nursing Women (2006)	
	National Aeronautics and Space Administration: www.nasa.gov/		14 CFR 1230, Subpart A	
	National Science Foundation: www.nsf.gov/		45 CFR 690, Subpart A	
<i>Drugs</i>	Food and Drug Administration: www.fda.gov	1. Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (Device coverage – Section 360) (2004): http://www.fda.gov/opacom/laws/fdeact/fdctoc.htm 2. Public Health Service Act, 42 USC Section 262 (1944): http://www.fda.gov/opacom/laws/phsvcaact/phsvcaact.htm	1. 21 CFR 50 (1980) 2. 21 CFR 312 (1987) 3. 21 CFR 56 (2001) 4. 21 CFR 812 (2007)	1. Good Clinical Practice in FDA-Regulated Clinical Trials: www.fda.gov/oc/gcp 2. Other: www.fda.gov/oc/ohrt/irbs/default.htm
<i>Privacy/Data Protection</i>	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/	1. Privacy Act, 5 U.S.C. § 552a (1974): http://www.usdoj.gov/oip/04_7_1.html 2. Health Insurance Portability and Accountability Act (1996): http://www.hhs.gov/ocr/hipaa/privrulepd.pdf	1. HIPAA Privacy Rule: Standards for Privacy of Individually Identifiable Health Information, Final Rule, 45 CFR parts 160 and 164 (2002): http://www.hhs.gov/ocr/hipaa/privrulepd.pdf 2. HIPAA Security Rule, 45 CFR parts 160, 162, and 164: http://www.hhs.gov/ocr/hipaa/	NIH: 1. Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule (2004) http://privacyruleandresearch.nih.gov/pr_02.asp 2. Research Repositories, Databases, and the HIPAA Privacy Rule (2004): http://privacyruleandresearch.nih.gov/research_repositories.asp 3. Institutional Review Boards and the

Country	Key Organizations	Legislation	Regulations	Guidelines
				HIPAA Privacy Rule (2004): http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp
<i>Human Biological Materials</i>	1. Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/ 2. Food and Drug Administration Office of In Vitro Diagnostic Device Evaluation and Safety: http://www.fda.gov/cdrh/oivd/			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) FDA: Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable (2006): http://www.fda.gov/cdrh/oivd/guidance/1588.pdf
<i>Genetic Research</i>	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, Appendix M (2002): http://www4.od.nih.gov/oba/RAC/guidelines_02/NIH_Guidelines_Apr_02.htm
<i>Embryos, Stem Cells, and Cloning</i>	1. National Institutes of Health 2. Office of the President 3. 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 Academy of Sciences (NAS): http://www.nationalacademies.org/nrc/	Research on Transplantation of Fetal Tissue. Public Law 103-43	Office of the President: 1. President George W. Bush's Policy (2001) 2. President Bush's Executive Order 13435 (2007): Expanding Approved Stem Cell Lines in Ethically Responsible Ways: http://img.slate.com/media/40/13435-stemcells.pdf	FDA: Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products. October 14, 1993. 58 FR 53248 NIH: 1. Approval Process for the Use of Human Pluripotent Stem Cells in NIH-Supported Research (2000) 2. NIH Guidelines for Research Using Human Pluripotent Stem Cells (2000): http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2000_register&docid=00-21760-filed.pdf OHRP: Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles (2002)

Country	Key Organizations	Legislation	Regulations	Guidelines
				<p>NAS:</p> <ol style="list-style-type: none"> 1. Guidelines for Human Embryonic Stem 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 3. 2008 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research: http://books.nap.edu/catalog.php?record_id=12260

Country	Key Organizations	Legislation	Regulations	Guidelines
EUROPE				
European-wide				
<i>General</i>	1. Council of Europe, Bioethics Division (CoE): http://www.coe.int/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, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol on Biomedical Research, CETS No. 195 (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
<i>Drugs</i>	1. European Commission, Enterprise Directorate-General, Pharmaceuticals Unit (EC): http://europa.eu.int/comm/enterprise/pharmaceuticals/index_en.htm 2. European Medicines Agency (EMA): http://www.emea.europa.eu/	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)	EMA: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997) EC: Notice to Applicants: Questions & Answers, Clinical Trial Documents (2005)
<i>Privacy/Data Protection</i>	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/		

Country	Key Organizations	Legislation	Regulations	Guidelines
		<p>sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31995L0046&model=guichett</p> <p>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)</p>		
<i>Human Biological Samples</i>	<p>1. European Commission (EC): http://europa.eu.int/ 2. Council of Europe, Bioethics Division (CoE): http://www.coe.int/bioethics 3. European Group on Ethics in Science and New Technologies (EGE): http://europa.eu.int/comm/european_group_ethics/index_en.htm 4. European Medicines Agency (EMA): http://www.ema.europa.eu/</p>	<p>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/lex/pri/en/oj/dat/2004/l_102/l_10220040407en00480058.pdf</p> <p>CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG</p>		<p>EGE: Ethical Aspects of Human Tissue Banking (1998)</p> <p>EMA: Concept Paper on the Development of a Guideline on Biobanks Issues Relevant to Pharmacogenetics (2005)</p> <p>CoE: Recommendation Rec (2006) 4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin (2006): http://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75</p>
<i>Genetic Research</i>	<p>Council of Europe, Bioethics Division: http://www.coe.int/bioethics</p>	<p>1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol on Biomedical Research, CETS No. 195 (2005):</p>		<p>1. Recommendation No. R (92) on Genetic Testing and Screening for Health Care Purposes (1992): http://wcd.coe.int/ViewDoc.jsp?id=612007&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75 2. Recommendation Rec(2006)4 of the Committee of Ministers to Members States on Research on Biomedical Materials of Human Origin (2006):</p>

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		http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG		http://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75
<i>Embryos, Stem Cells, and Cloning</i>	1. Council of Europe, Bioethics Division (CoE): http://www.coe.int/bioethics 2. European Society of Human Reproduction and Embryology: http://www.eshre.com/	CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol on Prohibition of Human Cloning, ETS No. 168 (1998): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=168&CM=7&DF=9/15/2008&CL=ENG		
Confederation of Independent States				
<i>General</i>	Interparliamentary Assembly: http://www.iacis.ru/html/index-eng.php			Model Law on the Protection of Human Rights and Dignity in Biomedical Research in the CIS Member States (2005): http://www.iacis.ru/html/index-eng.php?id=54&pag=596&nid=9
Armenia Note: For an overview of human subject protections in Armenia, see “Ethical Review of Biomedical Research in the CIS Countries,” Chapter 3, Section 1: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
<i>Drugs</i>	1. Agency on Medicines and Medical Technologies 2. National Ethics Committee	1. Law of the Republic of Armenia of May 4, 1996: About Medical Aid, The Maintenance of the Population, Article 21 2. Resolution of the Government of Armenia of January 24, 2002: Procedure for Clinical Trials of New Medications in Armenia		
Austria				
<i>General</i>	1. Forum of Austrian Ethics Committees (German): http://www.ethikkommissionen.at 2. Ministry of Health (German): http://www.bmgfj.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/bundesr		Forum of Austrian Ethics Committees: Various guidelines.

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		echt/ (After the word “Suchworte“ enter "Krankenanstalten." Then push the “Suche Starten” key. The Hospital Act is seen at “Krankenanstalten-und Kuranstaltengesetz”)		
<i>Drugs</i>	1. Ministry of Health (German): http://www.bmgfj.gv.at 2. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/ueber-uns/english-what-is-ages/	Austrian Drug Law (2005) (German): http://www.ris.bka.gv.at/bundesrecht/ (Suchworte: “Arzneimittel,” then look for “Arzneimittelgesetz”)	Regulation on Leading Ethics Committees: http://www.ris.bka.gv.at/bundesrecht/ (Suchworte: “Leit-Ethikkommissions-V“)	Forum of Austrian Ethics Committees: Various guidelines.
<i>Privacy/Data Protection</i>	Austrian Data Protection Commission: http://www.dsk.gv.at/indexe.htm	1. Federal Act Concerning the Protection of Persons (2000) (German): http://www.dsk.gv.at/site/6229/default.aspx English translation: http://www.dsk.gv.at/site/6230/default.aspx 2. Privacy/Data Protection laws in Austrian States (German): http://www.dsk.gv.at/site/6202/default.aspx		
<i>Genetic Research</i>	1. Ministry of Health (German): http://www.bmgfj.gv.at/cms/site/thema.html?channel=CH0697 2. Austrian Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	Gene Technology Act No. 510 (1994) (German): http://www.ris.bka.gv.at/bundesrecht/ (Suchworte: “Gentechnik,” then look for “Gentechnikgesetz”)		
<i>Embryos, Stem Cells, and Cloning</i>		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)		

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Belgium				
<i>General</i>	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)
<i>Drugs</i>	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)	
<i>Privacy/Data Protection</i>	Commission for the Protection of Privacy (French and Flemish): http://www.privacy.fgov.be/	Law of December 8, 1992 on Privacy Protection in Relation to the Processing of Personal Data as Modified by the Law of December 11, 1998 Implementing Directive 95/46/EC: http://www.law.kuleuven.ac.be/cri/itl/12privacylaw.php	Decree of February 13, 2001 Implementing the Law of December 8, 1999	
<i>Human Biological Materials</i>	1. Conseil Supérieur de la Santé/Hoge Gezondheidsraad (CSS) (French & Dutch): http://www.health.fgov.be/CSS_HGR 2. Federal Public Service: www.health.fgov.be	1. Royal Decree (1987), Regarding the Expression of Consent for the Removal of Organs and Tissues on Living Donors 2. Royal Decree (1997)		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/doc

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		Regarding the Removal and Allocation of Organs of Human Origin 3. Act on the Removal and Transplantation of Organs (2006) (French): http://www.staatsbladclip.be/lois/2006/08/28/loi-2006022815.html 4. 2007 Amendment (French): http://www.staatsbladclip.be/lois/2007/04/13/loi-2007022504.html		s/PAGE/INTERNET_PG/HOMEPAGE_MENU/ABOUTUS1_MENU/INSTITUTIONSAPPARENTEES1_MENU/HOGEGEZONDHEIDSRAAD1_MENU/ADVIEZENENAANBEVELINGEN1_MENU/ADVIEZENENAANBEVELINGEN1_DOCS/7691_SO_COMMUNS_2007_FR.PDF
<i>Embryos, Stem Cells, and Cloning</i>	1. Federal Public Service: www.health.fgov.be 2. Federal Commission for Medical and Scientific Research on Embryos in Vitro	1. Royal Decree Fixing the Criteria for the Program Applicable to the Care Programs ‘Reproductive Medicine’ (15/02/1999) 2. Act on Research on Embryos in Vitro (2003) (French): http://www.staatsbladclip.be/lois/2003/05/28/loi-2003022592.html 3. Law on Medically Assisted Reproduction and the Destination of Supernumerary Embryos and Gametes (2007) (French): http://www.staatsbladclip.be/lois/2007/07/17/loi-2007023090.html		
Bosnia				
<i>Drugs</i>	Ministry of Health	Law on Drugs and Pharmacies, Art. 28		
<i>Privacy/Data Protection</i>		Law on the Protection of Personal Data in Bosnia and Herzegovina (2001): http://www.privacyinternational.org/article.shtml?cmd[347]=x-347-63545		

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Bulgaria				
Note: For an overview of human subject protections in Bulgaria, see “National Regulations on Ethics and Research in Bulgaria:” http://ec.europa.eu/research/science-society/pdf/bg_eng_lr.pdf				
<i>General</i>	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	1. Constitution of the Republic of Bulgaria, Article 29 (1991) 2. Oviedo Convention on Human Rights and Biomedicine (2001) 3. Law Ratifying the Additional Protocol on Biomedical Research (2005) 4. Law on Medicinal Products in Human Medicine (2007) 5. Healthcare Act, Articles 199 and 200 (2007)		
<i>Drugs</i>	1. Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/ 2. Bulgarian Drug Agency (BDA): http://www.bda.bg/?lang=en	Law for Medicinal Products in Human Medicine (2007), Chapter 4	MOH: Regulation No. 31 on the Rules for GCP (August 12, 2007)	
<i>Privacy/Data Protection</i>	1. Bulgarian Commission for Personal Data Protection: http://www.ceeprivacy.org/main.php?s=2&k=bulgaria 2. Ombudsman: www.ombudsman.bg	Personal Data Protection Act (2006): http://www.ceeprivacy.org/pdf/law_bulgaria.pdf		
<i>Human Biological Materials:</i>	1. Executive Agency for Transplantation (Bulgarian): http://bgtransplant.bg/ 2. Council of Ministers, Ethics Committee for Transplantation	Law on Transplantation of Organs, Tissues, and Cells (2006)	Regulation No. 13 of 04 April 2007 for the Terms and Conditions of Informing Bulgarian Citizens on the Activities regarding the Transplantation of Organs, Tissues and Cells	
<i>Embryos, Stem Cells, and Cloning</i>	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	Law Ratifying the Convention for Human Rights (2007)		
Croatia				
<i>General</i>		Oviedo Convention on Human Rights and Biomedicine (2003)		
<i>Drugs</i>	1. Ministry of Health and Social Welfare: http://www.mzss.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.almp.hr/#	Law on Drugs (2007)	Regulations on Clinical Research and Good Clinical Practice (2007)	
<i>Privacy/Data Protection</i>	Croatian Personal Data Protection Agency (Croatian):	Personal Data Protection Act (2008):		

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	http://www.azop.hr/default.asp	http://www.legal500.com/c/croatia/developments/4908		
<i>Embryos, Stem Cells, and Cloning</i>		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2003) 2. Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (2007)		
Cyprus				
<i>General</i>		Law No. 31 (III)/2001 (Oviedo Convention on Human Rights and Biomedicine)		
<i>Drugs</i>	1. National Health Authority (Medicines Council) 2. Ministry of Health, National Bioethics Committee: http://www.moh.gov.cy	Law for Good Clinical Practice (2004)		
<i>Privacy/Data Protection</i>	Commissioner for Personal Data Protection: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/index_en/index_en?opendocument	Processing of Personal Data (Protection of Individuals) Law 138 (I) 2001: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/\$FILE/138(I)-2001_en.pdf As amended in 2003: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/\$FILE/37(I)-2003_en.pdf		
<i>Embryos, Stem Cells, and Cloning</i>		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		

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		Medicine, on the Prohibition of Cloning Human Beings (2002)		
Czech Republic				
<i>General</i>	Ministry of Health, Central Ethics Committee (Czech): http://www.mzcr.cz	1. Act No. 20/1996 on the Care for the Health of People 2. Oviedo Convention on Human Rights and Biomedicine (2001) 3. Act No. 130/2002 Collection on the Research and Development Support as Amended		
<i>Drugs</i>	1. Ministry of Health (MOH) (Czech): http://www.mzcr.cz 2. State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lred=1	Act No. 378/2007 Collection on Pharmaceuticals	MOH: Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products	SUKL: 1. KHL-8: Clinical Trial Protocol and Protocol Amendments (1998) 2. KLH-10: Terminology and Principles of Good Clinical Practice (1998) 3. KLH-11: Ethics Committees (1998) 4. KLH-10: Terminology and Principles of Good Clinical Practice (1998) 5. KLH-19: Documentation Required for an Approval of a Clinical Trial on a Human Pharmaceutical (2001) 6. KLH-20: Application for Approval/ Notification of a Clinical Trial (2004)
<i>Privacy/Data Protection</i>	Office for Personal Data Protection (Czech): http://www.uoou.cz/	Act on the Protection of Personal Data and on Amendment to Some Related Acts (No. 101 of April 4, 2000): http://www.uoou.cz/index.php?l=en&m=left&mid=01:01&u1=&u2=&t=	Position No. 3/2004 Personal Data Processing in the Context of Clinical Testing of Drugs and Other Medical Substances: http://www.uoou.cz/index.php?l=en&m=left&mid=02:109&u1=&u2=&t=	
<i>Embryos, Stem Cells, and Cloning</i>	1. Ministry of Education, Youth, and Sport: http://www.msmt.cz/index.php?lchan=1&lred=1 2. Research and Development Council, Bioethical Commission: http://www.vyzkum.cz/FrontClanek.aspx?idsekce=15908	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2001) 2. Act of 26 April 2006 on Research on Human Embryonic Stem Cells		

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Denmark				
Note: For an overview of human subject protections in Denmark, see http://www.cvk.sum.dk/cvk/site.aspx?p=119 .				
<i>General</i>	Danish National Committee on Biomedical Research Ethics (CVK): http://www.cvk.sum.dk/cvk/site.aspx?p=119	1. Oviedo Convention on Human Rights and Biomedicine (1999) 2. Act on the Biomedical Research Ethics Committee System (2003): http://www.cvk.sum.dk/cvk/site.aspx?p=150 3. Act Amending the Act on the Biomedical Research Ethics Committee System (2006) http://www.cvk.sum.dk/cvk/site.aspx?p=152	Ministerial Order No. 806 of 12 July 2004 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects (2004): http://www.cvk.sum.dk/cvk/site.aspx?p=156	CVK: 1. Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics (2008) 2. Appendices (2008)
<i>Drugs</i>	Danish Medicines Agency: http://www.dkma.dk	Medicinal Product Act No. 382 (2003)	1. Executive Order No. 935 on Informed Consent from Patients in Biomedical Trials (2000) 2. Executive Order on Clinical Trials on Medicinal Products, Human Use (2004) 3. Danish Guideline on Notification of Clinical Trials of Medicinal Products in Humans (2004)	Guideline on Informed Consent from Patients in Biomedical Trials (2000)
<i>Privacy/Data Protection</i>	Danish Data Protection Agency (DPA): http://www.datatilsynet.dk/english/	The Act on Processing of Personal Data (Act No. 429) (2007): http://www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/		DCE: Protection of Sensitive Personal Information Other guidelines can be accessed at: http://www.privireal.group.shef.ac.uk/content/dp/denmark.php
<i>Human Biological Materials</i>	Danish National Committee on Biomedical Research Ethics (CVK): http://www.cvk.sum.dk/cvk/site.aspx?p=119	Health Law, Chapter 7 (2005) http://147.29.40.90/DELFIN/HTML/A2005/0054630.htm#K7		
<i>Embryos, Stem Cells, and Cloning</i>	Danish Council of Ethics (DCE): http://www.etiskraad.dk/sw293.asp	1. Act on Medically Assisted Procreation (1997) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		DCE: 1. Cloning (2001) 2. Research in Human Gametes, Fertilized Ova, Embryos and Fetuses (2004)

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Estonia				
Note: For an overview of human subject protections in Estonia, see “National Regulations on Ethics and Research in Estonia:” http://ec.europa.eu/research/science-society/pdf/et_eng_lr.pdf				
<i>General</i>	Estonian Council of Bioethics: http://www.ut.ee/eetikakeskus/download/ethics-committees	1. Constitution of the Republic of Estonia, Paragraph 18 (1992) 2. Oviedo Convention on Human Rights and Biomedicine (2002)		Code of Ethics of Estonian Scientists: http://www.akadeemia.ee/repository/File/ALUSDOKUD/Code-ethics.pdf
<i>Drugs</i>	1. Minister of Social Affairs (MSA) 2. State Agency of Medicines: http://www.sam.ee/index.aw?set_lang_id=2	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 be Submitted in Order to Obtain Approval (2001)	
<i>Privacy/Data Protection</i>	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/andm_ebaas/tekst.asp?loc=text&dok=X70030&keel=en&pg=1&ptyyp=RT&tyyp=X&query=data%2BprotectionLink		
<i>Genetic Research</i>		Human Genes Research Act (RT I 2000, 104, 685) (2000): http://www.geenivaramu.ee/index.php?id=98		
<i>Embryos, Stem Cells, and Cloning</i>		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002) 2. Artificial Insemination and Embryo Protection Act (2003)		
Finland				
<i>General</i>	1. Ministry of Social Affairs and Health (MSAH) 2. ETENE Sub-Committee on	Medical Research Act No. 295/2004: http://www.finlex.fi/en/laki/kaan	MSAH: 1. Decree on the National Advisory Board on Health Care	TUKIJA: Checklist for Researchers and Members of Ethics Committees (2001)

Country	Key Organizations	Legislation	Regulations	Guidelines
	<p>Medical Research Ethics (TUKIJA): http://www.etene.org/e/tukija/index.shtml</p> <p>3. National Advisory Board on Research Ethics (TENK): http://pro.tsv.fi/tenk/english1.htm</p>	<p>nokset/1999/en19990488</p>	<p>Ethics No. 494/1998</p> <p>2. Decree on Medical Research and Subsidiary Regulations Issued in Pursuance Hereof, No. 898/1999, as amended 313/2004.</p> <p>3. Decree on the National Research Ethics Council of Finland No. 1347/2002</p>	
<i>Drugs</i>	<p>1. National Agency for Medicines (NAM): http://www.nam.fi/index.html</p> <p>2. Ministry of Social Affairs and Health (MSAH): http://www.stm.fi</p>	<p>Medicines Act and Decree No. 296/2004</p>	<p>NAM: Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2004</p> <p>MSAH: Decree on Clinical Trials No. 316/2005</p>	
<i>Privacy/Data Protection</i>	<p>Office of the Data Protection Ombudsman: http://www.tietosuoja.fi/1560.htm</p>	<p>1. Personal Data Act No. 523/1999: http://www.tietosuoja.fi/uploads/hopxtvf.HTM</p> <p>2. Act on the Amendment of the Personal Data Act No. 986/2000: http://www.tietosuoja.fi/uploads/p9qzq7zr3xxmm9j.rtf</p>		
<i>Human Biological Materials</i>		<p>Act on the Medical Use of Human Organs and Tissues No. 101/2001: http://www.finlex.fi/pdf/saadkaan/E0010101.PDF</p>		
<i>Genetic Research</i>		<p>Gene Technology Act No. 377/1995</p>		
<i>Embryos, Stem Cells, and Cloning</i>	<p>National Advisory Board on Research Ethics</p>	<p>1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)</p> <p>2. Medical Research Act No. 295/2004: http://www.finlex.fi/en/laki/kaanokset/1999/en19990488</p>		<p>Human Stem Cells, Cloning, and Research (2005) (Finnish): http://videnskabsministeriet.dk/site/forside/publikationer/2000/guidelines-on-biomedical-experiments/html/guidelines.pdf</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
France <i>General</i>	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) 2. Decree No. 97-555 Concerning the National Consultative Ethics Committee for Health and Life Sciences (1997) (French): http://www.ccne-ethique.fr/decree_n_97555.php	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/opinions.php 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 Level – Ethical Issues (2003)
<i>Drugs</i>	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)
<i>Privacy/Data Protection</i>	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)

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<i>Human Biological Materials</i>	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)
<i>Genetic Research</i>	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)
<i>Embryos, Stem Cells, and Cloning</i>	National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	1. Bioethics Law (1994) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		CCNE: Commercialisation of Human Stem Cells and Other Cell Line (2006)
Georgia				
Note: For an overview of human subject protections in Georgia, see “Ethical Review of Biomedical Research in the CIS Countries,” Chapter 3, Section 4: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
<i>General</i>		Oviedo Convention on Human Rights and Biomedicine (2000)		
<i>Drugs</i>	Drug Agency of the Ministry of Labor, Health, and Social Affairs: http://www.healthministry.ge/eng/index.php	1. Drug and Pharmacy Law No. 659 (1997) 2. Licenses and Approvals Law (2005)	Regulation about the Rules and Conditions of Issuing of the Approval of Clinical Trials Approved #176 (2005)	
<i>Embryos, Stem Cells, and Cloning</i>		Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2000)		

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Germany Note: For an overview of human subject protections in Germany, see http://www.eurecnet.org/bodies/germany/index.html				
<i>General</i>	1. German Medical Association (BÄK): http://www.bundesaerztekammer.de/page.asp?his=4.3569 2. Central Ethics Commission of the BÄK (German): www.zentrale-ethikkommission.de/ 3. Working Group of the Medical Ethics Committees in Germany (German): http://www.ak-med-ethik-komm.de/ 4. German Ethics Council (NER): http://www.ethikrat.org/en_index.php 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
<i>Drugs</i>	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/cln_029/EN/Home/homepage_node.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/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	Medicinal Products Act, Sections 40-42 (2007) (German): http://www.bmg.bund.de/cln_110/nn_1200354/SharedDocs/Downloads/DE/GV/GT/Arzneimittel/AMG.templateId=raw.property=publicationFile.pdf/AMG.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 Use (2006) BMBF: Principles and Responsibilities Related to Clinical Studies (2003)	
<i>Privacy/Data Protection</i>	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 enacted laws about data		

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		<p>protection in the non-federal public sector (German): http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html</p>		
<i>Human Biological Materials</i>	<ol style="list-style-type: none"> 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 Ethics Council (NER): http://www.ethikrat.org/en_index.php 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 	<ol style="list-style-type: none"> 1. Transplantation Law (2007) (German): http://www.bmg.bund.de/cln_110/nn_1200474/SharedDocs/Downloads/DE/GV/GT/Organspende/TransplantationsG.templateId=raw.property=publicationFile.pdf/TransplantationsG.pdf 2. Transfusion Law (2007) (German): http://www.bmg.bund.de/cln_110/nn_1200364/SharedDocs/Downloads/DE/GV/GT/Blutprodukte/3-Gesetz-zur-Regelung-des-Trans-.templateId=raw.property=publicationFile.pdf/3-Gesetz-zur-Regelung-des-Trans-.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 	<p>DGCH Rule for the Production of Human Tissues (German)</p>	<p>BÄK: http://www.bundesaerztekammer.de/page.asp?his=0.7.45&all=true</p> <p>NER: Opinion on Biobanks for Research (2004): http://www.ethikrat.org/english/publications/Opinion_Biobanks-for-research.pdf</p> <p>ZEKO (German): http://www.zentrale-ethikkommission.de/downloads/Koerpermat.pdf</p> <p>DIZG: <ol style="list-style-type: none"> 1. Ethical Code (2000) 2. Common Standards: Tissues and Cell Banking (2004) </p>
<i>Genetic Research</i>	<ol style="list-style-type: none"> 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?_nn=true 	<p>Law of 20 June 1990/16.12.1993 to Regulate Matters Related to Gene Technology (2006)</p>		<p>BÄK: Guideline on Gene Transfer (1995) (German) http://www.bundesaerztekammer.de/30/Richtlinien/Richtidx/Gentransferpdf.pdf</p> <p>GFHEV: <ol style="list-style-type: none"> 1. Position Paper of the German Society of Human Genetics (1996) 2. DNA Banking and Personal Data in Biomedical Research: Technical, Social, and Ethical Questions (2004) </p>

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				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
<i>Embryos, Stem Cells, and Cloning</i>	1. German Ethics Council (NER): http://www.ethikrat.org/en_index.php 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 (2008): English translation of 2002 version: http://www.bmj.bund.de/files/-/1146/Stammzellgesetz%20englisch.pdf	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/stammzellforschung_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				
<i>Drugs</i>	1. National Organization for Medicines (NOM): http://www.eof.gr/eof_en/enhome.html 2. National Bioethics Commission	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	NOM: 1. Ministerial Decision A6/10983/1/12-20.12.1984 on Clinical Trials and Protection of the Human Being (1984)	NBC: 1. Report on Biomedical Experimentations Involving Human Subjects and Clinical Trials of Medicinal Products (2005):

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	(NBC): http://www.bioethics.gr/index.php?category_id=3	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	2. Ministerial Decision DYG3/89292/31.12.2003 (2003)	http://www.bioethics.gr/media/pdf/reports/report_ct_en.pdf 2. Code of Medical Ethics (2005)
<i>Privacy/Data Protection</i>	1. Hellenic Data Protection Authority (Greek): http://www.dpa.gr/	1. Greek Constitution 1975/1986/2001 Article 9.1 2. Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998) 3. 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) (Greek): http://www.dpa.gr/Documents/Eng/2472engl_all.doc 4. Act 3418/2005 Code of Medical Ethics		
<i>Genetic Research</i>	1. Hellenic Data Protection Authority (HDDPA) (Greek): http://www.dpa.gr/ 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. Greek Constitution 1975/1986/2001, Article 5.5 2. Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998)		HDDPA: Opinion No. 15/2001 NBC: Report on the Collection and Use of Genetic Data http://www.bioethics.gr/media/pdf/reports/report_genetic_data_eng.pdf
<i>Embryos, Stem Cells, and Cloning</i>	1. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3 2. National Authority for Medically Assisted Reproduction (Greek): http://www.iya.gr	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998) 2. Act 3089/2002 on Medically Assisted Human Reproduction		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 (2002): http://www.bioethics.gr/media/pdf/reports/stem_cell_report_eng.pdf

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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			
<i>General</i>	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 XX of 1949 on the Constitution of the Republic of Hungary, Article 54. 2. Act CLIV of 1997 on Health Care, Chapter VIII 3. Act IV of 1978 on the Criminal Code Title II of Chapter XII. Crimes Against the Order of Medical Interventions and Medical Research and Against Self-Determination Related to Health Issues 4. Act VI. of 2002 on the promulgation of the Oviedo Convention on Human Rights and Biomedicine 5. Act LXXXI of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research	EüM: Decree 23/2002 (V. 9.) EüM on Biomedical Research on Human Beings	
<i>Drugs</i>	1. National Institute of Pharmacy: http://www.ogyi.hu/main_page 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	
<i>Privacy/Data Protection</i>	Parliamentary Commissioner for Data Protection and Freedom of Information: http://www.obh.hu/indexen.htm	1. Act LXIII of 1992 on Protection of Personal Data and Disclosure of Data of Public Interest, Amended by the Parliamentary Act No XLVIII of 2003: http://abiweb.obh.hu/dpc/index.php?menu=gyoker/relevant/national/1992_LXIII 2. Act XLVII of 1997 on the		

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		Handling of Medical and Other Related Data: http://abiweb.obh.hu/dpc/index.php?menu=gyoker/relevant/national/1997_XLVII		
<i>Human Biological Materials</i>	Ministry of Health (EüM): http://www.eum.hu/english	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	Decree 18/1998 (XII 27) EüM on Implementing Act CLIV of 1997 on Health Care as regards Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations	
<i>Genetic Research</i>		Act XXI of 2008 on the Rules of Protection of Human Genetic Data, of Human Genetic Examinations and Research and of the Operation of Biobanks		
<i>Embryos, Stem Cells, and Cloning</i>	1. Ministry of Health (EüM): http://www.eum.hu/english 2. Medical Research Council	1. Act CLIV of 1997 on Health Care, Chapters IX and XI 2. Act VI of 2002 on the Promulgation of the Convention on Human Rights and Medicine and the Additional Protocol on Cloning	Decree 30/1998 (VI. 24.) NM on Regulations on Specific Procedures for Human Reproduction	
Iceland				
<i>General</i>	1. Ministry of Health and Social Security (MOH): http://ministryofhealth.is 2. National Bioethics Committee (NBC): www.visindasidanefnd.is , then select "English" in the upper-right hand corner.	1. Act on the Rights of Patients No. 74 (1997): http://ministryofhealth.is/laws-and-regulations//nr/34 2. Oviedo Convention on Human Rights and Biomedicine (2004)	MOH: Regulation on Scientific Research in the Biomedical field, No. 286 (2008) http://eng.heilbrigdisraduneyti.is/laws-and-regulations/Regulations//nr/2847	NBC: 1. Research Projects 2. Withdrawal
<i>Drugs</i>	1. Icelandic Medicines Control Agency (MCA): http://www.imea.is/ 2. 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	
<i>Privacy/Data Protection</i>	Data Protection Authority: http://www.personuvernd.is/informati	1. Judgement by the Supreme Court of Iceland Concerning the	Government Regulation on a Health Sector Database No. 32	

Country	Key Organizations	Legislation	Regulations	Guidelines
	on-in-english/	Health Sector Database (2003): http://www.personuvernd.is/information-in-english/ 2. Act on the Protection of Privacy as Regards the Processing of Personal Data, No. 77/2000, as Amended (2003): http://www.personuvernd.is/information-in-english/	(2000): http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/670	
<i>Human Biological Materials</i>	1. Ministry of Health: 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
<i>Embryos, Stem Cells, and Cloning</i>		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2004) 2. Artificial Fertilization Act No. 55/1996 as Amended by Laws No. 65/2006, 27/2008, and 54/2008 (Icelandic): http://althingi.is/lagas/nuna/1996055.html English translation of 1996 law: http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/685		
Ireland				
<i>General</i>	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)
<i>Drugs</i>	Irish Medicines Board: http://www.imb.ie/	These Statutory Instruments can be viewed at: http://www.dohc.ie/issues/clinical_trials/ 1. European Communities (Clinical Trials on Medicinal		

Country	Key Organizations	Legislation	Regulations	Guidelines
		<p>Products for Human Use) Regulations, 2004</p> <p>2. European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 878 of 2004)</p> <p>3. European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment No. 2) Regulations 2006 (S.I. 374 of 2006)</p> <p>4. European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 to 2006 (Informal Codification Text)</p>		
<i>Privacy/Data Protection</i>	Data Protection Commissioner: http://www.dataprotection.ie/docs/Home/4.htm	Data Protection Act (1988), as amended (2003): http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html		
<i>Human Biological Materials</i>	Irish Council for Bioethics: http://www.bioethics.ie			Human Biological Material: Recommendations for Collection, Use, and Storage in Research (2005): http://www.bioethics.ie/pdfs/BioEthics_fi_n.pdf
<i>Genetic Research</i>	Irish Medicines Board: http://www.imb.ie/			Guidelines for Pharmacogenetic Research (2006): http://www.imb.ie/images/uploaded/documents/AUT-G0003_Guidelines_for_pharmacogenetic_research_v1.pdf
<i>Embryos, Stem Cells, and Cloning</i>		Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		
Italy				
<i>General</i>	<p>1. National Federation of Ethics Committees (FNACE) (Italian): http://www.unich.it/fnace/</p> <p>2. National Monitoring Center for Clinical Trials (OSS): https://oss-sper-</p>	<p>Statute on the National Federation of Ethics Committees (1995) (Italian): http://www.unich.it/fnace/statuto.htm</p>	<p>FNACE: Regulation Implementing the Statute on the National Federal of Ethics Committees (1995)</p> <p>OSS:</p>	<p>NBC: Opinion of the National Bioethics Committee on the European Protocol on Biomedical Research (1999)</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
	<p>clin.agenziafarmaco.it/index_ingl.htm</p> <p>3. National Bioethics Committee (NBC): http://www.governo.it/bioetica/eng/index.html</p> <p>4. Ministry of Health (Italian): http://www.ministerosalute.it</p>		<p>Ministerial Decree: Terms of Reference for the Establishment and the Functioning of Ethics Committees (May 12, 2006)</p>	
<i>Drugs</i>	<p>1. National Monitoring Center for Clinical Trials: https://oss-sper-clin.agenziafarmaco.it/index_ingl.htm</p> <p>2. Italian Medicines Agency (Italian): http://www.agenziafarmaco.it/</p> <p>3. Ministry of Health (MOH) (Italian): http://www.ministerosalute.it</p>	<p>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.</p> <p>2. Legislative Decree No. 211: Transposition of Directive 2001/20/EC Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Clinical Use (2003) (Italian): http://oss-sper-clin.agenziafarmaco.it/normativa/decreto_24062003_inglese.pdf</p> <p>English translation: https://oss-sper-clin.agenziafarmaco.it/normativa/decreto_24062003_inglese.pdf</p> <p>3. Legislative Decree No. 200: Transposition of Directive 2005/28 EC Laying down Principles and Detailed Guidelines as Regards Investigational Medical Products for Human Use, as well as the Requirements for Authorizing of Manufacturing or</p>	<p>Italy has numerous regulations that govern drug research (Italian): http://oss-sper-clin.agenziafarmaco.it/normativa/</p> <p>The following are the most important:</p> <ol style="list-style-type: none"> 1. Ministerial Decree: Composition and Functions of Regional Bioethics Committees (1999) 2. Ministerial Decree: Controlled Clinical Trials in General Practice and Pediatrics (2001) 3. Ministerial Decree: Non-profit Controlled Clinical Trials with Medicines (2004) 4. Ministerial Decree: Minimum Requirements for the Institution, Organization, and Functioning of Ethics Committees for Clinical Experimentation of Drugs (2006) 5. Ministerial Decree: Modalities of Submission (2007) (Italian): http://www.aifa.gov.it/allegati/decreto_21dicembre2007.pdf 	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Importing of such Products (2007) (Italian): http://www.aifa.gov.it/allegati/dlgs_200-6nov2007.pdf		
<i>Privacy/Data Protection</i>	Italian Data Protection Independent Authority	Italian Personal Data Protection Code, Legislative Decree No. 196 of June 30, 2003: http://www.garanteprivacy.it/garante/doc.jsp?ID=1030925	Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000)	
<i>Genetic Research</i>	1. Istituto 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/0478.1106653420.pdf SIGU: Guidelines for Genetic Biobanks (2004): http://www.gaslini.org/DPPM/BIOBANK_GUIDELINES.pdf

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				
<i>Drugs</i>	1. State Agency of Medicines: http://www.vza.gov.lv/index.php?setlang=en&large= 2. Central Medical Ethics Committee	Pharmaceutical Law, Amended April 24, 2008: 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, Amended January 15, 2008	
<i>Privacy/Data Protection</i>	1. Data State Inspectorate: http://www.dvi.gov.lv/eng/ 2. Central Medical Ethics Committee	1. Medical Treatment Law, Amended May 8, 2008 2. Personal Data Protection Law, Amended February 21, 2008: http://www.dvi.gov.lv/eng/legislation/pdp/		

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Human Biological Materials</i>	Central Medical Ethics Committee	Law on the Protection of Dead Human Beings and Use of Human Organs and Tissue, Amended February 6, 2004	Cabinet of Ministers Regulation No. 208 (2007): Order of Use of Human Biological Materials	
<i>Genetic Research</i>	1. Ministry of Health 2. Data State Inspectorate: http://www.dvi.gov.lv/eng/ 3. Central Medical Ethics Committee	1. Human Genome Research Law, Amended January 3, 2005 2. Law on the Development and Use of the National DNA Database, Amended March 9, 2006	Regulation of the Cabinet of Ministers, "Procedures for Genetic Research" (2004)	
<i>Embryos, Stem Cells, and Cloning</i>	1. Ministry of Health 2. Central Medical Ethics Committee	Sexual and Reproductive Health Law, amended March 29, 2007: http://www.ttc.lv/New/lv/tulkojumi/E0750.doc	Cabinet Regulation No. 716 (2003.16.12): Order of Medically-Assisted Procreation, Donor Registry, and Donor Bank	
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				
<i>General</i>	1. Ministry of Health (MOH): http://www.sam.lt/en/ 2. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1702632112	1. Oviedo Convention on Human Rights and Biomedicine (2002): http://conventions.coe.int/treaty/en/treaties/html/164.htm 2. Law on Ethics of Biomedical Research, No. VIII-1679 (2007): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=326057	MOH: 1. Decree on the Procedure for the Estimation and Covering of Expenses Incurred by Research Subjects, No. 677 (2000) 2. 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) 3. Decree on the Procedure to Issue Approvals to Conduct Biomedical Research, No. V-2 (2008) 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)	
<i>Drugs</i>	1. State Medicines Control Agency (SMCA):	1. Law on Ethics of Biomedical Research, No. VIII-1679 (2000):	SMCA: 1. Decree on Pediatric Clinical	LBEC: Recommendations on the Advertisements

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.vvkt.lt/index.php?3327723903 2. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1702632112 3. Ministry of Health (MOH): http://www.sam.lt/en/	http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=326057 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	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. 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)	for Trial Subjects
<i>Privacy/Data Protection</i>	State Data Protection Protectorate	Law Amending the Law on Legal Protection of Personal Data, No. X-1444 (2008): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=315633		
<i>Human Biological Materials</i>		Law on Human Tissue and Organ Donation and Transplantation (2000): http://www3.lrs.lt/pls/inter2/dokpaieska.showdoc_l?p_id=112278		
<i>Embryos, Stem Cells, and Cloning</i>	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=326057 2. Additional Protocol to the	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	

Country	Key Organizations	Legislation	Regulations	Guidelines
		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	Territory of the Republic of Lithuania, No. V-660 (2007)	
Luxembourg				
<i>General</i>		Hospitals Act of 1998, Article 25		
<i>Drugs</i>	1. Ministry of Health (French): http://www.ms.etat.lu/ 2. National Committee on Ethics in Research (CNER) (French): http://www.cne.lu 3. Division of Pharmacy and Medicines: http://www.ms.etat.lu/DPM/index.html		Grand-Ducal Decree of 30th of May, 2005 on Good Clinical Practice	
<i>Privacy/Data Protection</i>	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 law of July 27, 2007 (French): http://www.legilux.public.lu/leg/a/archives/2007/1310808/1310808.pdf#page=11	Grand-Ducal Decree of October 2 nd , 1992 on the Use of Personal Medical Data in IT Processing	
Macedonia				
<i>General</i>	Ministry of Health of Macedonia: http://www.moh.gov.mk/eng/			
<i>Drugs</i>	Macedonian Drug Agency	Drug Law (1998) (Macedonian)	Regulations on Clinical Trials of Medicinal Products on Human Subjects (1998)	
<i>Privacy/Data Protection</i>	Directorate for Personal Data Protection (Macedonian): http://www.dpdp.gov.mk/	Law on Personal Data Protection (2005): http://www.ceecprivacy.org/pdf/Law%20on%20Personal%20Data%20Protection.pdf		

Country	Key Organizations	Legislation	Regulations	Guidelines
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				
<i>General</i>	Health Ethics Committee: http://sahha.gov.mt/pages.aspx?page=134			
<i>Drugs</i>	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) (English translation begins half way through document): http://www.doi.gov.mt/EN/legalnotices/2004/11/LN490.pdf	Guidance Notes on Good Clinical Practice (2005)
<i>Privacy/Data Protection</i>	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				
<i>General</i>		Oviedo Convention on Human Rights and Biomedicine (2002)		
<i>Drugs</i>	Ministry of Public Health, National Ethics Committee	Moldova Republic Law on Medicines of December 17, 1997, Articles 11 and 12	Ordinance No. 10: On Performance of Clinical Trials in the Republic of Moldova (2002)	
<i>Embryos, Stem Cells, and Cloning</i>		Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002)		
Montenegro				
<i>Drugs</i>	Ministry of Health of Montenegro: www.mz.cg.yu	Law for Drugs and Pharmacies of Montenegro, Articles 37-39		
Netherlands				
<i>General</i>	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): http://www.ccmo-online.nl/hipe/uploads/download	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	Manual for the Review of Medical Research Involving Human Subjects (2002)

Country	Key Organizations	Legislation	Regulations	Guidelines
		s_catw/Medical%20Research%20involving%20Human%20Subjects%20Act%20March%2001%202006.pdf 3. Medical Research (Human Subjects) Compulsory Insurance Decree (2003): http://www.ccmo-online.nl/hipe/uploads/downloads/Verzekeringsbesluit_2003-ENG(1).pdf	Members (2003) 4. External Review Guideline (2004)	
<i>Drugs</i>	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/cbg/en/default.htm	Medicines Act (2007) (Dutch): http://wetten.overheid.nl/cgi-bin/deeplink/law1/title=Geneesmiddelenwet	MHWS: 1. Medicines Act Decree (2007) (Dutch): http://wetten.overheid.nl/cgi-bin/deeplink/law1/title=Besluit%20Geneesmiddelenwet 2. Medicines Act Regulation (2007) (Dutch): http://wetten.overheid.nl/cgi-bin/deeplink/law1/title=Regeling%20Geneesmiddelenwet	CCMO: Clinical Research with Medicinal Products in the Netherlands: Instructional Manual (2005): http://www.ccmo-online.nl/hipe/uploads/downloads_cati/Instruction%20manual%20versie%202.pdf
<i>Privacy/Data Protection</i>	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.cbpreweb.nl/downloads_wetten/WBP.PDF English translation of 2002 version: http://www.dutchdpa.nl/downloads_wetten/wbp.pdf?refer=true&theme=purple		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
<i>Human Biological Materials</i>	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/?s=1&m=78&p=&v=4
<i>Genetic Research</i>	1. Ministry of Housing, Spatial Planning, and Environment (VROM): www.vrom.nl 2. Dutch Health Care Inspectorate (IGZ): http://www.igz.nl/ 3. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/	Medical Research Involving Human Subjects Act (2006): http://www.ccmo-online.nl/hipe/uploads/downloads_catw/Medical%20Research%20involving%20Human%20Subjects%20Act%20March%2001%202006.pdf		VROM, IGZ, and CCMO: Guidelines for Researchers and Sponsors with Regard to the Assessment by Official Bodies of Clinical Research Involving Gene Therapeutics in the Netherlands (2007): http://213.154.234.72/Documenten/Documenten%20IM/Guidelines%20gene%20therapy%20applications.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Embryos, Stem Cells, and Cloning</i>	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl	1. Foetal Tissue Act (2001): http://www.minvws.nl/includes/dl/openbestand.asp?File=/images/Foetal%20act_tcm20-107821.pdf 2. Embryos Act (2002) http://www.minvws.nl/includes/dl/openbestand.asp?File=/images/eng-embryowettekst_tcm20-107819.pdf		Explanatory Notes to the Embryos Act: http://www.minvws.nl/includes/dl/openbestand.asp?File=/images/explanatory-notes-to-the-embryos-bill_tcm20-108037.pdf
Norway				
<i>General</i>	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	1. Oviedo Convention on Human Rights and Biomedicine (2006) 2. Law regarding Ethics and Integrity in Research (2006): http://www.ub.uio.no/ujur/ulovdata/lov-20060630-056-eng.pdf 3. Act on Research in Health Care (2008) (Norwegian): http://www.lovdato.no/cgi-wif/wiftdles?doc=/usr/www/lovdato/all/nl-20080620-044.html&emne=helseforskning_slov*&&	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
<i>Drugs</i>	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
<i>Privacy/Data Protection</i>	Data Inspectorate (DI): http://www.datatilsynet.no/templates/Page_194.aspx	Personal Data Act No. 31 (2000): http://www.datatilsynet.no.htest.osl.basefarm.net/upload/Dokumenter/regelverk/lov_forskrift/lov-20000414-031-eng.pdf	Regulations on the Processing of Personal Data (2003): http://www.datatilsynet.no.htest.osl.basefarm.net/upload/Dokumenter/regelverk/lov_forskrift/lov-20000414-031-eng.pdf	
<i>Human Biological Materials</i>	1. Ministry of Health and Care Services (MHCS):	1. Act on Biobanks (February 21, 2003, No. 12):	MHCS: Guidelines for the Norwegian Act	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.odin.no/hod/english/bn.html 2. Ministry of Education and Research (MER): http://www.odin.no/kd/english/bn.html	http://www.regjeringen.no/upload/kilde/hod/red/2005/0078/ddd/pdfv/242629-act_relating_to_biobanks_biobankloven.pdf 2. Act Relating to the Application of Biotechnology in Human Medicine, etc. (December 5, 2003, No. 100)	on Biobanks (2003) (Norwegian): http://odin.dep.no/hod/norsk/publ/rundskriv/042051-990014/	
<i>Genetic Research</i>	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		
<i>Embryos, Stem Cells, and Cloning</i>	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				
<i>General</i>	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)
<i>Drugs</i>	Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/english/index.htm	1. Pharmaceutical Law, Act of Sept. 6, 2001, Article 6 2. Law of 20/04/2004 on Amendment of the Pharmaceutical Law, Law on the Profession of Medical Doctor, and Regulations Introducing the Pharmaceutical Law, Law on	1. Order of the Minister of Health in the Matter of Central Register of Clinical Trials (2004) 2. Decree of the Minister of Health on Clinical Trials on Minors (2004) 3. Order of the Minister of Finance Concerning the	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Medical Devices, and Law on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws No. 92, Item 882)	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)	
<i>Privacy/Data Protection</i>	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		
<i>Human Biological Materials</i>		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				
<i>General</i>	National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/	Oviedo Convention on Human Rights and Biomedicine (2001)		1. Opinion 4/CNE/93 on Clinical Trials (1993) 2. Opinion 9/CNE/94 on Ethics Commissions (1994) 3. Doc. 13/CNECV/95 on Legislation on Clinical Trials and Ethics Committees (1995) 4. Doc. 34/CNECV/2001 on the Helsinki Declaration (2001)
<i>Drugs</i>	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_FARMACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/portaria_57-2005.pdf	Decree-Law No. 102/2007 of April 2	
<i>Privacy/Data Protection</i>	National Data Protection Commission:	1. Constitution, Article 35 (1997)		

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.cnpd.pt/english/index_en.htm	2. Act on the Protection of Personal Data, No. 67/98 (1998): http://www.cnpd.pt/english/bin/legislation/Law6798EN.HTM		
<i>Genetic Research</i>	Ministry of Health	Law 12/2005		
<i>Embryos, Stem Cells, and Cloning</i>	National Council of Ethics for the Life Sciences: http://www.cnecev.gov.pt/cnecev/en/	Oviedo Convention on Human Rights and Biomedicine, Additional Protocol on Prohibition of Human Cloning (2001)		1. Opinion 15/CNECV/95 on Embryo Research (1995) 2. Opinion 47/CNECV/2005 on Stem Cell Research (2005): http://www.cnecev.gov.pt/NR/rdonlyres/F13B34FD-F9F7-4C9D-96DC-419999D9B693/0/47CNECV2005.pdf 3. Opinion 48/CNECV/2006 on Human Cloning (2006): http://www.cnecev.gov.pt/NR/rdonlyres/770EA390-9326-4FF9-B28D-D70A7E9AD961/0/p048_en.pdf
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				
<i>General</i>	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)	
<i>Drugs</i>	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. 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) 3. Order of MOH No. 1117/2004: Detailed Guidance for the Request for Authorization of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authorities, Approval of Substantial Amendments and	MOH: Guideline for Clinical Trials in Pediatric Populations (CPMP/ICH/2711/99) (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
			Declaration of the End of the Trial (2004) 4. Order of MOH No. 904/25.07.2006 Transposing Directive 2001/20/EC of the European Parliament and of the Council (2006)	
<i>Privacy/Data Protection</i>	National Supervisory Authority for Personal Data Processing: http://www.dataprotection.ro/index.jsp?page=documents&lang=en	Law No. 667/2001 On the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data: http://www.dataprotection.ro/servlet/ViewDocument?id=174		
<i>Embryos, Stem Cells, and Cloning</i>		Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2001)		
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				
<i>General</i>	1. Federal Service on Surveillance in Healthcare and Social Development (FSSHSD) (Russian): http://www.roszdravnadzor.ru/ 2. Ethics Committee of the Federal Service on Surveillance in Healthcare and Social Development (Russian): http://www.roszdravnadzor.ru/etika/et/norm	Constitution of the Russian Federation, Article 21 (1993): http://www.constitution.ru/en/10003000-03.htm	FSSHSD: Order No. 2314-Pr/07 17 on August 2007 About the Ethics Committee (Russian): http://www.roszdravnadzor.ru/about/news/11698	
<i>Drugs</i>	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/etika/et/norm 4. Scientific Center for Expertise of	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)	

Country	Key Organizations	Legislation	Regulations	Guidelines
	the Remedies for Medicinal Use (Russian): http://www.regmed.ru/			
<i>Privacy/Data Protection</i>		1. Federal Law of the Russian Federation on Information, Information Technologies, and Protection of Information (2006) 2. Federal Law of the Russian Federation No. 152-FZ on Personal Data (2006): http://pda.eng.www.kadastr.ru/upload/www/files/152_fz.pdf English translation: http://www.hunton.com/files/tbl_s47Details/FileUpload265/1625/Privacy_Russia_White_Paper.pdf		
<i>Genetic</i>		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)		
San Marino				
<i>General</i>		Oviedo Convention on Human Rights and Biomedicine (1998)		
Serbia				
<i>Drugs</i>	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				
<i>General</i>	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. 2004 law: http://www.privireal.org/content/rec/documents/Slovakia_ActNo_576_Healthcare_2004.pdf		

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Oviedo Convention on Human Rights and Biomedicine (1998) 3. Additional Protocol on Biomedical Research (2005)		
<i>Drugs</i>	State Institute for Drug Control (Slovak): 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)	
<i>Privacy/Data Protection</i>	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		
<i>Human Biological Materials</i>		Law No. 277/1994 Coll. on Health Care, Sections 45-47		
<i>Embryos, Stem Cells, and Cloning</i>		Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998)		
Slovenia				
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				
<i>General</i>		1. Oviedo Convention on Human Rights and Biomedicine (1998) 2. Additional Protocol on Biomedical Research (2006)		Slovenian Code of Medical Deontology, Articles 47-50 (1992)
<i>Drugs</i>	1. National Medical Ethics Committee (NMEC): http://www.mf.uni-lj.si/kme-nmec/ 2. Agency for Medicinal Products and Medical Devices (Slovenian): http://www.jazmp.si/index.php?id=56		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	

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Privacy/Data Protection</i>	Inspectorate for Personal Data Protection (Slovenian): http://www.ip-rs.si/	1. Personal Data Protection Act No. 59 (1999) 2. Act Amending the Personal Data Protection Act No. 57/2001		
<i>Human Biological Materials</i>	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)
<i>Embryos, Stem Cells, and Cloning</i>		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002) 2. Law on Biomedically Assisted Fertilization No. 70 (2000)		
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.				
<i>General</i>	1. Spanish Bioethics Committee 2. Coordinating Center for Ethical Committees on Clinical Research (Spanish): http://www.msc.es/profesionales/farmacia/ceic/home.htm	1. Oviedo Convention on Human Rights and Biomedicine (1999) 2. Law 14/2007 on Biomedical Research: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
<i>Drugs</i>	Spanish Agency for Medications and Health Products, Clinical Trials (Spanish): http://www.agemed.es/profHumana/ensayosClinicos/home.htm	Royal Decree 223/2004: Regulation of Medication Clinical Trials (Spanish): http://www.agemed.es/actividad/legislacion/espana/ensayos.htm	1. Order SCO/256/2007 That Establishes the Principles and Detailed Directives on Good Clinical Practice, and the Requirements to Approve the Manufacture and Import of Research Medications for Human Use (Spanish): http://www.agemed.es/actividad/legislacion/espana/ensayos.htm 2. Order SCO/362/2008 that Modifies Order SCO/256/2007 (Spanish):	

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.agemed.es/actividad/legislacion/espana/ensayos.htm	
<i>Privacy/Data Protection</i>	Spanish Data Protection Authority	<p>1. Organic Law 15/1999 of December 13 on the Protection of Personal Data: https://www.agpd.es/upload/Ley%20Org%20Unica%2015-99_ingles.pdf</p> <p>2. Law 14/2007 on Biomedical Research, Title I, Article 5: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf</p>		
<i>Human Biological Materials</i>	Ministry of Health and Consumption (MOH): http://www.msc.es/en/home.htm	<p>1. Royal Decree 1301/2006 of November 10 Regarding the Use of Cells and Human Tissue: http://www.ont.es/legislacion/ficherosPDF/RD1301.pdf</p> <p>2. Royal Decree 2070/1999 of December 30, Regarding Activities of Collection and Clinical Use of Human Organs for Organ Transplants and Tissues</p> <p>3. Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf</p>	Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples (2006)	
<i>Genetic</i>	Spanish Bioethics Committee (Spanish): http://www.isciii.es/htdocs/investigacion/investigacion_presentacion.jsp	Law 14/2007 of July 3 on Biomedical Research, Title I, Articles 6-9; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
<i>Embryos, Stem Cells, and Cloning</i>	Spanish Bioethics Committee (Spanish): http://www.isciii.es/htdocs/investigacion/investigacion_presentacion.jsp	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to		

Country	Key Organizations	Legislation	Regulations	Guidelines
		<p>the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2000)</p> <p>2. Law 14/2006 on Methods of Assisted Human Reproduction</p> <p>3. Law 14/2007 of July 3 on Biomedical Research, Title III: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf</p>		
Srpska				
<i>Drugs</i>	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				
<i>General</i>	<p>1. Central Ethical Review Board (CEPN): http://www.epn.se/start/startpage.aspx</p> <p>2. Swedish Research Council (SRC): http://www.vr.se/english</p>	Law No. 460 on the Ethical Review of Research Involving Humans (2003)	<p>CEPN:</p> <p>1. Ordinance No. 615 Concerning the Ethical Vetting of Research Involving Humans (2003)</p> <p>2. Statute No. 616 Containing Instructions for Regional Ethical Review Boards (2003)</p> <p>3. Statute No. 617 Containing Instructions for the Central Ethical Review Boards (2003)</p>	<p>CEPN: Information for Research Participants</p> <p>SRC: 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)</p>
<i>Drugs</i>	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	<p>1. Medical Products Agency's Provisions and Guidelines on the Clinical Trials of Medicinal Products (1999)</p> <p>2. Medical Product Agency's Provisions and Guidelines on Clinical Trials of Medicinal Products for Human Use, Code of Statutes No. 6 (2003)</p>	
<i>Privacy/Data Protection</i>	Swedish Data Inspection Board: http://www.datainspektionen.se/in-english/	1. Personal Data Act No. 204 (2002): http://www.datainspektionen.se/pdf/ovrigt/pul-eng.pdf		

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Human Biological Materials</i>	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/	2. 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)
<i>Genetic Research</i>	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) (Swedish): http://www.notisum.se/rnp/sls/la/g/20060351.htm		Genetics and Gene Technology in the Health Care: State of the Art and Guidelines for Ethical Considerations (1999)
<i>Embryos, Stem Cells, and Cloning</i>		Act on Genetic Integrity (2006:351) (Swedish): http://www.notisum.se/rnp/sls/la/g/20060351.htm	Legal Regulation of Stem Cell Research 2002:119: http://www.regeringen.se/sb/d/108/a/2717	
Switzerland				
<i>General</i>	1. Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/ 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		Many of the Swiss cantons have implemented regulations regarding human subject research (French): http://www.swissethics.ch/fileadmin/user_upload/Dokumente/f_RegelungenKant.doc	SAMS: Guidelines on Human Research (1997)
<i>Drugs</i>	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/HMG_Engl.pdf	Ordinance on Clinical Trials of Therapeutic Products, RS 812.214.2 (2004): http://www.swissmedic.ch/files/pdf/VKlin%20e_%202005-03-14.pdf	
<i>Privacy/Data Protection</i>	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/fr/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/fr/rs/235_154/index.html 3. Confidentiality in Medical Research (2006) (French):		

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.admin.ch/ch/fr/rs/311_0/a321bis.html Note: Many Swiss cantons have enacted laws regarding data collection in the public sector.		
<i>Human Biological Materials</i>	Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/			Biobanks: Obtainment, Preservation and Utilization of Human Biological Material (2006)
<i>Genetic Research</i>	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	
<i>Embryos, Stem Cells, and Cloning</i>	Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE)			NEK-CNE: Research Involving Human Embryos and Fetuses. Opinion No. 11/206: http://www.sq3.it/en/lsc/docs/materials/Embryo_engl.pdf
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				
<i>General</i>	Ministry of Health	1. Turkish Constitution, Article 17 2. Health Services Basic Law No. 3359 (1987) 3. Oviedo Convention on Human Rights and Biomedicine (2004)	1. Regulation on Medical Deontology, Article 11 (1960) 2. Regulation on Medical Research (1993) 3. Bylaw on Patient Rights No. 23420 (1998)	
<i>Drugs</i>	Ministry of Health	Turkish Penal Law, Article 90 (2005)	Note: Many of these documents can be accessed at the website of the Turkish Clinical Research Association: http://www.clinicstr.org/ 1. Regulation on Drug Research in Turkey (1993) 2. Bylaw on the Clinical Trials Conducted by Medical Products Used in Humans (1993) 3. Bylaw on the Evaluation and Monitoring of the Safety of Medical Products (2005)	Note: Many of these documents can be accessed at the website of the Turkish Clinical Research Association: http://www.clinicstr.org/ 1. Guideline of Good Clinical Practice (1995) 2. Guideline of Compassionate Use of Experimental Drugs (2006) 3. Guidance on Observational Studies Performed with Drugs (2008)

Country	Key Organizations	Legislation	Regulations	Guidelines
			4. Regulation Regarding the Implementation and Inspection of the Support for Research and Development Activities (2008)	
<i>Human Biological Materials</i>		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)
<i>Genetic Research</i>			Regulation on Centers for Diagnosis and Genetic Diseases, No. 23368 (1998)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14 (1999)
<i>Embryos, Stem Cells, and Cloning</i>			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

<i>General</i>	1. Ethical Commission with the Higher Education Committee (EC-HEC) 2. Ukrainian Ministry of Health: http://www.moz.gov.ua/en/		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) MOH: 1. Order No. 485 About Creation and Composition of Central Ethics Committee of Ministry of Health of the Ukraine (2006) (Ukrainian): http://www.moz.gov.ua/ua/main/docs/?docID=6893 2. Order No. 142 About Optimization of Work of Central Ethics Committee of Ministry of Health of the Ukraine (2007) (Ukrainian): http://www.moz.gov.ua/ua/main/docs/?docID=7989	
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Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Drugs</i>	<p>1. State Pharmacological Center: http://www.pharma-center.kiev.ua/view/all_information</p> <p>2. Ukrainian Ministry of Health, Central Ethics Committee: http://www.moz.gov.ua/en/main/siterubr/</p>	<p>On Medicines, Articles 7 and 8 No. 123/96BP (1996): http://www.pharma-center.kiev.ua/site/file_uploads/en/new_doc/law_en.doc</p>	<p>1. Ukrainian Ministry of Health Decree No. 373 About Approval of Documents Related to the Standardization, Registration and Conduct of Clinical Trials of Study Drugs 42-7.0:2005 (2005)</p> <p>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/site/file_uploads/en/new_doc/66_p.doc</p>	<p>MOH Central Ethics Committee:</p> <ol style="list-style-type: none"> 1. Information Letters on Ethics Questions of Clinical Trials and Implementation of Medicines (2006) 2. Ethics Expertise of Clinical Trials Medicines (2007) 3. Methodological Aspects of Central EC Activity of Ukrainian Ministry of Health (2007)
<i>Privacy/Data Protection</i>		Information Act from the Cabinet of Ministers of the Ukraine (2002)		
<i>Human Biological Materials</i>	<p>Ukrainian Ministry of Health: http://www.moz.gov.ua/en/main/siterubr/</p>		<p>Ukrainian Ministry of Health Order No. 630 About Approval of Procedure for Conduction Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) (Ukrainian): http://www.moz.gov.ua/ua/main/docs/?docID=8767</p>	
<i>Genetic Research</i>	Academy of Medical Sciences of the Ukraine			Medical and Ethical Guidelines for Genetic Investigations in Humans
<i>Embryos, Stem Cells, and Cloning</i>	<p>National Bioethics Committee of the National Academy of Sciences of the Ukraine (NBC)</p> <p>Ukrainian Ministry of Health: http://www.moz.gov.ua/en/main/siterubr/</p>	<p>1. About the Ban of Human Reproductive Cloning (2004)</p> <p>2. About Organs and Other Human Materials Transplantology No. 1007-XIV (2007)</p>	<p>1. Recommendation No. 1046, Use of the Human Fetus for the Purpose of Diagnosis, Therapy, Research, Industrial Purchase, and Trading (1986)</p> <p>2. Ukrainian Ministry of Health Order No. 630 About Approval of Procedure for Conduction Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007): http://www.moz.gov.ua/ua/main/docs/?docID=8767</p>	<p>NBC: Ethical Regulations and Problems of Embryo-Tissue Storage (Recommendations)</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
United Kingdom				
Note: Unless otherwise noted, all laws, regulations, and guidelines listed for England apply to the entire United Kingdom.				
<i>General</i>	<p><i>England:</i></p> <ol style="list-style-type: none"> 1. Department of Health (DH): http://www.dh.gov.uk/Home/fs/en 2. National Research Ethics Service (NRES): http://www.nres.npsa.nhs.uk/home 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 I Ethics Committees (AAPEC) http://www.aapec.org.uk/ 7. Economic and Social Research Council (ESRC): http://www.esrc.ac.uk/ 	<p>Mental Capacity Act 2005, Sections 30-34 (England and Wales):</p> <p>http://www.opsi.gov.uk/acts/acts/2005/20050009.htm</p>		<p>DH:</p> <ol style="list-style-type: none"> 1. Governance Arrangements for NHS Research Ethics Committees (2001) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005727 2. Research Governance Framework for Health and Social Care (2005) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962 <p>NRES:</p> <ol style="list-style-type: none"> 1. NRES Guidance on Information Sheets and Consent Forms (2007) 2. NRES Guidance on Research Involving Adults Unable to Consent for Themselves (Including Guidance on the Mental Capacity Act 2005) (2007) 3. Guidance for Applicants to NRES (2007) 4. Standard Operating Procedures for Research Ethics Committees in the United Kingdom (2008) 5. NRES Leaflets (2008): <ul style="list-style-type: none"> • Building on Improvement • Research Ethics Timeline • Defining Research • Explaining Research <p>Integrated Research Application System (2008): https://www.myresearchproject.org.uk/</p> <p>MRC:</p> <ol style="list-style-type: none"> 1. MRC Guidelines for Good Clinical Practice in Clinical Trials (1998) 2. Good Research Practice (2000) 3. Personal Information in Medical Research (2000) 4. Research Involving Human Participants

Country	Key Organizations	Legislation	Regulations	Guidelines
				<p>in Developing Societies (2004)</p> <p>5. Medical Research Involving Children (2004)</p> <p>RCP: Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants (2007)</p> <p>ESRC: Research Ethics Framework</p>
	<i>Northern Ireland:</i>			
	Northern Ireland Health and Personal Social Services: http://www.dhsspsni.gov.uk/			Research Governance Framework for Health and Social Care (2002)
	<i>Scotland:</i>			
	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)
	<i>Wales:</i>			
	Wales Office of Research and Development for Health and Social Care			Research Governance Framework for Health and Social Care in Wales (2001)
<i>Drugs</i>	<p>1. Medicines and Healthcare Products Regulatory Agency (MHRA): http://www.mhra.gov.uk</p> <p>2. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm</p> <p>3. National Research Ethics Service (NRES): http://www.nres.npsa.nhs.uk/home</p>	<p>Medicines Act (1968): http://www.legislation.gov.uk/RevisedStatutes/Acts/ukpga/1968/cukpga_19680067_en_1</p>	<p>MHRA:</p> <p>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</p> <p>2. Amendment Regulations (SI 2006/1928) http://www.opsi.gov.uk/si/si2006/20061928.htm</p> <p>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</p>	<p>MHRA: Consultation Letter on the Medicines for Human Use (Clinical Trials) Regulations (2003)</p> <p>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)</p> <p>NRES: Memorandum of Understanding between MHRA, COREC, and GTAC (2006) http://www.nres.npsa.nhs.uk/rec-community/guidance/</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
			2006/2984): http://www.opsi.gov.uk/si/si2006/20062984.htm	
<i>Privacy/Data Collection</i>	<i>England:</i> 1. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm 2. Information Commissioner Office: http://www.informationcommissioner.gov.uk/ 3. National Research Ethics Service (NRES): http://www.nres.npsa.nhs.uk/home	Data Protection Act (1998): http://www.opsi.gov.uk/acts/acts1998/19980029.htm A number of Statutory Instruments have been developed to implement the Data Protection Act: http://www.dca.gov.uk/ccpd/dpsubleg.htm		MRC: Personal Information in Medical Research (2000) NRES: Ethical Review of Research Databases (2008): http://www.nres.npsa.nhs.uk/rec-community/guidance/#useofpersonaldata NHS Information Governance: Security of NHS Patient Data Shared for Research Purposes (2008): http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/whatsnew
	<i>Scotland:</i> NHSScotland: http://www.show.scot.nhs.uk/			Protecting Patient Confidentiality (2002)
	<i>Human Biological Materials</i>	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	
<i>Genetics Research</i>	1. Advisory Committee on Genetic Testing (ACGT): http://www.advisorybodies.doh.gov.uk/genetics/acgt/			ACGT: Advice to Research Ethics Committees (1998)

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Public Health Genetics Unit: http://www.phgu.org.uk/index.php			
<i>Embryos, Stem Cells, and Cloning</i>	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				
<i>General</i>	National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/about/committees/ahec/index.htm	National Health and Medical Research Council Act (1992): http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/all/search/4AFACF8FAAF9ED97CA25719C0081EF9F		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. National Statement on Ethical Conduct in Human Research (2007) 4. Australian Code for the Responsible Conduct of Research (2007)
<i>Drugs</i>	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)
<i>Privacy/Data Protection</i>	<i>Federal:</i>			
	Office of the Privacy Commissioner: http://www.privacy.gov.au/	Privacy Act No. 119 (1998), Incorporating Amendments up to Act No. 73 (2008): http://www.comlaw.gov.au/comlaw/Legislation/ActCompilation1.nsf/0/3A1206B175472E8CCA2574900028FE7C?OpenDocument		
	<i>New South Wales:</i>			
	Office of the NSW Privacy Commissioner: http://www.lawlink.nsw.gov.au/lawlink/privacynsw/ll_pnsw.nsf/pages/PNSW_index	Privacy and Personal Information Protection Act (2005): http://www.austlii.edu.au/au/legis/nsw/consol_act/papipa1998464/index.html		
<i>Victoria:</i>				
Office of the Privacy Commissioner: http://www.privacy.vic.gov.au/	Information Privacy Act No. 98 (2000): http://www.dms.dpc.vic.gov.au/Domino/Web_Notes/LDMS/PubLawToday.nsf?OpenDatabase			

Country	Key Organizations	Legislation	Regulations	Guidelines
		Select "Acts," then the letter "I," then "Information Privacy Act."		
<i>Human Biological Materials</i>	National Health and Medical Research Council, Australian Health Ethics Committee (AHEC): http://www.nhmrc.gov.au/about/committees/ahec/index.htm			AHEC: National Statement on Ethical Conduct in Human Research (2007): 1. Chapter 3.2 Databanks 2. Chapter 3.4 Human Tissue Samples
<i>Genetic Research</i>	National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/about/committees/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)
<i>Embryos, Stem Cells, and Cloning</i>	1. National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/about/committees/ahec/index.htm 2. National Health and Medical Research Council Embryo Research Licensing Committee	1. Prohibition of Human Cloning 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				
<i>General</i>	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			
<i>Drugs</i>	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		
<i>Human Biological Materials</i>	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			Guidelines for Transfer of Human Biological Materials Abroad for Research Purposes (2004)
Burma (Myanmar)				
<i>General</i>	1. Ministry of Health National Ethics Committee on Clinical Research: www.moh.gov.mm		DMR: Operational Guidelines for Institutional Ethical Review	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Department of Medical Research (DMR)		Committee (2005)	
China, People's Republic of				
<i>General</i>	1. Ministry of Health (MOH) (Mandarin): http://www.moh.gov.cn/ 2. Chinese Association for Science and Technology (CAST) 3. Ministry of Science and Technology	Law on Practicing Doctors (June 26, 1998), Articles 26 and 37		MOH: Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2007) (Mandarin): http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohkjys/s3581/200804/18816.htm CAST: Moral Standards for Scientists (2007)
<i>Drugs</i>	State Food and Drug Administration: http://www.sfda.gov.cn/	Drug Administration Law (2001)	1. Chinese Good Clinical Practice (2003) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/24473.html 2. Qualification and Evaluation of Clinical Trial Sites 3. Regulation on Drug Registration (2007)	Guideline for HIV Vaccine Research Technology (2003)
<i>Privacy/Data Protection</i>	<i>Hong Kong:</i>			
	Privacy Commissioner for Personal Data: www.pco.org.hk	Personal Data (Privacy) Ordinance (1996): http://www.pco.org.hk/english/ordinance/ordfull.html		
<i>Human Biological Materials</i>	Ministry of Health (Mandarin): http://www.moh.gov.cn/			
<i>Genetic Research</i>	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)	
<i>Embryos, Stem Cells, and Cloning</i>	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)
	<i>Hong Kong:</i>			
	Government of the Hong Kong Special Administrative Region		Human Reproductive Technology Ordinance, Chapter 561 (2002): http://www.hklii.org.hk/hk/legis/ord/561/	
India				
<i>General</i>	1. Indian Council of Medical Research (ICMR):			NCESSRH: Ethical Guidelines for Social Science

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.icmr.nic.in/human_ethics.htm 2. National Committee for Ethics in Social Science Research in Health (NCESSRH)			Research (2000) ICMR: Ethical Guidelines for Biomedical Research on Human Participants (2006)
<i>Drugs</i>	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): http://www.icmr.nic.in/human_ethics.htm	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)
<i>Genetic Research</i>	1. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm 2. Department of Biotechnology (DBT): http://dbtindia.nic.in/	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)
<i>Embryos, Stem Cells, and Cloning</i>	1. Department of Biotechnology (DBT): http://dbtindia.nic.in/ 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			DBT and ICMR: National Guidelines for Stem Cell Research and Therapy (2006): http://icmr.nic.in/stem_cell/Stem_cell_guidelines.pdf
Indonesia				
<i>General</i>	Ministry of Health, National Institute of Health Research and Development	Indonesian Health Act No.23/1992 Section on Health Research, Article 69	Regulation No. 39/1995 on Health Research & Development	National Guidelines on Ethics in Health Research (2003)
<i>Drugs</i>	Indonesian FDA		Guidelines on Good Clinical Practice (2001)	
<i>Human Biological Materials</i>			National Guidelines on Use of Stored Biological Materials (2005)	
Iran				
<i>General</i>	Ministry of Health and Medical Education, Office for the Study of Humanistic and Islamic Science in		Protection Code for Human Subjects in Medical Research (1999)	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Medicine and Medical Ethics: http://www.mohme.gov.ir/			
Israel				
<i>General</i>	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	
<i>Drugs</i>	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 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	Guidelines for Clinical Trials in Human Subjects (2006) (English): http://www.health.gov.il/Download/pages/GuidelinesforClinicalTrials.doc
<i>Privacy/Data Protection</i>	Israeli Law and Information Technologies Authority	1. Privacy Protection Act 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)		
<i>Genetic Research</i>	Ministry of Health: http://www.health.gov.il/english/	Genetic Information Law (2000) (Hebrew): http://www.moital.gov.il/NR/eres/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
<i>Embryos, Stem Cells, and Cloning</i>		Genetic Intervention Prohibition Law (Human Cloning and Genetic Changes in Reproduction Cells) (1999)		

Country	Key Organizations	Legislation	Regulations	Guidelines
Japan				
<i>General</i>	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 (2008) (Japanese): http://www.mhlw.go.jp/general/seido/kous/ei/i-kenkyu/index.html
<i>Drugs</i>	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 (2008)	
<i>Privacy/Data Protection</i>	Data Protection Authority, Ministry of Internal Affairs and Communications (Japanese): http://www.soumu.go.jp/	Personal Information Protection Act (2003)		
<i>Genetic Research</i>	1. Council for Science and Technology (CST) 2. Ministry of Education, Culture, Sports, Science, and Technology (MEXT) 3. Ministry of Health, Labor, and Welfare (MHLW) 4. Ministry of Economy, Trade, and Industry (METI)			CST: Fundamental Principles of Research on the Human Genome (2000): http://www.mext.go.jp/a_menu/shinkou/shisaku/pri00614.pdf MEXT, MHLW, and METI: Ethical Guidelines for Human Genome/Gene Analysis Research (2005) (Japanese): http://www.mhlw.go.jp/general/seido/kous/ei/i-kenkyu/genome/0504sisin.html MEXT and MHLW: Guidelines for Clinical Research in Gene Therapy (2004)
Jordan				
<i>Drugs</i>	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)		

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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				
<i>General</i>	Ministry of Health, Central Bioethics Commission			Guidelines on Ethics in Health Research. (2007)
<i>Drugs</i>	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)
<i>Privacy/Data protection</i>	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/		
Korea, South				
<i>Drugs</i>	Korea Food and Drug Administration (Korean): www.kfda.go.kr/	Pharmaceutical Affairs Act (No. 91235) Articles 10 and 31-34 (2008)	Enforcement Rule of Pharmaceutical Affairs Act Articles 22, 31-34	1. Korean Good Clinical Practice Public Notification of Food and Drug Administration, No. 2007-4 (2007) 2. Guideline for Investigational New Drug Application: Public Notification No. 2004-51 (2004)
<i>Privacy/Data Protection</i>	Ministry of Public Administration and Security: http://www.mopas.go.kr	Act on the Protection of Personal Information Maintained by Public Agencies No. 8871 (2008)		
<i>Genetic Research</i>	Ministry of Health, Welfare, and Family Affairs: http://english.mw.go.kr/	Bioethics and Safety Act, Chapters 2, 6, 9, 24, 31, 38, and 41 (2008)	Enforcement Decree of Bioethics and Safety Act, Articles 2, 3, 13, 14-21, 27, and 28 (2008)	Guidelines for Research Involving Recombinant DNA Molecules (1997)
<i>Embryos, Stem Cells, and Cloning</i>	Ministry of Health, Welfare, and Family Affairs: http://english.mw.go.kr/	Bioethics and Safety Act, Articles 2, 18-21, 38, 41, and 45 (2008)	1. Enforcement Decree of Bioethics and Safety Act, Articles 3, 12, and 19-2 (2008) 2. Enforcement Regulation of Bioethics and Safety Act, Articles 2, 7, and 13 (2008)	Guideline for Stem Cell Research of Cell by Stem Cell Research Center (2006)
Kuwait				
<i>General</i>	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

Country	Key Organizations	Legislation	Regulations	Guidelines
Nepal				
<i>General</i>	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_et_hicalguidelines_2001.pdf
<i>Drugs</i>	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				
<i>General</i>	<ol style="list-style-type: none"> 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 Commissioner (HDC): http://www.hdc.org.nz/ 5. Health and Disability Ethics Committees: http://www.ethicscommittees.health.govt.nz/ 6. Ministry of Science, Research, and Technology (MoRST): http://www.morst.govt.nz/ 	<ol style="list-style-type: none"> 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 5. Injury Prevention, Rehabilitation, and Compensation Act 2001 <p>Note: All New Zealand acts can be accessed by going to: http://www.legislation.govt.nz/act/searchquick.aspx Then search for the name of the law under Statutes of New Zealand.</p>	HDC: The Code of Health and Disability Services Consumers' Rights (the Code of Rights) (2004):	<p>HRC:</p> <ol style="list-style-type: none"> 1. Guidelines for Researchers on Health Research Involving Māori (1998) 2. Guidelines on Ethics in Health Research (2005): http://www.hrc.govt.nz/assets/pdfs/publications/Ethics%20Guidelines%20July%202006.pdf <p>NEAC:</p> <ol style="list-style-type: none"> 1. Goals, Objectives, and Desired Outcomes of an Ethical Review System (2003) 2. Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (2006) <p>MOH: Operational Standard for Ethics Committees (2006)</p>
<i>Drugs</i>	<ol style="list-style-type: none"> 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)		<p>RMI: Guidelines on Clinical Trials: Compensation for Injury Resulting from Participation in an Industry Sponsored Clinical Trial (1997)</p> <p>Medsafe: New Zealand Regulatory Guidelines for Medicines, Vol. 3: Interim Good Clinical Research Practice Guidelines (1998)</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Privacy/Data Protection</i>	Privacy Commissioner: http://www.privacy.org.nz/	1. Official Information Act (1982) 2. Public Records Act (2005) 3. Privacy Act 1993 (2006): http://www.legislation.govt.nz/act/public/1993/0028/latest/viewpdf.aspx	Health Information Privacy Code 1994	
<i>Human Biological Materials</i>	1. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/root/Ethics/Ethics%20Overview/HRC_Ethics_Committee.html 2. Human Specimen Ethical Guidelines Committee (HPEGC) 3. Te Puni Kokiri (TPK): http://www.tpk.govt.nz/ 4. Office of the Health and Disability Commissioner (HDC): http://www.hdc.org.nz 5. Ministry of Research Science and Technology: http://www.morst.govt.nz/wayfinder/index.asp	1. Health Act 1956 (2005) 2. Human Tissue Act 2008		HPEGC: 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)
<i>Genetic Research</i>	1. Environmental Risk Management Authority: 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	Hazardous Substances and New Organisms Act 1996 (2005)		
<i>Embryos, Stem Cells, and Cloning</i>	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/ethiccommittees/	Human Assisted Reproductive Technology Act (2004): http://gpacts.knowledge-basket.co.nz/gpacts/public/text/2004/an/092.html		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

Country	Key Organizations	Legislation	Regulations	Guidelines
				and Non-viable Embryos (Interim) MOH: Guidelines on Using Cells from Established Human Embryonic Stem Cell Lines for Research (2005): http://www.moh.govt.nz/moh.nsf/0/DF32587ABFCA33C5CC2570C800708A24/\$File/GuidelinesUsingCells.pdf
Philippines				
<i>General</i>	1. Philippine Health Research Ethics Board (PHREB): http://www.pchrd.dost.gov.ph/index.php?option=com_frontpage&Itemid=1 2. National Ethics Committee (NEC) 3. Department of Science and Technology: http://www.dost.gov.ph/			NEC: 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: <ol style="list-style-type: none"> 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 Research on Populations Traumatized in Emergencies and Disasters g. Ethical Guidelines for HIV/AIDS Research h. Ethical Guidelines for Research on Assisted Reproductive Technology
<i>Drugs</i>	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
<i>Genetic Research</i>	National Ethics Committee (NEC)			Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research

Country	Key Organizations	Legislation	Regulations	Guidelines
				(2006): https://webapps.sph.harvard.edu/live/grem_ap/files/ph_natl_ethical_gdlns.pdf
<i>Embryos, Stem Cells, and Cloning</i>	National Ethics Committee (NEC)			Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research (2006): https://webapps.sph.harvard.edu/live/grem_ap/files/ph_natl_ethical_gdlns.pdf
Singapore				
<i>General</i>	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)
<i>Drugs</i>	1. Ministry of Health National Medical Ethics Committee (NMEC) 2. Health Sciences Authority of Singapore (HSA): http://www.hsa.gov.sg	All the acts can be found at: http://statutes.agc.gov.sg/ 1. Medicines Act Section 74 (Cap. 176) (1975): 2. Medicines (Clinical Trials) Regulations (2000) 3. Health Products Act (2007)	Singapore Guideline for Good Clinical Practice (1998)	NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)
<i>Privacy/Data Protection</i>	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)
<i>Human Biological Materials</i>	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)
<i>Genetic Research</i>	1. Ministry of Health National Medical Ethics Committee (NMEC)			NMEC: Ethical Guidelines for Gene Technology

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org			(2001) BAC: Genetic Testing and Genetic Research (2005): http://www.bioethics-singapore.org/uploadfile/55211%20PMGT%20Research.pdf
<i>Embryos, Stem Cells, and Cloning</i>	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				
<i>General</i>	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 (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
<i>Drugs</i>	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)
<i>Privacy/Data Protection</i>	Ministry of Justice: http://www.moj.gov.tw/mp095.html	Computer-Processed Personal Data Protection Law (1995):		

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.privacyexchange.org/legal/nat/omni/taiwan.html		
<i>Human Biological Materials</i>				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
<i>Genetic Research</i>	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)
<i>Embryos, Stem Cells, and Cloning</i>	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				
<i>General</i>	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 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				
<i>General</i>	1. National Research Council of Thailand (NCRT) (Thai): http://nrct.go.th/ 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	MCT: 1. National Guideline for Ethical Research on Human Subjects (2002) 2. The Ethical Guidelines for Research on Human Subject in Thailand (2007)

Country	Key Organizations	Legislation	Regulations	Guidelines
			the Observance of Medical Ethics (2006)	
<i>Drugs</i>	Food and Drug Administration, Drug Control Division: http://www.fda.moph.go.th/eng/index.stm/	Consumer Protection Act (2007)		Thailand Good Clinical Practice Guidelines (2002)
<i>Privacy/Data Protection</i>	Office of the Information Commission	1. Official Information Act, B.E. 2540 (1997) 2. National Health Act, B.E. 2549 (2006)		
Vietnam				
<i>General</i>	Ministry of Health: http://www.moh.gov.vn/homebyt/en/portal/index.jsp		Decision No. 2626/QD-BYT on Promulgation of the “Procedure of Organizing and Functioning Ethical Committee for Bio-Medical research, Mission 2008 – 2012” (2008) (Vietnamese)	
<i>Drugs</i>	Ministry of Health: http://www.moh.gov.vn/homebyt/en/portal/index.jsp		1. Regulation on Clinical Trials (2007) 2. Decision No. 799/QD-BYT of the Minister of Health on the Promulgation of the “Guidelines on Good Clinical Practice of Clinical Trials” (2008) 3. Decision No. 23 /2008/QD-BYT of the Minister of Health on the Promulgation of the “Regulations on Utilization of Vaccine and Medical Immuno-Biological Products in Prevention and Treatment” (2008)	Guidelines on Good Clinical Practice of Clinical Trials (2008)

Country	Key Organizations	Legislation	Regulations	Guidelines
LATIN AMERICA and CARIBBEAN				
Pan American Health Organization				
<i>Drugs</i>	Pan American Health Organization: http://www.paho.org/			Good Clinical Practices: Document for the Americas (2004): http://www.paho.org/english/ad/th/s/ev/GC/P-Eng-doct.pdf
Argentina				
<i>General</i>	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	
	<i>Cordoba Province:</i>			
			Ministerial Resolutions No. 00493/2006, No. 00523/06, and No. 00609/06	
	<i>Neuquén Province:</i>			
		Law on Biomedical Research in Human Beings (1997)		
<i>Drugs</i>	<i>National:</i>			
	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	
	<i>Buenos Aires Province:</i>			
		Requirements for Health Research, Law 11.044 (1991)		
<i>Privacy/Data Protection</i>	National Personal Data Protection Authority (Spanish): http://www.jus.gov.ar/datospersonales/index.html	Personal Data Protection Act No. 25.326 (2000) (Spanish): http://www.derhuman.jus.gov.ar/normativa/pdf/LEY_25326.pdf English translation: http://www.protecciondedatos.com.ar/law25326.htm		
Bolivia				
<i>General</i>	Ministry of Health and Sport: http://www.sns.gov.bo/			Research Ethics and Guidelines for Clinical Trials (2003)

Country	Key Organizations	Legislation	Regulations	Guidelines
Brazil				
<i>General</i>	<p>1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/</p> <p>2. National Commission on Research Ethics (CONEP) (Portuguese): http://www.conselho.saude.gov.br/comissao/eticapesq.htm</p>	<p>CNS: Decree 98 830: Collection by Foreigners of Data and Scientific Materials in Brazil (1990) (Portuguese): http://ibama2.ibama.gov.br/cnia/2/renima/cnia/lema/lema_texto/HTM-ANTIGOS/98830-90.HTM</p>	<p>CONEP: 1. Resolution 196/96: Rules on Research Involving Human Subjects (1996): http://www.conselho.saude.gov.br/resolucoes/1996/Reso196.doc http://www.conselho.saude.gov.br/docs/Resolucoes/reso_196_english.doc</p> <p>2. Resolution 304/2000: On Complimentary Rules for Research Involving Indigenous People (2000): http://www.conselho.saude.gov.br/resolucoes/2000/Reso304.doc</p> <p>3. Internal CONEP Regulation (2001) (Portuguese): http://www.conselho.saude.gov.br/Web_comissoes/conep/aquivos/conep/regimento.doc</p> <p>4. Regulation of Resolution CNS 292/99 on Research with Foreign Cooperation (2002) (Portuguese): http://www.conselho.saude.gov.br/resolucoes/1999/Reso292.doc http://www.ensp.fiocruz.br/etica/docs/cns/Res292i.pdf (English)</p> <p>5. Resolution 346/2005: On Multicenter Research (2005) (Portuguese): http://www.conselho.saude.gov.br/docs/Resolucoes/Reso346.doc</p>	
<i>Drugs</i>	<p>1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/</p> <p>2. National Healthcare Surveillance Agency (Portuguese): http://www.anvisa.gov.br</p>		<p>CNS: Resolution 251/1997: On Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests (1997): http://www.ensp.fiocruz.br/etica/docs/cns/Res251i.pdf</p>	
<i>Human Biological Materials</i>	National Commission on Research Ethics (CONEP) (Portuguese):		CONEP: CNS Resolution 347/05	CONEP: Approval Guidelines for Ethical Analysis

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.conselho.saude.gov.br/comissao/eticapesq.htm		Approval Guidelines for Ethical Analysis of Research Projects Involving Storage of Materials or Use of Materials Stored by Previous Research (Portuguese): http://conselho.saude.gov.br/docs/Reso347.doc	of Research Projects Involving Storage of Materials or Use of Materials Stored by Previous Research: Resolution 347/05 (2005)
<i>Genetic Research</i>	1. National Commission on Research Ethics (CONEP) (Portuguese): http://www.conselho.saude.gov.br/Web_comissoes/conep/index.html 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 340/2004 : On Research on Human Genetics (2004) (Portuguese): http://conselho.saude.gov.br/docs/Reso340.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)
<i>Embryos, Stem Cells, and Cloning</i>	National Biosafety Technical Commission (Portuguese): http://www.ctnbio.gov.br	Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/3671.html	CTNBio: Decree No. 5,591, of November 22, 2005: http://www.ctnbio.gov.br/index.php/content/view/3670.html	
Chile				
<i>General</i>	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)	
<i>Drugs</i>	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)

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Privacy/Data Protection</i>		Law for the Protection of Private Life No. 19.628 (1999) (Spanish): http://www.bcn.cl/leyes/141599		
<i>Genetic Research</i>		1. Law No. 26.027 (2005) 2. Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2007)		
<i>Embryos, Stem Cells, and Cloning</i>		Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2007)		
Colombia				
<i>General</i>	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)	
<i>Drugs</i>	National Institute of Drug and Food Surveillance (Spanish): http://www.invima.gov.co/		Resolution No. 2378 of 2008	
<i>Privacy/Data Protection</i>		Constitution, Article 15 (2003)		
<i>Human Biological Materials</i>	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)	
<i>Genetic Research</i>	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 III, Chapter II (1993)	
Costa Rica				
<i>General</i>	1. National Council on Health Research (CONIS) Network of Scientific Ethics Committees 2. Social Security Fund (CCSS), Research and Bioethics Subarea: http://www.cendeisss.sa.cr/etica/01-PRESENa.html	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) (Spanish): http://www.ministeriodesalud.go.cr/reglamentos/31078-s.pdf CCSS:	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

Country	Key Organizations	Legislation	Regulations	Guidelines
	3. Ministry of Health: http://www.ministeriodesalud.go.cr/		Regulation of Clinical Investigation in the Assistance Services of the Social Security Fund (2005) http://www.cendeiss.sa.cr/etica/registrobiomedica.pdf	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
<i>Drugs</i>	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
<i>Human Biological Materials</i>	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				
<i>General</i>	Ministry of Health: http://www.moh.gov.jm			Ministry of Health Guidelines for the Conduct of Research on Human Subjects (2002)
Mexico				
<i>General</i>	Secretariat of Health: http://www.salud.gob.mx/	General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2007): www.consejomexicano.org.mx/documentos/lgs.pdf	Regulation on the General Health Law in the Matter of Health Research (1984) (Spanish): www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html	
<i>Drugs</i>	Federal Commission for Protection Against Health Risks: www.cofepris.gob.mx/	General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2005): www.consejomexicano.org.mx/documentos/lgs.pdf	Regulation on the General Health Law in the Matter of Health Research, Title Three (1984) (Spanish): www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html	
<i>Privacy/Data Protection</i>	Federal Institute on Access to Public Information (Mexico): www.ifai.org.mx/			
<i>Human Biological Materials</i>	Secretariat of Health: http://www.salud.gob.mx/	General Health Law, Title XIV, Articles 313-342 (2005): www.consejomexicano.org.mx/documentos/lgs.pdf		

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Genetic Research</i>	National Institute of Genomic Medicine: http://www.inmegen.gob.mx/	1. Biosafety Law on Genetically Modified Organisms (2008) (Spanish): http://www.inmegen.gob.mx/images/stories/noticias/2008/pdf/soberania_genomica.pdf 2. Modifications to the General Health Law to Protect Genomic Sovereignty (2008): http://www.inmegen.gob.mx/index.php?option=com_content&task=view&id=816&Itemid=155		
Panama				
<i>General</i>	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
<i>Human Biological Materials</i>		Law 52 of 1995, Official Gazette 22,929		
<i>Embryos, Stem Cells, and Cloning</i>		Law 3 of 2004, Official Gazette 24,969		
Peru				
<i>General</i>	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)		
<i>Drugs</i>	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				
<i>Human Biological Materials</i>	Ministry of Public Health (Spanish): http://www.msp.gub.uy/index_1.html		Circular No. 40/95 Establishing Rules Regarding the Donation of	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Organs and Tissues for Scientific and Therapeutic Purposes (1995)	
Venezuela				
<i>General</i>	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)	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
<i>Drugs</i>	National Institute of Hygiene “Rafael Rangel” (Spanish): http://www.inhrr.gov.ve	Medicines Act, Articles 72 and 73		
<i>Genetic Research</i>	Venezuelan Institute of Scientific Research, Bioethics Commission (Spanish)			1. Contract for Accessing Genetic Resources (2003) (Spanish) 2. Revised Outline of the International Declaration of Human Genetic Data (2003)

Country	Key Organizations	Legislation	Regulations	Guidelines
AFRICA				
Botswana				
<i>General</i>	Ministry of Health, Research and Development Committee: http://www.moh.gov.bw/	Anthropological Research Act 45 (1967)		1. Guide for a Consent Form (2005) 2. Guidelines for the Review of Research Proposals (2005)
<i>Drugs</i>	Ministry of Health, Drug Regulatory Unit: http://www.moh.gov.bw/		Drugs and Related Substances Regulations (1993)	SADC Guidelines for Regulating Clinical Trials in Human Subjects (2006)
<i>Privacy/Data Protection</i>	Botswana Telecommunications Authority: http://www.bta.org.bw/background.html			
Egypt				
<i>General</i>	Medical Profession Union	Constitution of the Arab Republic of Egypt, Article 43: http://www.sis.gov.eg/En/Politics/Constitution/Text/040703000000000001.htm	Professional Ethics Regulations: Conducting Medical Research on Human Beings Articles 52-61 (2003) Scroll to bottom of page, click to Download Code of Ethics: http://www.ems.org.eg/2_4/2_4_4_4/2_4_4.htm	
<i>Human Biological Materials</i>			Professional Ethics Regulations: Conducting Medical Research on Human Beings Articles 49-51 (2003): http://www.ems.org.eg/2_4/2_4_4_4/2_4_4.htm	
Ethiopia				
<i>General</i>	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
<i>Human Biological Materials</i>	Ethiopian Science and Technology Commission, Health Department: http://www.estc.gov.et/			National Health Research Ethics Review Guideline, Fourth Edition, Section 8 (2005)
Gambia				
<i>Genetic Research</i>	Medical Research Council (UK) The Gambia: http://www.mrc.gm/			Guidelines of the National DNA Bank (2001)
Kenya				
<i>General</i>	1. National Council for Science and Technology (NCST)	1. Science and Technology Act (2001)	NCST: Guidelines for Ethical Conduct of	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of Health (MOH): http://www.health.go.ke/index.html	2. HIV and AIDS Prevention and Control Act, Chapter 14 (2006)	Biomedical Research Involving Human Subjects in Kenya (2004): https://webapps.sph.harvard.edu/lieve/gremap/files/ke_NCST_guidelines.pdf MOH: Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005)	
<i>Drugs</i>	Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/	Pharmacy and Poisons Act, Chapter 244 (2001)		
<i>Human Biological Materials</i>	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)	
Malawi				
<i>General</i>	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 30 th 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
<i>Drugs</i>	Pharmacy, Medicines, and Poisons Board of Malawi	Pharmacy, Medicines, and Poisons Act, Act 15 of 1988)		
<i>Genetic Research</i>	National Research Council of Malawi (NRCM)		Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002)	
Nigeria				
<i>General</i>	National Health Research Ethics Committee: http://nhrec.net/	National Health Bill 2004		National Code of Health Research Ethics (2006)
<i>Drugs</i>	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				
<i>General</i>	1. Department of Health (DH):	National Health Act No. 61,		DH:

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.doh.gov.za 2. Medical Research Council of South Africa (MRC): http://www.mrc.ac.za 3. National Health Research Ethics Council: http://www.doh.gov.za/nhrec/	Chapter 9 (2003): http://www.doh.gov.za/docs/legislation-f.html		Ethics in Health Research: Principles, Structures, and Processes (2004): http://www.doh.gov.za/nhrec/norms/ethics.pdf 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)
<i>Drugs</i>	1. Department of Health (DH): http://www.doh.gov.za 2. Medicines Control Council: http://www.mccza.com		DH: Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006): http://www.doh.gov.za/nhrec/norms/gcp.pdf	
<i>Human Biological Materials</i>	Department of Health (DH): http://www.doh.gov.za	National Health Act No. 61, Chapter 8, Sections 53-68 (2003): http://www.doh.gov.za/docs/legislation-f.html		
<i>Genetic Research</i>	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
<i>Embryos, Stem Cells, and Cloning</i>	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za	National Health Act No. 61, Chapter 8, Section 57 (2003): http://www.doh.gov.za/docs/legislation-f.html		MRC: Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.sahealthinfo.org/ethics/book2.htm
Sudan				
<i>Drugs</i>	Ministry of Health	Act on Pharmaceuticals and Poisons (2001)		
Tanzania				
<i>General</i>	1. Ministry of Health (MOH) 2. National Institute for Medical Research (NIMR), National Health Research Ethics Committee (NHREC):	1. National Institute for Medical Research, Act of Parliament No. 23, of 1979: http://www.parliament.go.tz/Polis/PAMS/Docs/23-1979.pdf	NIMR: 1. Coordination of Health Research in Tanzania 2. Coordination of Formation of Institutional Health Research	NHREC: 1. Guidelines on Ethics for Health Research in Tanzania (2001) 2. Brochure for Health Researchers in Tanzania (2006)

Country	Key Organizations	Legislation	Regulations	Guidelines
	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	2. Tanzania Commission for Science and Technology, Act No. 7 of 1986 3. Amendment of NIMR Act 1997, Tanzania Government Gazette, No. 675	Committees to Formally Approve for Local Health Research 3. Coordination of Research in Tanzania	COSTECH: COSTECH Guidelines on Research Permits and Clearance (2006)
<i>Drugs</i>	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				
<i>General</i>	Uganda National Council on Science and Technology (UNCST): http://www.uncst.go.ug/			National Guidelines for Research Involving Humans as Research Participants (2007)
<i>Drugs</i>	National Drug Authority: http://www.nda.or.ug/	National Drug Authority Statute (1993)		
Zimbabwe				
<i>General</i>	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
<i>Drugs</i>	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
<i>Human Biological Materials</i>	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

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