International Compilation of Human Research Protections

2011 Edition

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

PURPOSE

This Compilation lists over 1,000 laws, regulations, and guidelines that govern human subjects research in 101 countries, as well as the standards from a number of international and regional organizations. This Compilation was developed for IRBs/Research 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 these standards are followed appropriately.

In addition to numerous additions and updates to the 2010 Edition provided by in-country contact persons, the 2011 Edition features:

1. A new sub-section on the laws, regulations, and guidelines on *medical device* research, which is found in the "Drugs and Devices" section.
2. The laws, regulations, and/or guidelines for five new countries: *Belarus, Grenada, Pakistan, Rwanda,* and *Tunisia*.

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 and Devices (Also see the World Health Organization website: http://www.who.int/medical_devices/policies/en/)
3. Privacy/Data Protection (Also see the Privacy Laws and Business website: http://www.privacylaws.com/)
4. Human Biological Materials
5. Genetic (Also see 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, and legislative decrees, as well as constitutional provisions 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 – pertain 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 there may be other applicable laws that are not necessarily labeled as pertaining to research.

HOW TO ACCESS A DESIRED DOCUMENT

Listed documents can be accessed in five possible ways:

1. Link to the web address (URL), when provided.
2. 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; or e-mail a request for the document.
3. Perform an Internet search on the document title.
4. 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 standards from the state or local levels. Nor does the Compilation cover:

1. Laws, regulations, or guidelines specific to clinical bioethics, insurance requirements, product liability, clinical trial inspection procedures, 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, commentaries, or discussion papers.

Updates and Broken Links

Updates and broken links should be reported to the attention of Edward E. Bartlett, PhD, International Human Research Liaison, Office for Human Research Protections 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 in-country persons have been contacted to review listings to assure their accuracy and completeness, researchers and other individuals should check with local authorities and/or research ethics committees before starting research activities.

Country	Key Organizations	Legislation	Regulations	Guidelines
INTERNATIONAL				
General	1. International Committee of the Red Cross (ICRC): www.icrc.org 2. Office of the United Nations High Commissioner for Human Rights (OHCHR): http://www.ohchr.org/english/ 3. World Health Organization (WHO): http://www.who.int/en/ 4. Council for International Organizations of Medical Sciences (CIOMS): http://www.cioms.ch/ 5. United Nations Educational, Scientific, and Cultural Organization, Bioethics Program (UNESCO): http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html 6. UNAIDS: http://www.unaids.org/en/default.asp 7. World Medical Association (WMA): http://www.wma.net/e/	ICRC: 1. Geneva Convention Relative to the Treatment of Prisoners of War, Articles 13 and 130 (1950): http://www.icrc.org/Web/Eng/siteeng0.nsf/html/genevaconventions#a1 2. Additional Protocol I Relating to the Protection of Victims of International Armed Conflicts, Article 11 (1977): http://www.icrc.org/ihl.nsf/7c4d08d9b287a42141256739003e636b/f6c8b9fee14a77fdc125641e0052b079 OHCHR: International Covenant on Civil and Political Rights, Articles 4 and 7 (1976): http://www2.ohchr.org/english/law/ccpr.htm		WHO: Operational Guidelines for Ethics Committees that Review Biomedical Research (2000): http://whqlibdoc.who.int/hq/2000/TDR_PRD_ETHICS_2000.1.pdf CIOMS: 1. International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) 2. International Guidelines for Ethical Review of Epidemiological Studies (2009) UNESCO: Universal Declaration on Bioethics and Human Rights (2005) UNAIDS: Ethical Considerations in Biomedical HIV Prevention Trials (2007): http://data.unaids.org/pub/Report/2007/JC1399_ethical_considerations_en.pdf WMA: Declaration of Helsinki (2008): http://www.wma.net/en/30publications/10policies/b3/index.html
Drugs and Devices	*Drugs*			
	1. International Conference on Harmonization (ICH): http://www.ich.org/ 2. World Health Organization (WHO): http://www.who.int/en/			ICH: E6 Good Clinical Practice: Consolidated Guidance (1996): http://www.ich.org/cache/compo/475-272-1.html#E6 WHO: 1. Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation (2002): http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
				2. Operational Guidance: Information Needed to Support Clinical Trials of Herbal Products (2005)
	Devices			
	1. Global Harmonization Task Force (GHTF): http://www.ghtf.org/ 2. International Standards Organization: http://www.iso.org/iso/home.html			GHTF: 1. SG5/N2R8: 2007 Clinical Evaluation: http://www.ghtf.org/documents/sg5/sg5_n2r8_2007final.pdf 2. SG5(WD)/N3R6: 2007 Clinical Investigations: http://www.ghtf.org/documents/sg5/sg5_n3_2010.pdf 3. GHTF SG5/N1R8: 2007 Clinical Evidence – Key Definitions and Concepts: http://www.ghtf.org/documents/sg5/sg5_n1r8_2007final.pdf ISO: Clinical Investigation of Medical Devices for Human Subjects -- Good Clinical Practice. Standard Number 14155:2010: http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=45557
Privacy/Data Protection	World Medical Association: http://www.wma.net/e/index.htm			Declaration on Ethical Considerations Regarding Health Databases (2002): http://www.wma.net/en/30publications/10policies/d1/index.html
Human Biological Materials	1. World Health Organization: http://www.who.int/en/ 2. International Air Transport Association (IATA): http://www.iata.org/ 3. International Society for Biological and Environmental Repositories (ISBER): http://www.isber.org			WHO: Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research (2003): http://www.who.int/reproductive-health/hrp/tissue.pdf IATA: Infectious Substances and Diagnostic Specimens Shipping Guidelines (2005)

Country	Key Organizations	Legislation	Regulations	Guidelines
				ISBER: Best Practices for Repositories I: Collection, Storage and Retrieval of Human Biological Materials for Research (2005)
Genetic Research	1. Human Genome Organization (HUGO): http://www.hugo-international.org/ 2. UNESCO Bioethics Program: http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html			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) UNESCO: 1. Universal Declaration on the Human Genome and Human Rights (1997) 2. International Declaration on Human Genetic Data (2003)
Embryos, Stem Cells, and Cloning	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				
General Note: Several Canadian provinces and territories also have standards on human subjects research.	*National:*			
	1. National Defence 2. Correctional Service of Canada 3. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 4. National Council on Ethics in Human Research: http://www.ncehr-cnerh.org/english/home.php			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): http://www.pre.ethics.gc.ca/eng/policy-politique/tcps-eptc/
Drugs and Devices	*Drugs*			
	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): http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php 2. Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials) (2004): http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php	
	Devices			
	Health Canada, Medical Devices: http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php		Medical Devices Regulations (SOR/98-282) (1998): http://laws.justice.gc.ca/en/f-27/sor-98-282/text.html	
Privacy/Data Protection Note: Each of the Canadian provinces	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):	1. Privacy Act, Sections 7-8 (1983): http://www.privcom.gc.ca/legislation/02_07_01_e.asp 2. Personal Information	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)

Country	Key Organizations	Legislation	Regulations	Guidelines
and territories has also enacted privacy legislation.	http://www.pre.ethics.gc.ca/eng/index 3. Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html	Protection and Electronic Documents Act, Articles 5 and 7 (2001): http://www.privcom.gc.ca/legislation/02_06_01_e.asp		CIHR: CIHR Best Practices for Protecting Privacy in Health Research (2005): http://www.cihr-irsc.gc.ca/e/documents/pbp_sept2005_e.pdf
Human Biological Materials	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 10: Human Tissue (2005)
Genetic Research	1. Canadian Biotechnology Advisory Committee (CBAC): http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/Home 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 3. Biologics and Genetic Therapies Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php			CBAC: Genetic Research and Privacy (2004) PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 8: Human Genetic Research (2005)
Embryos, Stem Cells, and Cloning	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 2. Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html	Assisted Human Reproduction Act (2004): http://www.hc-sc.gc.ca/hl-vs/reprod/hc-sc/legislation/index_e.html	Assisted Human Reproduction (Section 8 Consent) Regulations (2007)	PRE: Tri-Council Policy Statement: Ethical 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 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: • 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) • Subpart E: Institutional Review Board Registration Requirements (2009)				
General	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

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	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) *Army:* 1. AR 70-25 2. AR 40-38 *Navy:* SECNAVINST 3900.39 series *Air Force:* AFI 40-402 (2005) *Office of the Under Secretary of Defense for Personnel and Readiness:* USUHS Instruction 3201 *Defense Threat Reduction Agency:* 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/humansubjects/guidance/statute.htm	45 CFR 46, Subparts A, B, C, D, and E	Various: http://www.hhs.gov/ohrp/policy/index.html#topics
	Department of Homeland Security: www.dhs.gov/	Public Law 108-458, Section 8306		

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	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, Program in Human Research Ethics: http://www.epa.gov/osa/phre/		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 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)	Scientific and Ethical Approaches for Observational Exposure Studies (2008): http://www.epa.gov/nerl/sots/SEAOES_doc20080707.pdf
	National Aeronautics and Space Administration: www.nasa.gov/		14 CFR 1230, Subpart A	
	National Science Foundation: www.nsf.gov/		45 CFR 690, Subpart A	

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	*Drugs*			
	Food and Drug Administration: http://www.fda.gov/Drugs/default.htm	1. Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (2004): http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm 2. Public Health Service Act, 42 USC Section 262 (1944): http://www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm	1. 21 CFR 50 (1980) 2. 21 CFR 312 (1987) 3. 21 CFR 56 (2001)	1. General: Good Clinical Practice and Human Subject Protections in FDA-Regulated Clinical Trials: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm 2. Drug-Specific: Numerous: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
	Devices			
	Food and Drug Administration, Center for Devices and Radiological Health: http://www.fda.gov/MedicalDevices/default.htm	Food, Drug, and Cosmetic Act, 21 USC Section 360 (2004): http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm	1. 21 CFR 50 (1980) 2. 21 CFR 56 (2001) 3. 21 CFR 807, Subpart E (2007) 4. 21 CFR 812 (2008) 5. 21 CFR 814 (2009)	1. General: Good Clinical Practice and Human Subject Protections in FDA-Regulated Clinical Trials: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm 2. Device-Specific: Numerous: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm
Privacy/Data Protection	Department of Health and Human Services: a. National Institutes of Health (NIH): http://privacyruleandresearch.nih.gov/ b. Office for Civil Rights (OCR): http://www.hhs.gov/ocr/hipaa/	1. Privacy Act, 5 U.S.C. § 552a (1974): http://www.justice.gov/opcl/privacyact1974.htm 2. Health Insurance Portability and Accountability Act (1996): http://www.gpo.gov/fdsys/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf 3. Confidential Information Protection and Statistical Efficiency Act (2002): http://www.eia.doe.gov/oss/CIPSEA.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/privacy/hipaa/administrative/index.html	DHHS: Various on the Privacy Rule: http://privacyruleandresearch.nih.gov/
Human Biological Materials	1. Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/ 2. Food and Drug Administration a. Office of In Vitro Diagnostic Device Evaluation and Safety: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm			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 (2008) FDA: 1. Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using

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	b. Center for Biologics Research and Evaluation: - Office of Cellular, Tissue and Gene Therapies - Office of Blood Research and Review: http://www.fda.gov/BiologicsBloodVaccines/default.htm			Leftover Human Specimens That are Not Individually Identifiable (2006): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078384.htm 2. In Vitro Diagnostic (IVD) Device Studies - Frequently Asked Questions (2010) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071230.pdf 3. CBER-Specific: Numerous: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/ucm094338.htm
Genetic Research	1. Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/ 2. National Institutes of Health, Office of Biotechnology Activities: http://www4.od.nih.gov/oba/	1. Research on Transplantation of Fetal Tissue, Public Law 103-43 2. Genetic Information Nondiscrimination Act (2008): http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ233.110.pdf		OHRP: Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (2009): http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html NIH: NIH Guidelines for Research Involving Recombinant DNA Molecules, Appendix M (2009): http://www4.od.nih.gov/oba/RAC/guidelines_02/NIH_Guidelines_Apr_02.htm
Embryos, Stem Cells, and Cloning	1. Food and Drug Administration, Center for Biologics Evaluation and Research: http://www.fda.gov/BiologicsBloodVaccines/default.htm 2. National Academy of Sciences (NAS): http://www.nationalacademies.org/nrc/ 3. National Institutes of Health: http://stemcells.nih.gov/index.asp	Research on Transplantation of Fetal Tissue. Public Law 103-43		FDA: Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products. October 14, 1993. 58 FR 53248 NAS: 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

Country	Key Organizations	Legislation	Regulations	Guidelines
				3. 2008 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research: http://books.nap.edu/catalog.php?record_id=12260 4. 2010 Final Report of the National Academies Human Embryonic Stem Cell Research Advisory Committee and 2010 Amendments to the National Academies Guidelines for Human Embryonic Stem Cell Research: http://www.nap.edu/catalog.php?record_id=12923 NIH: http://stemcells.nih.gov/policy : 1. Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Executive Order 13505 (2009) 2. NIH Guidelines on Human Stem Cell Research (2009) 3. NIH Human Embryonic Stem Cell Registry (2009)

Country	Key Organizations	Legislation	Regulations	Guidelines
EUROPE				
European-wide				
General	1. Council of Europe, Bioethics Division (CoE): http://www.coe.int/bioethics 2. European Commission Ethics Review Sector: http://cordis.europa.eu/fp7/ethics_en.html 3. European Commission Group on Ethics in Science and New Technologies (EGE): http://ec.europa.eu/european_group_ethics/index_en.htm	CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol Concerning Biomedical Research, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG		Ethics Review Sector: Various: http://cordis.europa.eu/fp7/ethics_en.html EGE: Ethical Aspects of Clinical Research in Developing Countries (2003): http://ec.europa.eu/european_group_ethics/docs/avis17_en.pdf
Drugs and Devices	*Drugs*			
	1. European Commission, SANCO Pharmaceuticals Unit: http://ec.europa.eu/health/index_en.htm 2. European Medicines Agency (EMEA): http://www.emea.europa.eu/	EC: 1. Directive 2001/20/EC: http://europa.eu/eur-lex/pri/en/oj/dat/2001/l_121/l_121220010501en00340044.pdf 2. Directive 2005/28/EC: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_091/l_09120050409en00130019.pdf	EC: See EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10_en.htm	EMEA: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997) EC: See EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10_en.htm
	Devices			
	European Commission, SANCO Cosmetics and Medical Devices: http://ec.europa.eu/consumers/index_en.htm	1. Directive 93/42/EEC Concerning Medical Devices: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF 2. Directive 98/79/EC on in vitro Diagnostic Medical Devices (IVDD): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20031120:en:PDF 3. Directive 2007/47/EC of the European Parliament and of the		Various: http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
		Council of 5 September 2007 Amending Council Directive 90/385/EEC on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices: http://ec.europa.eu/consumers/sectors/medical-devices/files/revision_docs/2007-47-en_en.pdf		
Privacy/Data Protection	1. European Commission (EC): http://europa.eu.int/ 2. Council of Europe (CoE), Public and Private Law Division: http://www.coe.int/t/dghl/standardsetting/dataprotection/default_EN.asp 3. Council of Europe (CoE), Bioethics Division: http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/	EC: Data Protection Directive 95/46/EC of the European Parliament and of the Council (1995): http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31995L0046&model=guichett CoE, Public and Private Law Division: 1. Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1985) 2. Recommendation No. R (97) 5 on the Protection of Medical Data (1997)		
Human Biological Samples	1. European Commission (EC): http://europa.eu.int/ 2. Council of Europe, Bioethics Division (CoE): http://www.coe.int/bioethics 3. European Group on Ethics in Science and New Technologies (EGE): http://europa.eu.int/comm/european_group_ethics/index_en.htm 4. European Medicines Agency (EMEA): http://www.emea.europa.eu/	EC: Directive 2004/23/EC on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage, and Distribution of Human Tissues and Cells: http://europa.eu/eur-lex/pri/en/oj/dat/2004/l_102/l_1022004040 7en00480058.pdf CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22, ETS		EGE: Ethical Aspects of Human Tissue Banking (1998) EMEA: Concept Paper on the Development of a Guideline on Biobanks Issues Relevant to Pharmacogenetics (2005) 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&Si

Country	Key Organizations	Legislation	Regulations	Guidelines
		No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG		te=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75
Genetic Research	Council of Europe, Bioethics Division: http://www.coe.int/bioethics	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol Concerning Biomedical Research, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG		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): http://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75
Embryos, Stem Cells, and Cloning	1. Council of Europe, Bioethics Division (CoE): http://www.coe.int/bioethics 2. European Commission (EC), Directorate-General for Research: http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=22 3. European Group on Ethics in Science and New Technologies (EGE): http://ec.europa.eu/european_group_ethics/index_en.htm	CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 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 EC: Decision No. 1982/2006/EC: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_412/l_41220061230en00010041.pdf		EGE: Opinion No. 15 - Ethical Aspects of Human Stem Cell Research and Use (2000) 2. Opinion No. 22 - The Ethics Review of hESC FP7 Research Projects (2007)

Country	Key Organizations	Legislation	Regulations	Guidelines
Confederation of Independent States				
General	Interparliamentary Assembly: http://www.iacis.ru/html/index-eng.php			Model Law on the Protection of Human Rights and Dignity in Biomedical Research in the CIS Member States (2005): http://www.iacis.ru/html/index-eng.php?id=54&pag=596&nid=9
Armenia Note: For an overview of human subject protections in Armenia, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 1: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
Drugs and Devices	1. Drug and Medical Technology Agency 2. National Ethics Committee	1. Law of the Republic of Armenia of May 4, 1996: About Medical Aid, The Maintenance of the Population, Article 21 2. Resolution of the Government of Armenia of January 24, 2002: Procedure for Clinical Trials of New Medications in Armenia		
Austria				
General	1. Forum of Austrian Ethics Committees (German): http://www.ethikkommissionen.at 2. Ministry of Health (German): http://www.bmg.gv.at 3. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	1. University Act (2008): http://www.ris.bka.gv.at/Dokument.wxe?Abfrage=Erv&Dokumentnummer=ERV_2002_1_120&ResultFunctionToken=7323e174-9167-4ce6-b47d-2bbfb8982d55&Titel=&Quelle=&ImRisSeit=Undefined&ResultPageSize=50&Suchworte=* 2. Hospitals Act (2010) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010285&ShowPrintPreview=True	Regulation on Leading Ethics Committees (2004) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20003352&ShowPrintPreview=True	Forum of Austrian Ethics Committees: Various guidelines.
Drugs and Devices	*Drugs*			
	1. Ministry of Health (German): http://www.bmg.gv.at 2. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/ueber-uns/english-what-is-ages/ 3. Austrian Federal Office for Safety in Health Care: http://www.basg.at/en/austrian-federal-office-for-safety-in-health-care/	Austrian Drug Law (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True		Various: http://www.basg.at/arzneimittel/vor-der-zulassung/klinische-pruefungen/

Country	Key Organizations	Legislation	Regulations	Guidelines
	Devices			
	Same as for Drugs.	Medical Devices Act (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003		Various: http://www.basg.at/medizinprodukte/formulare/klinische-pruefung/
Privacy/Data Protection Note: A number of Austrian states have privacy/data protection laws (German): http://www.dsk.gv.at/site/6202/default.aspx	Austrian Data Protection Commission: http://www.dsk.gv.at/DesktopDefault.aspx?alias=dsken	1. Federal Act Concerning the Protection of Personal Data (2009): http://www.ris.bka.gv.at/Dokument.wxe?Abfrage=Erv&Dokumentnummer=ERV_1999_1_165&ResultFunctionToken=7323e174-9167-4ce6-b47d-2bbfb8982d55&Titel=&Quelle=&ImRisSeit=Undefined&ResultPageSize=50&Suchworte=*		
Human Biological Materials	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	1. Law on Safety of Blood (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011145&ShowPrintPreview=True 2. Law on Quality and Safety of Human Tissue and Cells (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005698&ShowPrintPreview=True	Regulation on Tissue Banks (2008) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005848&ShowPrintPreview=True	Bioethics Commission: 1. Opinion of the Bioethics Commission at the Federal Chancellery: Biobanks for Medical Research (2007): http://www.bundeskanzleramt.at/DocView.axd?CobId=25510 2. Ruling of the Bioethics Commission: Cord Blood Banking (2008): http://www.bundeskanzleramt.at/DocView.axd?CobId=31001
Genetic Research	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	Gene Technology Act (2006) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826&ShowPrintPreview=True		
Embryos, Stem Cells, and Cloning	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	1. Reproductive Medicine Act (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10003046&ShowPrintPreview=True 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning		Bioethics Commission: Research on Human Embryonic Stem Cells (2009) (German): http://www.bundeskanzleramt.at/DocView.axd?CobId=34240

Country	Key Organizations	Legislation	Regulations	Guidelines
		(2002)		
Belarus Note: For an overview of human subject protections in Belarus, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 3: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
General	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. National Bioethics Committee	1. Constitution of the Republic of Belarus, Article 25 (2004) (Russian): http://www.pravo.by/WEBNPA/text.asp?RN=v19402875 2. Law on Health Care System, Articles 40, 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: 1. Decree No. No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html 2. Ordinance No. 274 on Establishing the National Bioethics Committee (2006)	MOH: 1. Code of Medical Ethics (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37726.html 2. Guidelines for Ethics Committees on Standard Operational Proceedings (No. 55-0004, 2000) (Russian): http://www.levonevski.net/pravo/norm2009/num35/d35896/index.html
Drugs and Devices	*Drugs*			
	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. State Pharmacological Committee 3. Centre for Expertise and Testing in Health Care: http://rceth.by/indexeng.htm	1. Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435 2. Law on Drugs, Articles 15,16 (2009) (Russian): http://pravo.by/webnpa/text.asp?RN=h10600161	MOH: 1. Decree No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html 2. Ordinance No. 254 on Clinical Drug Trials and Good Clinical Practice (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num36/d36922/index.html 3. Decree No. 50 on certain aspects of Clinical Drug Trials (2009) (Russian): http://86.57.250.247/data/pravo/ipb_prikazmz/N50_2009.html 4. Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37336.html	MOH: Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004) (Russian): http://www.levonevski.net/pravo/norm2009/num24/d24926.html
	Devices			
	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. Centre for Expertise and Testing in Health Care: http://rceth.by/indexeng.htm	Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: 1. Decree No. 216 on certain aspects of Clinical Trials of Medical Devices (2008) (Russian):	MOH: Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://86.57.250.247/data/pravo/ipb_prikazmz/N216_2008.htm 2. Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37336.html	Devices (No. 55-0504, 2004) (Russian): http://www.levonevski.net/pravo/norm2009/num24/d24926.html
Privacy/Data Protection	1. Ministry of Health: http://minzdrav.by/en/ 2. National Bioethics Committee	1. Constitution of the Republic of Belarus, Article 28 (2004) (Russian): http://www.pravo.by/WEBNPA/text.asp?RN=v19402875 2. Law on Health Care System, Article 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435		
Human Biological Materials	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. National Bioethics Committee 3. National Pathology Service 4. State Service of Forensic Medicine	Law on Health Care System, Articles 40 and 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: Ordinance No. 111 on Further Development of National Pathology Service (1993) (Russian): http://86.57.250.247/data/pravo/ipb_prikaznew/N111_1993(1994).doc State Service of Forensic Medicine: Ordinance No. 38-c on Rules for Conducting Morphological Examinations (1999)	
Belgium				
General	Belgium Advisory Committee on Bioethics: https://portal.health.fgov.be/portal/page?_pageid=56,512676&_dad=portal&_schema=PORTAL	Law Relating to Experimentation on Humans (2004)		1. Opinion No. 13: Regarding Experimentation on Man (2001) 2. Opinion No. 31: Regarding Experimentation Involving Pregnant and Breastfeeding Women (2004)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	Medicines Directorate-General (French): https://portal.health.fgov.be/portal/page?_pageid=56,512460&_dad=portal&_schema=PORTAL		1. Royal Decree of September 27, 1994. 2. Royal Decree of June 30, 2004 Determining the Implementation Measures of the Law 3. Royal Decree of June 30, 2004 Modifying the Royal Decree of June 6, 1960 4. Royal Decree of July 15, 2004 Determining Payments for Ethical Opinions or Authorization for the Conduct of a Clinical Trial or Experiment. 5. Application of the Law of May 7, 2004 Relating to Experiments on Human Volunteers who Participate in Phase I Trials (2004) 6. Explanations Concerning the Submission of a Request for an Ethical Opinion or Authorization for the Conduct of a Clinical Trial (2004)	
Privacy/Data Protection	Commission for the Protection of Privacy (French and Flemish): http://www.privacy.fgov.be/	Law of December 8, 1992 on Privacy Protection in Relation to the Processing of Personal Data as Modified by the Law of December 11, 1998 Implementing Directive 95/46/EC: http://www.law.kuleuven.ac.be/icri/itl/12privacylaw.php	Decree of February 13, 2001 Implementing the Law of December 8, 1999	
Human Biological Materials	1. Conseil Supérieur de la Santé/Hoge Gezondheidsraad (CSS) (French and Dutch): http://www.health.fgov.be/CSS_HGR 2. Federal Public Service: www.health.fgov.be	1. Royal Decree (1987), Regarding the Expression of Consent for the Removal of Organs and Tissues on Living Donors 2. Royal Decree (1997) Regarding the Removal and Allocation of Organs of Human Origin 3. Act on the Removal and Transplantation of Organs (2006) (French):		CSS: Common Quality Standards for All Tissues and Cells of Human Origin Intended for Human Application (2007) (French): https://portal.health.fgov.be/pls/portal/docs/PAGE/INTERNET_PG/HOMEPAGE_MENU/ABOUTUS1_MENU/INSTITUTIONSAPPARENTEES1_MENU/HOGEGEZONDHEIDSRAAD1_MENU/ADVIEZENENAANBEVELINGEN1_MENU/ADVIEZENENAANBEVELINGEN1_DOCS/7691_SQ_COMMUNS_2007_FR.PDF

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.staatsbladclip.be/lois/2006/08/28/loi-2006022815.html 4. 2007 Amendment (French): http://www.staatsbladclip.be/lois/2007/04/13/loi-2007022504.html		
Embryos, Stem Cells, and Cloning	1. Federal Public Service: www.health.fgov.be 2. Federal Commission for Medical and Scientific Research on Embryos in Vitro	1. Royal Decree Fixing the Criteria for the Program Applicable to the Care Programs 'Reproductive Medicine' (15/02/1999) 2. Act on Research on Embryos in Vitro (2003): http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Belgium/page.aspx/164 3. Law on Medically Assisted Reproduction and the Destination of Supernumerary Embryos and Gametes (2007) (French): http://www.staatsbladclip.be/lois/2007/07/17/loi-2007023090.html		
Bosnia and Herzegovina				
Drugs and Devices	*Federation of Bosnia and Herzegovina:* Ministry of Health: http://www.fmoh.gov.ba/	1. Law on Drugs No. 51/01 2. Law on Changes and Amendments of the Law on Drugs No. 29/05	1. Regulation on Good Clinical Practice and Clinical Trials No. 61/04 2. Regulation Amending the Regulation of Good Clinical Practice and Clinical Trials No. 56/05	
	Republic of Srpska: Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx	1. Law on Drugs No. 19/01 2. Law on Changes and Amendments of Law on Drugs No. 34/08	1. Regulation of Clinical Trials No. 64/05 2. Regulation on Changes and Amending the Regulation of Clinical Trials No. 23/07	
Privacy/Data Protection	Personal Data Protection Agency of Bosnia and Herzegovina	Law on the Protection of Personal Data in Bosnia and Herzegovina (2001): http://www.privacyinternational.org/article.shtml?cmd[347]=x-347-63545		

Country	Key Organizations	Legislation	Regulations	Guidelines
Bulgaria Note: For an overview of human subject protections in Bulgaria, see "National Regulations on Ethics and Research in Bulgaria:" http://ec.europa.eu/research/science-society/pdf/bg_eng_lr.pdf				
General	Ministry of Healthcare (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)		
Drugs and Devices	*Drugs*			
	1. Ministry of Healthcare (MOH) (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 (2007)	
	Devices			
	Bulgarian Drug Agency (BDA): http://www.bda.bg/?lang=en			Various: http://www.bda.bg/index.php?option=com_content&view=category&layout=blog&id=60&Itemid=117&lang=en
Privacy/Data Protection	1. Bulgarian Commission for Personal Data Protection: http://www.ceecprivacy.org/main.php?s=2&k=bulgaria 2. Ombudsman: www.ombudsman.bg	Personal Data Protection Act (2006): http://www.ceecprivacy.org/pdf/law_bulgaria.pdf		
Human Biological Materials:	1. Executive Agency for Transplantation (Bulgarian): http://bgtransplant.bg/ 2. Council of Ministers, Ethics Committee for Transplantation	Law on Transplantation of Organs, Tissues, and Cells (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	
Embryos, Stem Cells, and Cloning	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	Law Ratifying the Convention for Human Rights (2007) 2. SG No. 13/8, Article 134 (2008)		

Country	Key Organizations	Legislation	Regulations	Guidelines
Croatia				
General		Oviedo Convention on Human Rights and Biomedicine (2003)		
Drugs and Devices	*Drugs*			
	1. Ministry of Health and Social Welfare (MZSS): http://www.mzss.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.almp.hr/#	Law on Drugs (2007)	MZSS: Ordinance on Clinical Trials and Good Clinical Practice (2007) (Croatian): http://narodne-novine.nn.hr/clanci/sluzbeni/329774.html	
	Devices			
	Agency for Medicinal Products and Medical Devices: http://www.almp.hr/#	Medical Devices Act (2008): http://www.almp.hr/dl/engleski/Medical_devices_act_eng.pdf		
Privacy/Data Protection	Croatian Personal Data Protection Agency (Croatian): http://www.azop.hr/default.asp	Personal Data Protection Act (2008): http://www.legal500.com/c/croatia/developments/4908		
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2003) 2. Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (2007)		
Cyprus				
General		Law No. 31 (III)/2001 (Oviedo Convention on Human Rights and Biomedicine)		
Drugs and Devices	1. National Health Authority (Medicines Council): http://www.moh.gov.cy/moh/moh.nsf/index_en/index_en# 2. Ministry of Health, National Bioethics Committee: http://www.moh.gov.cy	Law for Good Clinical Practice (2004)		
Privacy/Data Protection	Commissioner for Personal Data Protection: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/index_en/index_	1. Processing of Personal Data (Protection of Individuals) Law 138 (1) 2001: http://www.dataprotection.gov.cy/d		

Country	Key Organizations	Legislation	Regulations	Guidelines
	en?opendocument	ataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/138(I)-2001_en.pdf 2. Amended in 2003: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/37(I)-2003_en.pdf		
Embryos, Stem Cells, and Cloning		Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002)		
Czech Republic				
General	Ministry of Health, Central Ethics Committee (Czech): http://www.mzcr.cz	1. Act No. 20/1996 on the Care for the Health of People 2. Oviedo Convention on Human Rights and Biomedicine (2001) 3. Act No. 130/2002 Collection on the Research and Development Support as Amended		
Drugs and Devices	*Drugs*			
	1. Ministry of Health (MOH) (Czech): http://www.mzcr.cz 2. State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lred=1	Act No. 378/2007 Collection on Pharmaceuticals	MOH: Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products	SUKL: Various: http://www.sukl.cz/medicinal-products-clinical-trials-guidelines-1
	Devices			
	State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lred=1	1. Act No 123/2000 Coll., on Medical Devices and on Amendments to Some Related Acts, as Amended 2. Act No 22/1997 Coll., on Technical Requirements for Products and Amendments to Some Related Acts	Various: http://www.sukl.cz/medical-devices?highlightWords=501%2F2000	Various: http://www.sukl.cz/medical-devices-guidelines
Privacy/Data Protection	Office for Personal Data Protection: http://www.uoou.cz/uoou.aspx	Act on the Protection of Personal Data and on	Position No. 3/2004 Personal Data Processing in the Context of	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Amendment to Some Related Acts (No. 101 of April 4, 2000): http://www.uoou.cz/uoou.aspx?menu=4&submenu=5	Clinical Testing of Drugs and Other Medical Substances	
Embryos, Stem Cells, and Cloning	1. Ministry of Education, Youth, and Sport: http://www.msmt.cz/index.php?lchan=1&lred=1 2. Research and Development Council, Bioethical Commission: 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 No. 227/2006 Sb. (Coll.) *Access:* http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Czech-Rep/page.aspx/165		
Denmark Note: For an overview of human subject protections in Denmark, see http://www.cvk.sum.dk/cvk/site.aspx?p=119 .				
General	Danish National Committee on Biomedical Research Ethics (CVK): http://www.cvk.sum.dk/CVK/Home/English.aspx	1. Oviedo Convention on Human Rights and Biomedicine (1999) 2. Act on the Biomedical Research Ethics Committee System (2003): http://www.cvk.sum.dk/English/actonabiomedicalresearch.aspx 3. Act Amending the Act on the Biomedical Research Ethics Committee System (2006) http://www.cvk.sum.dk/English/actamending.aspx	Ministerial Order No. 806 of 12 July 2004 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects (2004): http://www.cvk.sum.dk/English/ministerialorder806.aspx	CVK: 1. Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics (2008) 2. Appendices (2008)
Drugs and Devices	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	Guideline on Informed Consent from Patients in Biomedical Trials (2000)

Country	Key Organizations	Legislation	Regulations	Guidelines
			Medicinal Products in Humans (2004)	
Privacy/Data Protection	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
Human Biological Materials	Danish National Committee on Biomedical Research Ethics (CVK): http://www.cvk.sum.dk/CVK/Home/English.aspx	Health Law, Chapter 7 (2005)		
Embryos, Stem Cells, and Cloning	Danish Council of Ethics (DCE): http://www.etiskraad.dk/sw293.asp	1. Act on Medically Assisted Procreation (1997) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002) 3. Law No. 535, Chapter 7, Sections 25 and 28 (2008): http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Denmark/page.aspx/365		DCE: 1. Cloning (2001) 2. Research in Human Gametes, Fertilized Ova, Embryos and Fetuses (2004)
Estonia Note: For an overview of human subject protections in Estonia, see "National Regulations on Ethics and Research in Estonia:" http://ec.europa.eu/research/science-society/pdf/et_eng_lr.pdf				
General	Estonian Council on Bioethics: http://bioeetika.sm.ee	1. Constitution of the Republic of Estonia, Paragraph 18 (1992) 2. Oviedo Convention on Human Rights and Biomedicine (2002)		Code of Ethics of Estonian Scientists: http://www.akadeemia.ee/_repository/File/ALUSDOKUD/Code-ethics.pdf
Drugs and Devices	1. State Agency of Medicines: http://www.sam.ee/index.aw?set_lang_id=2 2. Minister of Social Affairs (MSA): http://www.sm.ee/eng.html	Medicinal Products Act, Chapter 5 (2005): http://www.ravimiamet.ee/orb.aw/class=file/action=preview/id=5118/EstonianAct-10May2005.doc	MSA: 1. RTL 2001, 90, 1258: Requirements for Membership of Medical Ethics Committees for Clinical Trials, Rules of Procedures for Committee, Rate of Fee for Evaluation of Clinical Trials, and List of Information to be Submitted in Order to Obtain Approval (2001)	

Country	Key Organizations	Legislation	Regulations	Guidelines
			2. Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 (2005): http://www.sam.ee/627	
Privacy/Data Protection	Estonian Data Protection Inspectorate: http://www.aki.ee/eng/	Personal Data Protection Act (2008): http://www.aki.ee/eng/?part=html&id=105		
Genetic Research		Human Genes Research Act (RT I 2000, 104, 685) (2000): http://www.geenivaramu.ee/index.php?id=98		
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002) 2. Artificial Insemination and Embryo Protection Act (2003)		
Finland				
General	1. Ministry of Social Affairs and Health (MSAH): http://www.stm.fi/en/frontpage 2. Sub-Committee on Medical Research Ethics (TUKIJA): http://www.etene.org/e/tukija/index.shtml 3. National Advisory Board on Research Ethics (TENK): http://pro.tsv.fi/tenk/english1.htm	Medical Research Act No. 488/1999: http://www.finlex.fi/en/laki/kaannokset/1999/en19990488	MSAH: 1. Decree on the National Advisory Board on Health Care Ethics No. 494/1998 2. Decree on the National Research Ethics Council of Finland No. 1347/2002 3. Decree on Medical Research and Subsidiary Regulations Issued in Pursuance Hereof, No. 313/2004 4. Decree on Clinical Trials on Medicinal Products No. 316/2005 5. Decree on Fees, No. 840/2010	TUKIJA: 1. Checklist for Researchers and Members of Ethics Committees (2009) (Finnish): http://www.tukija.fi/fi/julkaisut/ohjeet_ja_suositukset 2. Operating Procedures of National Committee on Medical Research Ethics (2010): http://www.tukija.fi/en/publications
Drugs and Devices	*Drugs* 1. Finish Medicines Agency (FIMEA): http://www.fimea.fi/fimea 2. Ministry of Social Affairs and Health (MSAH): http://www.stm.fi	Medicines Act and Decree No. 296/2004	FIMEA: Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 1/2007	

Country	Key Organizations	Legislation	Regulations	Guidelines
			MSAH: Decree on Clinical Trials No. 316/2005	
	Devices			
	National Supervisory Authority for Welfare and Health: http://www.valvira.fi/en/	Medical Devices Act (1505/94): http://www.valvira.fi/files/lomakkeet/TLT/En/english_medic_device_act_1505_94.pdf	Various: http://www.valvira.fi/en/licensing/medical_devices/legislation	
Privacy/Data Protection	Office of the Data Protection Ombudsman: http://www.tietosuoja.fi/1560.htm	1. Personal Data Act No. 523/1999: http://www.tietosuoja.fi/uploads/hopxtvf.HTM 2. Act on the Amendment of the Personal Data Act No. 986/2000: http://www.tietosuoja.fi/uploads/p9qzq7zr3xxmm9j.rtf		
Human Biological Materials		Act on the Medical Use of Human Organs and Tissues No. 101/2001: http://www.finlex.fi/pdf/saadkaan/E0010101.PDF		
Genetic Research		Gene Technology Act No. 377/1995		
Embryos, Stem Cells, and Cloning	National Advisory Board on Research Ethics: http://www.tenk.fi/ENG/function.htm	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002) 2. Medical Research Act No. 295/2004: http://www.finlex.fi/en/laki/kaannokset/1999/en19990488		Human Stem Cells, Cloning, and Research (2005) (Finnish): http://videnskabsministeriet.dk/site/forside/publikationer/2000/guidelines-on-biomedical-experiments/html/guidelines.pdf

France				
General	1. Ministry of Health and Sport (MHS) (French): http://www.sante-sports.gouv.fr/ 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr/?langue=2 3. National Conference of CPPRB (French): http://cncp.med.univ-tours.fr/html/index.php	1. Decree No. 97-555 Concerning the National Consultative Ethics Committee for Health and Life Sciences (1997): http://www.ccne-ethique.fr/decree_n_97555.php 2. Biomedical Research (Loi Huriet-Sérusclat), Articles L1121-1 to L1126-7 (2004)	MHS: 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 - Various: http://www.ccne-ethique.fr/opinions.php

Country	Key Organizations	Legislation	Regulations	Guidelines
		Access: The laws can be found at the following web site (French): http://www.legifrance.gouv.fr/ From there, go to "Les Codes en Vigeur." Go to the "Recherche d'un article au sein d'un code" box. In the "Nom de code" box select "Code de la Santé Publique" and in the "Numéro d'article" box enter the number of the desired article.		
Drugs and Devices	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr 2. French Health Products Safety Agency (AFSSAPS): http://agmed.sante.gouv.fr/ang/indang.htm	Medications for Human Use, Articles L5121-11, L5124-1, and L5126-1) (2004): http://www.legifrance.gouv.fr/		CCNE: 1. Phase I Trials in Cancer (2002) 2. Transposition into French Law of the European Directive Relating to Clinical Trials on Medicinal Products: A New Ethical Framework for Human Research (2003)
Privacy/Data Protection	1. National Commission of Information and Liberty (CNIL): http://www.cnil.fr/index.php?id=4 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	Law 2004-801 of August 6, 2004 Modifying Law 78-17 of January 6, 1978 Relating to the Protection of Data Subjects as Regards the Processing of Personal Data	CNIL: Decree No. 2005-1309 of 20 October 2005 Enacted for the Application of Act No. 78-17 of 6 January 1978 on Data Processing, Files and Individual Liberties (Amended by Decree 2007-451 of 25 March 2007): http://www.cnil.fr/fileadmin/documents/en/Decree%202005-1309.pdf	CCNE: 1. Ethical Questions Arising from the Transmission of Scientific Information Concerning Research in Biology and Medicine (1995) 2. Biometrics, Identifying Data and Human Rights (2007)
Human Biological Materials	National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	Donation and Use of the Components and Products of the Human Body, Articles L1211-1 to L1274-3 (2004) (French): http://www.legifrance.gouv.fr/		CCNE: 1. Umbilical Cord Blood Banks for Autologous Use for Research (2002) 2. Ethical Issues Raised by Collections of Biological Material and Associated Information Data: "Biobanks," "Biolibraries" (2003)
Genetic Research	National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr			CCNE: 1. Opinion on Gene Therapy (1990) 2. Opinion regarding the Application of Genetic Testing to Individual Studies, Family Studies and Population Studies. (Problems related to DNA "Banks," Cell

Country	Key Organizations	Legislation	Regulations	Guidelines
				"Banks," and Computerization) (1991) 3. Opinion that the Human Genome should not be Used for Commercial Purposes. Report. Thoughts Relating to Ethical Problems of Human Genome Research (1991) 4. Opinion on the Use of Somatic Gene Therapy Procedures. Report (1993)
Embryos, Stem Cells, and Cloning	National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002) 2. Law No. 2004-800 (2004) 3. Biomedical Research, Articles L2151-1, L2151-2, L2151-6, and L2151.7: http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/France/page.aspx/166		CCNE: Commercialization 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				
General		Oviedo Convention on Human Rights and Biomedicine (2000)		
Drugs and Devices	Drug Agency of the Ministry of Labor, Health, and Social Affairs: http://www.healthministry.ge/eng/index.php	1. Drug and Pharmacy Law No. 659 (1997) 2. Licenses and Approvals Law (2005)	Regulation about the Rules and Conditions of Issuing of the Approval of Clinical Trials Approved #176 (2005)	Order of Health Minister about Implementation of "ICH: E6 Good Clinical Practice: Consolidated Guidance (1996) including WMA: Declaration of Helsinki" (2010)
Embryos, Stem Cells, and Cloning		Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2000)		
Germany Note: For an overview of human subject protections in Germany, see http://www.eurecnet.org/information/germany.html				
General	1. German Medical Association (BÄK): http://www.bundesaerztekammer.de/page.asp?his=4.3569 2. Central Ethics Commission of the			BÄK: (Model) Professional Code of Conduct, Section 15 (2006) (German): http://www.bundesaerztekammer.de/page.asp?his=1.100.1143

Country	Key Organizations	Legislation	Regulations	Guidelines
	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			
Drugs and Devices	*Drugs*			
	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 (2008): http://www.bfarm.de/cln_028/nn_424928/EN/BfArM/BfArMService/AMG__en/amg-node-en.html__nnn=true	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): http://www.bmbf.de/en/1173.php http://www.bmbf.de/en/4861.php	BfArM: Third Announcement on Clinical Trials of Medicinal Products in Humans (2006): http://www.bfarm.de/cln_012/nn_1199716/EN/drugs/1__befAuth/clinTrials/clintrials-node-en.html__nnn=true
	Devices			
	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/cln_029/EN/Home/homepage__node.html__nnn=true 2. Paul Ehrlich Institute (PEI) (German): http://www.pei.de/cln_048/DE/home/de-node.html?__nnn=true	Act on Medical Devices (2002) (German): http://bundesrecht.juris.de/mpg/index.html Also see: http://www.dimdi.de/static/de/mpg/recht/index.htm	Various: http://www.dimdi.de/static/de/mpg/recht/index.htm	
Privacy/Data Protection Note: The 16	Federal Commissioner for Data Protection and Freedom of Information: http://www.bfdi.bund.de/cln_030/nn_533	Federal Data Protection Act, as Amended (2003): http://www.bfdi.bund.de/cln_029/nn_535764/EN/DataProtectionActs/Da		

Country	Key Organizations	Legislation	Regulations	Guidelines
German states also have data protection laws (German): http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html	554/EN/Home/homepage__node.html__nnn=true	taProtectionActs__node.html__nnn=true		
Human Biological Materials	1. German Society of Surgery (DGCH) (German): http://www.dgch.de/ 2. German Medical Association (BÄK): http://www.bundesaerztekammer.de/page.asp?his=4.3569 3. German 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	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	DGCH Rule for the Production of Human Tissues (German)	BÄK: http://www.bundesaerztekammer.de/page.asp?his=0.7.45&all=true NER: Opinion on Biobanks for Research (2004): http://www.ethikrat.org/_english/publications/Opinion_Biobanks-for-research.pdf ZEKO (German): http://www.zentrale-ethikkommission.de/downloads/Koerpermat.pdf DIZG: 1. Ethical Code (2000) 2. Common Standards: Tissues and Cell Banking (2004)
Genetic Research	1. German Medical Association (BÄK): http://www.bundesaerztekammer.de/page.asp?his=4.3569 2. German Society of Human Genetics (GFHEV): http://www.gfhev.de/en/gfh/ 3. Paul-Ehrlich-Institut (PEI) (English): http://www.pei.de/cln_048/nn_159030/EN/institute-en/institut-node-en.html?__nnn=true	Law of 20 June 1990/16.12.1993 to Regulate Matters Related to Gene Technology (2006)		BÄK: Guideline on Gene Transfer (1995) (German) http://www.bundesaerztekammer.de/30/Richtlinien/Richtidx/Gentransferpdf.pdf GFHEV: 1. Position Paper of the German Society of Human Genetics (1996) 2. DNA Banking and Personal Data in Biomedical Research: Technical, Social, and Ethical Questions (2004) PEI – Various: http://www.pei.de/cln_048/nn_162568/EN/info

Country	Key Organizations	Legislation	Regulations	Guidelines
				s-en/fachkreise-en/genther-fach-en/genther-fach-node-en.html?__nnn=true
Embryos, Stem Cells, and Cloning	1. Federal Ministry of Education and Research (BMBF): http://www.bmbf.de/en/index.php 2. German Ethics Council (NER): http://www.ethikrat.org/en_index.php 3. Central Ethics Commission of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/ 4. German Research Foundation (DFG): http://www.dfg.de/en/ 5. Central Ethics Committee for Stem-Cell Research (ZES): http://www.rki.de/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 BMBF: Law Allowing the Import of Embryonic Stem Cells (2002): http://www.bmbf.de/en/1056.php	Implementation Regulation for the Stem Cell Act (German): http://bundesrecht.juris.de/zesv/index.html	NER: 1. On the Import of Human Embryonic Stem Cells (2001): http://www.ethikrat.org/_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 ZEKO: 1. Stem Cell Research (2002) (German): http://www.zentrale-ethikkommission.de/downloads/Stammzell.pdf 2. Cloning (2006) (German): http://www.zentrale-ethikkommission.de/downloads/TherapKlonen.pdf DFG: Opinion on Stem Cell Research (2006) (German): http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/2006/download/stammzellforschung_deutschland_lang_0610.pdf
Greece				
Drugs and Devices	*Drugs*			
	1. National Organization for Medicines (NOM): http://www.eof.gr/web/guest/home , then click on flag icon in upper left hand section for English 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. A6/10983/1 (1984) 2. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 3. Greek Republic Gazette No. 1973 (2003) 4. Act 3418/2005 Code of Medical Ethics	NOM: 1. Ministerial Decision A6/10983/1/12-20.12.1984 on Clinical Trials and Protection of the Human Being (1984) 2. Ministerial Decision DYG3/89292/31.12.2003 (2003)	NBC: 1. A Guide for Research Ethics Committees for Biological Research (2009): http://www.bioethics.gr/document.php?category_id=55&document_id=808 2. Recommendation on Clinical Trials: http://www.bioethics.gr/media/pdf/recommendations/recom_clinical_trials_en.pdf
	Devices			

Country	Key Organizations	Legislation	Regulations	Guidelines
	National Organization for Medicines (NOM): http://www.eof.gr/web/guest/home , then click on flag icon in upper left hand section for English			Various: http://www.eof.gr/web/guest/clinicalmedical
Privacy/Data Protection	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		
Genetic Research	1. Hellenic Data Protection Authority (HDPA) (Greek): http://www.dpa.gr/ 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. Greek Constitution 1975/1986/2001, Article 5.5 2. Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998)		HDPA: Opinion No. 15/2001 NBC: 1. Recommendations on the Collection and Use of Genetic Data: http://www.bioethics.gr/media/pdf/recommendations/recom_genetic_data_eng.pdf
Embryos, Stem Cells, and Cloning	1. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3 2. National Authority for Medically Assisted Reproduction (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 3. Act 3305/2005		NBC: 1. On the Use of Stem Cells in Biomedical Research and Clinical Medicine (2002): http://www.bioethics.gr/media/pdf/recommendations/recom_stem_cells_eng.pdf 2. Recommendations on Prenatal and Pre-implantation Diagnostic Tests and the Question of Choice of Embryo: http://www.bioethics.gr/media/pdf/recommendations/1_pd_pgd_opin_eng2.pdf
Hungary Note: For an overview of human subject protections in Hungary, see "National Regulations on Ethics and Research in Hungary:" http://ec.europa.eu/research/science-society/pdf/hu_eng_lr.pdf				
General	1. Ministry of Health (EüM): http://www.eum.hu/?akt_menu=2&set_lang=2	1. Act XX of 1949 on the Constitution of the Republic of Hungary, Article 54.	EüM: Decree 23/2002 (V. 9.) EüM on Biomedical Research on Human	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Medical Research Council, Scientific and Research Ethics Committee	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	Beings	
Drugs and Devices	*Drugs*			
	1. National Institute of Pharmacy: http://www.ogyi.hu/main_page 2. Medical Research Council, Ethics Committee for Clinical Pharmacology: http://www.ett.hu/kfeb/kfeb.htm	Act XCV of 2005 on Medicinal Products for Human Use: http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=a0500095.tv&dbnum=62	EüM: Decree 35/2005 (VIII. 26) of the Minister of Health on the Clinical Trial and Application of Correct Clinical Practices of Investigational Medicinal Products Intended for Use in Humans: http://www.ogyi.hu/dynamic/Decree35_2005.doc	
	Devices			
	Authority for Medical Devices: http://www.eekh.hu/en/index.php?option=com_content&task=blogcategory&id=14&Itemid=28		Decree No. 16/ 2006 (2009): http://www.eekh.hu/en/download/decree_47.pdf	
Privacy/Data Protection	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		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Handling of Medical and Other Related Data: http://abiweb.obh.hu/dpc/index.php?menu=gyoker/relevant/national/1997_XLVII		
Human Biological Materials	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	
Genetic Research		Act XXI of 2008 on the Rules of Protection of Human Genetic Data, of Human Genetic Examinations and Research and of the Operation of Biobanks		Decree 60/2003 (X. 20.) on the Minimum Professional Requirements Necessary for Providing Health Services
Embryos, Stem Cells, and Cloning	1. Ministry of Health (EüM): http://www.eum.hu/english 2. Medical Research Council	1. Act CLIV of 1997 on Health Care, Articles 180-182: http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Hungary/page.aspx/557 2. Act VI of 2002 on the Promulgation of the Convention on Human Rights and Medicine and the Additional Protocol on Cloning	Decree 30/1998 (VI. 24.) NM on Regulations on Specific Procedures for Human Reproduction	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
Iceland				
General	1. Ministry of Health and Social Security (MOH): http://ministryofhealth.is 2. National Bioethics Committee (NBC): www.visindasidanefnd.is (Select "English" in the upper-right hand corner.)	1. Act on the Rights of Patients No. 74 (1997): 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
Drugs and Devices	*Drugs*			
	1. Icelandic Medicines Control Agency (MCA): http://www.imca.is/ 2. National Bioethics Committee (NBC): www.visindasidanefnd.is	Medicinal Products Act No. 93 (2009): http://eng.heilbrigdisraduneyti.is/laws-and-regulations/laws//nr/3128	MCA: Regulation on Clinical Trials of Medicinal Products in Humans No. 443 (2004): http://eng.heilbrigdisraduneyti.is/media/Reglugerdir-	

Country	Key Organizations	Legislation	Regulations	Guidelines
			enska/Regulation_on_clinical_trials_of_medicinal_products_in_humans_No443-2004.pdf	
	Devices			
	Ministry of Health: http://eng.heilbrigdisraduneyti.is/	Act on Medical Devices No 16/2001: http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/687	Regulation on Medical Devices No. 892/2004 (Icelandic): http://www.heilbrigdisraduneyti.is/log-og-reglugerdir/reglugerdir//nr/2917	
Privacy/Data Protection	Data Protection Authority: http://www.personuvernd.is/information-in-english/	1. Judgment by the Supreme Court of Iceland Concerning the 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/	Government Regulation on a Health Sector Database No. 32 (2000): http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/670	
Human Biological Materials	1. Ministry of 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 (no date)
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2004) 2. Artificial Fertilization Act No. 55/1996 as Amended by Laws No. 65/2006, 27/2008, 54/2008, and 55/2010 (Icelandic): http://althingi.is/lagas/nuna/1996055.html English translation of 1996 law: http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/685	Regulation on Artificial Fertilization No 144/2009 (Icelandic): http://stjornartidindi.is/Advert.aspx?ID=9442c80d-2b63-4a43-9526-41d03d9b2495	

Country	Key Organizations	Legislation	Regulations	Guidelines
Ireland				
General	1. Irish Council for Bioethics (ICB): http://www.bioethics.ie 2. Irish Medicines Board (IMB): http://www.imb.ie/			ICB: Operational Procedures for Research Ethics Committees: Guidance 2004 IMB: Guide to Clinical Trials (2004)
Drugs and Devices	*Drugs*			
	Irish Medicines Board: http://www.imb.ie/	1. European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 2. European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 878 of 2004) 3. European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment No. 2) Regulations 2006 (S.I. 374 of 2006) 4. European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 to 2006 (Informal Codification Text) *Access*: These Statutory Instruments can be viewed at: http://www.dohc.ie/issues/clinical_trials/		
	Devices			
	Irish Medicines Board: http://www.imb.ie/			Various: http://www.imb.ie/EN/Medical-Devices/PreMarket-Activities/Clinical-Investigations.aspx
Privacy/Data Protection	Data Protection Commissioner: http://www.dataprotection.ie/docs/Home/4.htm	Data Protection Act (1988), as amended (2003): http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html		
Human Biological Materials	Irish Council for Bioethics: http://www.bioethics.ie			Human Biological Material: Recommendations for Collection, Use, and Storage in Research (2005): http://www.bioethics.ie/pdfs/BioEthics_fin.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research	Irish Medicines Board: http://www.imb.ie/			Guidelines for Pharmacogenetic Research (2006): http://www.imb.ie/images/uploaded/documents/AUT-G0003_Guidelines_for_pharmacogenetic_research_v1.pdf
Embryos, Stem Cells, and Cloning		Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		
Italy				
General	1. National Federation of Ethics Committees (FNACE) (Italian): http://www.unich.it/fnace/ 2. National Monitoring Center for Clinical Trials (OSS): http://oss-sper-clin.agenziafarmaco.it/ 3. National Bioethics Committee (NBC): http://www.governo.it/bioetica/eng/index.html 4. Ministry of Health (Italian): http://www.ministerosalute.it	Statute on the National Federation of Ethics Committees (1995) (Italian): http://www.unich.it/fnace/statuto.htm	FNACE: Regulation Implementing the Statute on the National Federal of Ethics Committees (1995) OSS: Ministerial Decree: Terms of Reference for the Establishment and the Functioning of Ethics Committees (May 12, 2006)	NBC: Opinion of the National Bioethics Committee on the European Protocol on Biomedical Research (1999)
Drugs and Devices	*Drugs*			
	1. National Monitoring Center for Clinical Trials: http://oss-sper-clin.agenziafarmaco.it/ 2. Italian Medicines Agency (Italian): http://www.agenziafarmaco.it/ 3. Ministry of Health (MOH) (Italian): http://www.ministerosalute.it	1. Decree of the President of the Republic: Regulations to Simplify the Procedures and to Verify and Check New Systems and Experimental Therapeutic Protocols (September 21, 2001) (Italian): http://oss-sper-clin.agenziafarmaco.it/normativa/ , then select document in the left column. 2. Legislative Decree No. 211: Transposition of Directive 2001/20/EC Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Clinical Use (2003): http://oss-sper-clin.agenziafarmaco.it/	Italy has numerous regulations that govern drug research (Italian): http://oss-sper-clin.agenziafarmaco.it/normativa/ The following are the most important: 1. Ministerial Decree 21 December 2007: Modalities of Submission of the Application to the Competent Authority, for Communication of Substantial Changes and Declaration of Conclusion of the Clinical Trial, and for Request of an Ethics Committee Opinion 2. Ministerial Decree 31 March 2008: Definition of the Minimum	

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Legislative Decree No. 200: Transposition of Directive 2005/28 EC Laying down Principles and Detailed Guidelines as Regards Investigational Medical Products for Human Use, as well as the Requirements for Authorizing of Manufacturing or Importing of such Products (2007) (Italian): http://www.aifa.gov.it/allegati/dlgs_200-6nov2007.pdf	Requirements that Contract Research Organisations (CROs) Shall Satisfy in Order to Work on Clinical Trials on Medicinal Products 3. Ministerial Decree 14 of July 2009: Minimal Insurance Requirements for Subjects Involved in Clinical Trials	
	Devices			
	Ministry of Health, Directorate General for Medicines and Medical Devices (Italian): http://www.ministerosalute.it		Ministerial Decree 2 of August 2005: Procedures for the Presentation of Documentation to Notify about Clinical Investigations with Medical Devices: http://www.salute.gov.it/dispositivi/paginainterna.jsp?id=1523&menu=clinical&lingua=english	Administrative Procedures Concerning the Conduction of Clinical Investigations with CE-Marked Medical Devices (2007): http://www.salute.gov.it/imgs/C_17_pagineAree_1033_listaFile_itemName_0_file.pdf
Privacy/Data Protection	Italian Data Protection Independent Authority (Italian): http://www.garanteprivacy.it/garante/navig/jsp/index.jsp?solotesto=N	Italian Personal Data Protection Code, Legislative Decree No. 196 of June 30, 2003: http://www.garanteprivacy.it/garante/navig/jsp/index.jsp?folderpath=Normativa%2FItaliana%2FIl+Codice+in+materia+di+protezione+dei+dati+personali	1. Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000) 2. Regulation for the Implementation of Articles No. 20 and 21 of the Legislative Decree No. 196 of June 30, 2003 3. Ministerial Decree No. 277 (2007)	
Genetic Research	1. Instituto Superiore di Sanita (ISS): http://www.iss.it/chis/?lang=2 2. Italian Society of Human Genetics (SIGU): http://www.sigu.net/			ISS: Guidelines for Phase I Clinical Trials with Investigational Medicinal Products Employed in Gene Somatic Therapy (2004) (Italian): http://www.iss.it/binary/publ/publi/0478.1106653420.pdf SIGU: Guidelines for Genetic Biobanks (2004): http://www.gaslini.org/DPPM/BIOBANK_GUIDELINES.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning		Regulation of Medically Assisted Reproduction, Law No. 40, Article 13 (2004): http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Italy/page.aspx/167		

Latvia Note: For an overview of human subject protections in Latvia, see "National Regulations on Ethics and Research in Latvia:" http://ec.europa.eu/research/science-society/pdf/lv_eng_lr.pdf				
Drugs and Devices	*Drugs*			
	1. State Agency of Medicines: http://www.vza.gov.lv/index.php?setlang=en&large= 2. Central Medical Ethics Committee	1. Pharmaceutical Law, Section 26 (2009) http://www.ttc.lv/export/sites/default/docs/LRTA/Likumi/Pharmaceutical_Law.doc 2. Law on the Rights of Patients, Section 11 (2010): http://www.ttc.lv/export/sites/default/docs/LRTA/Likumi/Law_On_the_Rights_of_Patients.doc	Cabinet Regulation No. 289 Regulations on Conducting Clinical Trials and Non-interventional studies and Labelling of Investigational Medicinal Products, and Procedure for Conducting Inspections on Compliance with the Requirements of Good Clinical Practice (2010): http://www.vza.gov.lv/doc_upl/MK_not_Nr_289_31032010.pdf	
	Devices			
	Health Statistics and Medical Technologies State Agency: http://vsmtva.vec.gov.lv/web/en/index.aspx	Medical Treatment Law, Section 34 (2009): http://www.ttc.lv/export/sites/default/docs/LRTA/Likumi/Medical_Treatment_Law.doc	Rules of the Cabinet of Ministers Nr. 581: Order of the Registration, Conformity Assessment, Distribution, Exploitation and Technical Surveillance of the Medical Devices (2005): http://vsmtva.vec.gov.lv/web/en/departamenti/ierices/likumdosana/index.aspx	
Privacy/Data Protection	1. Data State Inspectorate: http://www.dvi.gov.lv/eng/ 2. Central Medical Ethics Committee	1. Personal Data Protection Law (2010): http://www.dvi.gov.lv/eng/legislation/pdp/ 2. Law on the Rights of Patients, Section 10 (2010): http://www.ttc.lv/export/sites/default/docs/LRTA/Likumi/Law_On_the_Rights_of_Patients.doc		

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	Central Medical Ethics Committee	Law on the Protection of Dead Human Beings and Use of Human Organs and Tissue (2008): http://www.ttc.lv/export/sites/default/docs/LRTA/Likumi/On_the_Protection_of_the_Body_of_Deceased_Human_Beings_and_the_Use_of_Human_Tissues_and_Organs_in_Medicine.doc	Cabinet of Ministers Regulation No. 208: Procedures for Banking, Storage and Utilisation of Human Tissues and Organs (2008): http://www.ttc.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._208_-_Bankingx_Storage_and_Utilisation_of_Human_Tissues_and_Organs.doc	
Genetic Research	1. Ministry of Health: http://www.vm.gov.lv/index.php?setlang=en 2. Data State Inspectorate: http://www.dvi.gov.lv/eng/ 3. Central Medical Ethics Committee	1. Human Genome Research Law (2005): http://www.ttc.lv/export/sites/default/docs/LRTA/Likumi/Human_Genome_Research_Law.doc 2. Law on the Development and Use of the National DNA Database (2006): http://www.ttc.lv/export/sites/default/docs/LRTA/Likumi/Development_and_Use_of_the_National_DNA_Database.doc	Regulation of the Cabinet of Ministers, "Procedures for Genetic Research" (2004)	
Embryos, Stem Cells, and Cloning	1. Ministry of Health: http://www.vm.gov.lv/index.php?setlang=en 2. Central Medical Ethics Committee	Sexual and Reproductive Health Law, Sections 15-20 (2004): http://www.ttc.lv/export/sites/default/docs/LRTA/Likumi/Sexual_and_Reproductive_Health_Law.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 "National Regulations on Ethics and Research in Lithuania:" http://ec.europa.eu/research/science-society/pdf/lt_eng_lr.pdf http://www.eurecnet.org/information/lithuania.html				
General	1. Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG/4 2. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1876243809	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 Territories Assigned to the Jurisdiction of the Regional Biomedical Research Ethics Committees, No. V-1078 (2007) 3. Decree on the Procedure to Issue Approvals to Conduct Biomedical Research, No. V-2 (2008)	LBEC: Various:http://bioetika.sam.lt/index.php?-463543156

Country	Key Organizations	Legislation	Regulations	Guidelines
			4. Decree on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor, No. 745 (2000) LBEC: Decree of the Chairman of the Lithuanian Bioethics Committee on the Requirements for the Patient Information Sheet and Informed Consent Form and for the CV of Investigator, No. V-10 (2004)	
Drugs and Devices	*Drugs*			
	1. State Medicines Control Agency (SMCA): http://www.vvkt.lt/index.php?3327723903 2. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1876243809 3. Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG/4 4. State Health Care Accreditation Agency Under the Ministry of Health (SHCA): http://www.vaspvt.gov.lt/index.php?1031290843	1. Law on Ethics of Biomedical Research, No. VIII-1679 (2000): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=326057 2. Law on Pharmacy, No. X-709 (2010): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=338139	SMCA: 1. 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, No. 1A-396 (2006) LBEC: 1. 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) 2. Decree on the Procedure for Issuing a Favorable Opinion for Substantial Amendment, No. V-10 (2008) MOH: 1. Decree on the Rules of Good Clinical Practice, No. 320 (2006) 2. Decree on the Procedure to Issue Approvals to Conduct	LBEC: Various:http://bioetika.sam.lt/index.php?-463543156

Country	Key Organizations	Legislation	Regulations	Guidelines
			Clinical Trial on Medicinal Product, No. V-435 (2010)	
	Devices			
	1. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1876243809 2. State Health Care Accreditation Agency Under the Ministry of Health (SHCA): http://www.vaspvt.gov.lt/index.php?1031290843		MOH: Decree on the Procedure to Issue Approvals to Conduct Biomedical Research, No. V-2 (2008) SHCA: Decree on the Procedure to Issue Recommendation to Conduct Clinical Trial on Medical Device, No. T1-149 (2007)	
Privacy/Data Protection	State Data Protection Inspectorate: http://www.ada.lt/index.php?lng=en	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		
Human Biological Materials	1. Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG/4 2. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1876243809	1. Law on Donation and Transplantation of Human Tissues, Cells and Organs (2006): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=314396 2. Law on Ethics of Biomedical Research, No. VIII-1679 (2000): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=326057	MOH: Decree on the Conditions of and the Procedure for the Donation, Procurement, Testing, Processing, Preservation, Storage, Distribution of Human Tissues and Cells No. V-397 (2007)	
Embryos, Stem Cells, and Cloning	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG/4	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 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings No. IX-1085 (2002): http://conventions.coe.int/Treaty/EN/Treaties/Html/168.htm	MOH: Decree on the Procedure to Issue Authorization for the Transit of Tissues of Human Embryonic Tissue, Embryonic Stem Cells and their Lines, Fetal Tissue, and Fetal Stem Cells throughout the Territory of the Republic of Lithuania, No. V-660 (2007) 2. Decree on the Procedure for Importing of the Stem Cells Taken from the Umbilical Cord or Placenta after the Birth of a Child and the Samples Taken for Genetic Research into the Territory of the Republic of Lithuania and Exporting There from, No. V-659 (2007)	

Country	Key Organizations	Legislation	Regulations	Guidelines
Luxembourg				
General		Hospitals Act of 1998, Article 25 (French): http://www.legilux.public.lu/leg/a/archives/1998/0078/a078.pdf#page=2		
Drugs and Devices	1. Ministry of Health (French): http://www.ms.public.lu and http://www.sante.lu 2. National Committee on Ethics in Research (CNER) (French): http://www.cne.lu 3. Division of Pharmacy and Medicines (French) http://www.ms.public.lu/fr/direction/divisions-services/pharmacie-medicaments/index.html		Grand-Ducal Decree of 30th of May, 2005 on Good Clinical Practice (French): http://www.legilux.public.lu/leg/a/archives/2005/0084/2005A15161.html	
Privacy/Data Protection	National Commission for Data Protection: http://www.cnpd.lu/en/index.html	Law of August 2, 2002 on the Protection of Persons with Regard to the Processing of Personal Data as amended by a law of July 27, 2007: http://www.cnpd.lu/objets/en/doc_loi02082002mod_en.pdf#zoom=125,0,0	Grand-Ducal Decree of October 2nd, 1992 on the Use of Personal Medical Data in IT Processing (French): http://www.legilux.public.lu/leg/a/archives/1992/0074/a074.pdf#page=12	
Macedonia				
Drugs and Devices	*Drugs*			
	Macedonian Drug Agency http://moh.gov.mk/index.php?category=39 http://www.reglek.com.mk/	1. Law for Drugs and Medical Devices (2007) 2. Pharmaco-Vigilance Law (2008)	Regulations on Clinical Trials of Medicinal Products on Human Subjects (2009)	
	Devices			
	Macedonian Drug Agency http://moh.gov.mk/index.php?category=39 http://www.reglek.com.mk/	Law for Drugs and Medical Devices (2007)		
Privacy/Data Protection	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		
Malta Note: For an overview of human subject protections in Malta, see "National Regulations on Ethics and Research in Malta:" http://ec.europa.eu/research/science-society/pdf/mt_eng_lr.pdf				
General	Health Ethics Committee: http://sahha.gov.mt/pages.aspx?page=134			

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	Medicines Authority: http://medicinesauthority.gov.mt/	Medicines Act, 2003 (English translation begins on page 43): 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 (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)
Privacy/Data Protection	Office of the Data Protection Commissioner: http://www.dataprotection.gov.mt/	Data Protection Act (2006): http://www.dataprotection.gov.mt/dbfile.aspx/DPA.pdf		
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				
General		Oviedo Convention on Human Rights and Biomedicine (2002)		
Drugs and Devices	1. Ministry of Health (MOH): http://www.ms.gov.md/en/ 2. Medicines Agency: http://www.amed.md/index_eng.html.	Moldova Republic Law on Medicines of December 17, 1997, Articles 11 and 12	MOH: Ordnance No. 10: On Performance of Clinical Trials in the Republic of Moldova (2002)	
Embryos, Stem Cells, and Cloning		Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being, on the Prohibition of Cloning Human Beings (2002)		
Montenegro				
Drugs and Devices	Ministry of Health of Montenegro: www.mz.cg.yu	Law for Drugs and Pharmacies of Montenegro, Articles 37-39		
Netherlands				
General	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl	1. Population Screening Act (1996): http://www.gr.nl/wbo.php?phpLang=en 2. Medical Research Involving Human Subjects Act (2006): http://www.ccmo-online.nl/hipe/uploads/downloads_catw/Medical%20Research%20involving%20Human%20Subjects%20Act%20March%2001%202006.pdf 3. Medical Research (Human Subjects) Compulsory Insurance Decree (2003): http://www.ccmo-	1. Concerning the Use of a Special Form (2002) 2. Concerning Requirements of Expertise of Accredited Review Board Members (2002) 3. Concerning the Organization and Working Method of Accredited Review Board Members (2003) 4. External Review Guideline (2004) 5. Research Contract Review Guideline (2009)	Manual for the Review of Medical Research Involving Human Subjects (2002)

Country	Key Organizations	Legislation	Regulations	Guidelines
		online.nl/hipe/uploads/downloads/Verzekeringsbesluit_2003-ENG(1).pdf		
Drugs and Devices	1. Ministry of Health, Welfare, and Sport (MHWS): http://www.minvws.nl/en/ 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
Privacy/Data Protection	1. Federation of Biomedical Scientific Societies (FMWV) (Dutch): http://www.federa.org/ 2. Dutch Data Protection Authority: http://www.dutchdpa.nl/index.stm	Personal Data Protection Act (2004) (Dutch): http://www.cbpweb.nl/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
Human Biological Materials	Federation of Biomedical Scientific Societies (Dutch): http://www.federa.org/	Civil Code, Article 467 (1994) (Dutch): http://www.healthlaw.nl/wgboeng.html		Code for Proper Secondary Use of Human Tissue in the Netherlands (2002): http://www.federa.org/?s=1&m=78&p=&v=4
Genetic Research	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
Embryos, Stem Cells, and Cloning	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 Bill (no date): http://www.minvws.nl/includes/dl/openbestand.asp?File=/images/explanatory-notes-to-the-embryos-bill_tcm20-108037.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Norway				
General	1. Regional Committees for Medical Research Ethics (REK): http://www.etikkom.no/English/NEM/REK 2. National Committee for Medical Research Ethics (NEM): http://www.etikkom.no/English 3. National Committee for Research Ethics in the Social Sciences and the Humanities (NESH): http://www.etikkom.no/English/NESH 4. National Committee for Research Ethics in Science and Technology (NENT): http://www.etikkom.no/English/NENT	1. Oviedo Convention on Human Rights and Biomedicine (2006) 2. Law regarding Ethics and Integrity in Research (2006): http://www.ub.uio.no/ujur/ulovdata/lov-20060630-056-eng.pdf 3. Act on Health Care Research (2008) (Norwegian): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&	REK: Terms of Reference for the Regional Committees for Medical Research Ethics, Norway (2003) http://www.etikkom.no/English/NEM/REK/reference	NEM: 1. Research Ethical Review in Norway (1998) 2. NEM: Standard Operating Procedures for the Regional Committees for Medical Research Ethics (2002) NESH: Guidelines for Research Ethics in the Social Sciences, Law, and the Humanities (2001) NENT: Research Ethics Guidelines for Science and Technology (2007) (Norwegian): www.etikkom.no/retningslinjer/nent
Drugs and Devices	*Drugs*			
	Norwegian Medicines Agency: http://www.regjeringen.no/en/dep/hod/About-the-Ministry/Subordinate-institutions/The-Norwegian-Medicines-Agency.html?id=279753		Regulation Relating to Clinical Trials on Medicinal Products for Human Use (2003)	1. Guidelines for the Regulations Concerning Clinical Trials of Human Drugs (1999) 2. Guidance to the Regulation (2004) (Norwegian): www.legemiddelverket.no/upload/78182/Endelig%20veiledning%202004.doc
	Devices			
	Ministry of Health and Care Services: http://www.regjeringen.no/en/dep/hod/Subjects/Pharmaceutical-products/medical-devices.html?id=86835			Guidelines on Notification for Clinical Investigation of Medical Devices in Norway (2005): http://www.helsedirektoratet.no/vp/multimedia/archive/00014/Guidelines_on_Notifi_14826a.doc
Privacy/Data Protection	Data Inspectorate: http://www.datatilsynet.no/templates/Page____194.aspx	Personal Data Act No. 31 (2000): http://www.datatilsynet.no.htest.osl.basefarm.net/upload/Dokumenter/regelverk/lov_forskrift/lov-20000414-031-eng.pdf	Regulations on the Processing of Personal Data (2003): http://www.datatilsynet.no.htest.osl.basefarm.net/upload/Dokumenter/regelverk/lov_forskrift/lov-20000414-031-eng.pdf	
Human Biological Materials	1. Ministry of Health and Care Services (MHCS): http://www.odin.no/hod/english/bn.html 2. Ministry of Education and Research (MER): http://www.odin.no/kd/english/bn.html	1. Act on Biobanks (February 21, 2003, No. 12): http://www.regjeringen.no/upload/kilde/hod/red/2005/0078/ddd/pdfv/242629-act_relating_to_biobanks_biobankloven_.pdf	MHCS: Guidelines for the Norwegian Act on Biobanks (2003) (Norwegian): http://odin.dep.no/hod/norsk/publ/rundskriv/042051-990014/	

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Act Relating to the Application of Biotechnology in Human Medicine, etc. (December 5, 2003, No. 100) 3. Act on Health Care Research (2008) (Norwegian): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&		
Genetic Research	1. Ministry of Health and Care Services (MHCS): http://www.odin.no/hod/english/bn.html 2. Norwegian Biotechnology Advisory Board: http://www.bion.no/index_eng.shtml 3. Regional Committees for Medical Research Ethics (REK): http://www.etikkom.no/English/NEM/REK	Act Relating to the Application of Biotechnology in Human Medicine, etc. (December 5, 2003, No. 100): http://www.odin.no/hod/english/doc/legislation/acts/048051-990012/dok-bn.html		
Embryos, Stem Cells, and Cloning	Directorate for Health and Social Affairs: http://www.helsedirektoratet.no/portal/page?_pageid=134,112387&_dad=portal&_schema=PORTAL&language=english	1. Revised Act Relating to the Application of Biotechnology in Human Medicine (June 15, 2007) Regarding Changes in the Act Related to Stem Cell Research and Pre-implantation Diagnostics (2007) 2. Norwegian Law on the Human-Medical Use of Biotechnology, Chapter 3: http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Norway/page.aspx/168		
Poland Note: For an overview of human subject protections in Poland, see "National Regulations on Ethics and Research in Poland:" http://ec.europa.eu/research/science-society/pdf/pl_eng_lr.pdf				
General	1. Ministry of Health, Bioethics Appeals Commission (MOH): http://www.kb.mz.gov.pl/index_en.html 2. Polish Chamber of Physicians and Dentists (NIL): http://www.nil.org.pl/xml/nil/wladze/nil_eng	1. Constitution of the Republic of Poland, Article 39 (1997) 2. Medical Profession Act, Articles 21-29 (1997)	MOH: Order of the Minister of Health and Social Welfare on How to Establish, Finance, and the Mode of Action of Bioethics Committees (1999)	NIL: Code of Medical Ethics, Chapter II (2003)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	*Drugs*			
	Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/english/index.htm	1. Pharmaceutical Law, 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 Medical Devices, and Law on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws No. 92, Item 882)	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 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)	
	Devices			
	Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products: http://www.urpl.gov.pl/english/index.htm	Act on Medical Devices	Various (Polish): http://www.urpl.gov.pl/	
Privacy/Data Protection	Inspector General for the Protection of Personal Data: http://www.giodo.gov.pl/168/j/en/	Act on the Protection of Personal Data (2006): http://www.giodo.gov.pl/data/filemanager_en/61.doc		
Human Biological Materials		1. Act of 26 October 1995 on the Collection and Transplantation of Cells 2. Act of 22 August 1997 on the Public Blood Service		

Portugal				
General	National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/	Oviedo Convention on Human Rights and Biomedicine (2001)		1. Opinion 4/CNE/93 on Clinical Trials (1993) 2. Opinion 9/CNE/94 on Ethics Commissions (1994) 3. Doc. 13/CNECV/95 on Legislation on Clinical Trials and Ethics Committees (1995) 4. Doc. 34/CNECV/2001 on the Helsinki Declaration (2001)
Drugs and Devices	*Drugs*			
	1. National Institute of Pharmacy and Medicines:	1. Approval of the Applicable Legal Standards for the Conduct	Decree-Law No. 102/2007 of April 2	

Country	Key Organizations	Legislation	Regulations	Guidelines
	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	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		
	Devices			
	National Institute of Pharmacy and Medicines: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS	Various: http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_V/TITULO_V_CAPITULO_II		Various: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS/NOTAS_INFORMATIVAS
Privacy/Data Protection	National Data Protection Commission: http://www.cnpd.pt/english/index_en.htm	1. Constitution, Article 35 (1997) 2. Act on the Protection of Personal Data, No. 67/98 (1998): http://www.cnpd.pt/english/bin/legislation/Law6798EN.HTM		
Genetic Research	Ministry of Health	Law 12/2005		
Embryos, Stem Cells, and Cloning	National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/	Oviedo Convention on Human Rights and Biomedicine, Additional Protocol on Prohibition of Human Cloning (2001) 2. Portuguese Law on Assisted Reproductive Technologies, Articles 7 and 9 (2006) http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Portugal/page.aspx/473		1. Opinion 15/CNECV/95 on Embryo Research (1995) 2. Opinion 47/CNECV/2005 on Stem Cell Research (2005): http://www.cnecv.gov.pt/NR/rdonlyres/F13B34FD-F9F7-4C9D-96DC-419999D9B693/0/47CNECV2005.pdf 3. Opinion 48/CNECV/2006 on Human Cloning (2006): http://www.cnecv.gov.pt/NR/rdonlyres/770EA390-9326-4FF9-B28D-D70A7E9AD961/0/p048_en.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Romania Note: For an overview of human subject protections in Romania, see "National Regulations on Ethics and Research in Romania:" http://ec.europa.eu/research/science-society/pdf/ro_eng_lr.pdf				
General	Ministry of Health (MOH) (Romanian): http://www.ms.ro/	1. Law 336/2002 2. Oviedo Convention on Human Rights and Biomedicine (2001)	Ordinance No. 57/16.08.2002 (2002)	
Drugs and Devices	1. Ministry of Health (MOH) (Romanian): http://www.ms.ro/ 2. National Medicines Agency: http://www.anm.ro/en/home.html		MOH: 1. 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 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)	MOH: Guideline for Clinical Trials in Pediatric Populations (CPMP/ICH/2711/99) (1999)
Privacy/Data Protection	National Supervisory Authority for Personal Data Processing: http://www.dataprotection.ro/index.jsp?page=documents&lang=en	Law No. 667/2001 On the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data: http://www.dataprotection.ro/servlet/ViewDocument?id=174		
Embryos, Stem Cells, and Cloning		Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to		

Country	Key Organizations	Legislation	Regulations	Guidelines
		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				
General	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	
Drugs and Devices	1. Ministry of Health (MOH) (Russian): http://www.minzdrav-rf.ru/ 2. Federal Agency for Technical Regulation and Metrology (GOST): http://www.gost.ru/wps/portal/pages.en.Main 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 the Remedies for Medicinal Use (Russian): http://www.regmed.ru/	On Medicinal Products, Federal Law No. 86-FZ, Articles 35-41 (2006) (1998 version in Russian): http://www.medtran.ru/rus/trials/gov/zakon_86.htm	MOH: 1. Ministry of Health Order No. 103 (March 24, 2000) 2. Clinical Practice Rules in the Russian Federation, Minister's Decree #266 (2003) GOST: Good Clinical Practice. GOST-R 52379-2005 (September 27, 2005)	
Privacy/Data Protection		1. Federal Law of the Russian Federation on Information, Information Technologies, and Protection of Information (2006) 2. Federal Law of the Russian Federation No. 152-FZ on Personal Data (2006): http://www.hunton.com/files/tbl_s47Details/FileUpload265/1625/Privacy_Russia_White_Paper.pdf		
Genetic		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)		

Country	Key Organizations	Legislation	Regulations	Guidelines
San Marino				
General		Oviedo Convention on Human Rights and Biomedicine (1998)		
Serbia				
Drugs and Devices	*Drugs*			
	1. Ministry of Health (MOH): http://www.zdravlje.gov.rs/ 2. Serbian Drug Agency http://www.alims.sr.gov.yu/	Law on Medicines and Medical Devices No. 84/2004 and 85/2005: http://www.alims.sr.gov.yu/eng/regulativa/zakon.php	MOH: 1. Regulation on the Conditions and Manner of Clinical Testing of Medicinal Products, Procedure and Contents of Documentation for Authorizing Clinical Trials of Medicinal Products No. 19/2007: http://www.alims.sr.gov.yu/eng/regulativa/pravilnici_l.php 2. Regulation on Changes of the Regulation on Conditions and Manner of Clinical Testing of Medicinal Products, Procedure and Contents of Documentation for Authorizing Clinical Trials of Medicinal Products No. 44/2009	
	Devices			
	1. Ministry of Health (MOH): http://www.zdravlje.gov.rs/ 2. Serbian Drug Agency http://www.alims.sr.gov.yu/	Law on Medicines and Medical Devices No. 84/2004 and 85/2005: http://www.alims.sr.gov.yu/eng/regulativa/zakon.php		
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 http://www.eurecnet.org/information/slovakia.html				
General	1. Ministry of Health (Slovak): http://www.health.gov.sk/ 2. Institute of Medical Ethics and Bioethics: http://www.bioethics.sk/	1. Act No. 576/2004 Coll on Health Care, as amended by Acts No. 350/2005, 282/2006, 662/2007, 345/2009 Coll.: http://www.privireal.org/content/rec/documents/Slovakia_ActNo576_Healthcare_2004.pdf 2. Oviedo Convention on Human Rights and Biomedicine (1998) 3. Additional Protocol on Biomedical Research (2005)		
Drugs and Devices	State Institute for Drug Control (Slovak): http://www.sukl.sk/	Act No. 140/1998 Coll. on Drugs and Medical Devices, as amended by Acts No. 9/2004	Ministerial Regulation No. 239/2004 Coll. on Requirements for Clinical Trials and Good	

Country	Key Organizations	Legislation	Regulations	Guidelines
		and 542/2006, 489/2008, and 402/2009 Coll.	Clinical Practice, as amended by Ministerial Regulation No. 148/2009 Coll.	
Privacy/Data Protection	Office for Personal Data Protection: http://www.dataprotection.gov.sk/buxus/generate_page.php3?page_id=413	Act No. 428/2002 Coll. on Protection of Personal Data, as amended by Act No. 90/2005 Coll.: http://www.privireal.org/content/dp/documents/SlovakiaAct428_2002%20_2005_PersonalData.pdf		
Human Biological Materials		1. Act No. 576/2004 Coll. on Health Care, Sections 35-39. 2. Act No. 489/2008 Coll. on Drugs and Medical Devices, Section 18 (29b).	Governmental Regulation No. 20/2007 Coll. on Tissue and Cell Collection	
Embryos, Stem Cells, and Cloning		1. Act No. 576/2004 Coll. on Health Care, Section 26.10.a. 2. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998)		
Slovenia Note: For an overview of human subject protections in Slovenia, see "National Regulations on Ethics and Research in Slovenia:" http://ec.europa.eu/research/science-society/pdf/sl_eng_lr.pdf				
General	National Medical Ethics Committee (NMEC)	1. Oviedo Convention on Human Rights and Biomedicine (1998) 2. Additional Protocol on Biomedical Research (2006)		Slovenian Code of Medical Deontology, Articles 47-50 (1992)
Drugs and Devices	*Drugs*			
	1. National Medical Ethics Committee (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-	

Country	Key Organizations	Legislation	Regulations	Guidelines
			nmec/Docu/Ocenjevanje_klin_studij_IV_faze.pdf	
	Devices			
	Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/index.php?id=56			Various: http://www.jazmp.si/index.php?id=115
Privacy/Data Protection	Inspectorate for Personal Data Protection (Slovenian): http://www.ip-rs.si/	1. Personal Data Protection Act No. 59 (1999) 2. Act Amending the Personal Data Protection Act No. 57/2001		
Human Biological Materials	1. National Medical Ethics Committee (NMEC) 2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/index.php?id=56		On Interventions into the Human Corpse Which are not Part of the Routine Autopsy and on Handling with Biologic Material of Human Origin (2004)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999)
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002) 2. Law on Biomedically Assisted Fertilization No. 70 (2000)		
Spain Note: For an overview of human subject protections in Spain, see "National Information – Spain": http://www.eurecnet.org/information/spain.html				
General	1. Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US 2. Coordinating Center for Ethical Committees on Clinical Research (Spanish): http://www.msc.es/profesionales/farmacia/ceic/home.htm 3. Institute of Health Carlos III, Ministry of Science and Innovation http://www.isciii.es/htdocs/en/index.jsp	1. Oviedo Convention on Human Rights and Biomedicine (1999) 2. Law 14/2007 on Biomedical Research: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Drugs and Devices Note: Many of the Spanish autonomous communities have their own laws and	*Drugs*			
	Spanish Agency for Medications and Health Products, Clinical Trials (Spanish): http://www.agemed.es/profHumana/ensayosClinicos/home.htm	1. 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	

Country	Key Organizations	Legislation	Regulations	Guidelines
regulations pertaining to drug research.		2. Royal Decree 1015/2009: Drug Availability for Special Purposes (Spanish): http://www.boe.es/boe/dias/2009/07/20/pdfs/BOE-A-2009-12002.pdf	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): http://www.agemed.es/actividad/legislacion/espana/ensayos.htm	
	Devices			
	Spanish Agency for Medications and Health Products, Clinical Trials (Spanish): http://www.aemps.es/actividad/pschb/home.htm	Various (Spanish): http://www.aemps.es/actividad/legislacion/espana/sanitarios.htm#implantables	Various (Spanish): http://www.aemps.es/actividad/pschb/implantables1.htm#circulares	
Privacy/Data Protection Note: Many of the Spanish autonomous communities have their own laws and regulations on privacy/data protection.	Spanish Data Protection Authority (Spanish): https://www.agpd.es/portalweb/index-ides-idphp.php	1. Organic Law 15/1999 of December 13 on the Protection of Personal Data: https://www.agpd.es/upload/Ley%20Org%E1nica%2015-99_ingles.pdf 2. Law 14/2007 on Biomedical Research, Title I, Article 5: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Human Biological Materials	Ministry of Health and Consumption: http://www.msc.es/en/home.htm	1. Royal Decree 1301/2006 of November 10 Regarding the Use of Cells and Human Tissue: http://www.ont.es/legislacion/ficherosPDF/RD1301.pdf 2. Royal Decree 2070/1999 of December 30, Regarding Activities of Collection and Clinical Use of Human Organs for Organ Transplants and Tissues 3. Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf	Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples (2006)	

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic	Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US	Law 14/2007 of July 3 on Biomedical Research, Title I, Articles 6-9; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Embryos, Stem Cells, and Cloning	Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2000) 2. Law 14/2006 on Methods of Assisted Human Reproduction, Chapters IV and V: http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Spain/page.aspx/170 3. Law 14/2007 of July 3 on Biomedical Research, Title III: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Sweden Note: For an overview of human subject protections in Sweden, see "CODEX: Rules and Guidelines for Research:" http://www.codex.uu.se/en/index.shtml				
General	1. Central Ethical Review Board (CEPN): http://www.epn.se/start/startpage.aspx 2. Swedish Research Council (SRC): http://www.vr.se/english	Law No. 460 on the Ethical Review of Research Involving Humans (2003): http://www.epn.se/start/regulations/the-act-(2003460).aspx	CEPN: 1. Ordinance No. 615 Concerning the Ethical Vetting of Research Involving Humans (2003): http://www.epn.se/start/regulations/the-statute-(2003615).aspx 2. Statute No. 2007:1069 Containing Instructions for Regional Ethical Review Boards (2007): http://www.epn.se/start/regulations/the-statute-%2820071069%29.aspx 3. Statute No. 2007:1068 Containing Instructions for the Central Ethical Review Boards (2007): http://www.epn.se/start/regulations/the-statute-(20071068).aspx	CEPN: Information for Research Participants 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)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	*Drugs*			
	Medical Products Agency: http://www.lakemedelsverket.se/Tpl/StartPage____395.aspx	Pharmaceuticals Act No. 1992: 859 (Swedish): http://www.notisum.se/rnp/SLS/LAG/19920859.HTM	1. Medical Products Agency's Provisions and Guidelines on the Clinical Trials of Medicinal Products (1996): http://www.lakemedelsverket.se/upload/foretag/humanlakemedel/Klinisk%20pr%c3%b6vning/Provisions%20and%20guidelines%20on%20clinical%20trials%201996-17.pdf 2. Medical Product Agency's Provisions and Guidelines on Clinical Trials of Medicinal Products for Human Use (2003): http://www.lakemedelsverket.se/upload/foretag/humanlakemedel/Klinisk%20pr%c3%b6vning/Provisions%20and%20guidelines%20on%20clinical%20trials%202003-11.pdf	
	Devices			
	Medical Products Agency: http://www.lakemedelsverket.se/english/product/Medical-devices/Clinical-Investigations/	1. Swedish Medical Devices Act (SFS 1993:584) 2. Medical Devices Ordinance (SFS1993:876)	1. Swedish Implementation of Directive 90/385/EEC -- LVFS 2001:5 2. Swedish Implementation of Directive 93/42/EEC -- LVFS 2003:11 with Amendment LVFS 2004:11	
Privacy/Data Protection	Swedish Data Inspection Board: http://www.datainspektionen.se/in-english/	1. Personal Data Act No. 204 (1998): http://www.datainspektionen.se/pdf/ovrigt/pul-eng.pdf		Swedish Data Inspection Board Report 2004:2
Human Biological Materials	1. National Board of Health and Welfare (SOS): http://www.socialstyrelsen.se/english 2. Swedish Research Council (SRC): http://www.vr.se/english 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)
Genetic Research	1. Ministry of Health and Social Affairs: http://www.sweden.gov.se/sb/d/2061 2. National Board of Health and Welfare: http://www.socialstyrelsen.se/english	Act on Genetic Integrity (2006:351) (Swedish): http://www.notisum.se/rnp/sls/lag/20060351.htm		Genetics and Gene Technology in the Health Care: State of the Art and Guidelines for Ethical Considerations (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning		Act on Genetic Integrity (2006:351) (Swedish): http://www.notisum.se/rnp/sls/lag/20060351.htm	Legal Regulation of Stem Cell Research 2002:119: http://www.regeringen.se/sb/d/108/a/2717	
Switzerland Note: For an overview of human subject protections in Switzerland, see "National Information – Switzerland:" http://www.eurecnet.org/information/switzerland.html				
General Note: Many Swiss cantons have implemented pertinent regulations (French): http://www.swissethics.ch/fileadmin/user_upload/Dokumente/f_RegelungenKant.doc	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: www.swissethics.ch	Swiss Federal Constitution, Article 118b (2010, French): http://www.admin.ch/ch/f/rs/101/a118b.html		SAMS: 1. Guidelines on Human Research (1997) 2. Memorandum Concerning Research on Human Beings (2009)
Drugs and Devices	*Drugs*			
	Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en	Federal Law on Medicinal Products and Medical Devices, RS 812.21 (2002, French): http://www.admin.ch/ch/f/rs/c812_21.html	Ordinance on Clinical Trials of Therapeutic Products, RS 812.214.2 (2001) (French): http://www.admin.ch/ch/f/rs/c812_214_2.html	
	Devices			
	Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/produktbereiche/00450/index.html?lang=en		Guide to the Regulation of Medical Devices: http://www.swissmedic.ch/php/modules/leitfaden/leitfaden.html?lang=en	
Privacy/Data Protection Note: Many Swiss cantons have enacted laws regarding data collection in the public sector.	Federal Data Protection Commissioner: http://www.edoeb.admin.ch/index.html?lang=en	1. Federal Law on Data Protection (1992) (French): http://www.admin.ch/ch/f/rs/c235_1.html 2. Regulation of June 14, 1993 Regarding the Release of Professional Secrets in the Area of Medical Research, RS 235.154 (French): http://www.admin.ch/ch/f/rs/235_154/index.html 3. Confidentiality in Medical Research (2006) (French): http://www.admin.ch/ch/f/rs/311_0/a321bis.html		
Human Biological Materials	Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/			Biobanks: Collection, Preservation and Utilization of Human Biological Material

Country	Key Organizations	Legislation	Regulations	Guidelines
				(2006)
Genetic Research	1. Swiss Academy of Medical Sciences: http://www.samw.ch/ 2. Swiss Society of Medical Genetics: http://www.ssgm.ch/	1. Swiss Federal Constitution, Article 119 (2006) (French): http://www.admin.ch/ch/f/rs/101/a119.html 2. Federal Act of 8 October 2004 on Human Genetic Testing (HGTA), RS 810.12 (French): http://www.admin.ch/ch/f/rs/c810_12.html	1. Ordinance on Clinical Trials of Therapeutic Products RS 812.214.2, Section 2 (2001) (French): http://www.admin.ch/ch/f/rs/c812_214_2.html 2. Ordinance of 14 February 2007 on Human Genetic Testing, RS 810.122.1 (French): http://www.admin.ch/ch/f/rs/810_122_1/index.html	
Embryos, Stem Cells, and Cloning	Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE): http://www.bag.admin.ch/nek-cne/04236/index.html?lang=en	Federal Act of 19 December 2003 on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), RS 810.13 (French): http://www.admin.ch/ch/e/rs/c810_31.html	Ordinance of 2 February 2005 on Research involving Embryonic Stem Cells (Stem Cell Research Ordinance, SCRO), RS 810.311 (French): http://www.admin.ch/ch/e/rs/c810_311.html	NEK-CNE: 1. Pre-Implantation Genetic Diagnosis, Opinion No. 10/2005 2. Research Involving Human Embryos and Fetuses. Opinion No. 11/2006 3. Pre-Implantation Genetic Diagnosis II, Opinion No. 14/2007 *Access:* http://www.bag.admin.ch/nek-cne/04229/04232/index.html?lang=en
Turkey				
General	Ministry of Health (Turkish): http://www.saglik.gov.tr/	1. Turkish Constitution, Article 17 2. Health Services Basic Law No. 3359 (1987) 3. Oviedo Convention on Human Rights and Biomedicine (2004)	1. Regulation on Medical Deontology, Article 11 (1960) 2. Bylaw on Patient Rights No. 23420 (1998)	
Drugs and Devices	*Drugs*			
	Ministry of Health , General Directorate of Pharmaceuticals and Pharmacy: www.iegm.gov.tr	Turkish Penal Law, Article 90 (2005)	1. Bylaw on the Evaluation and Monitoring of the Safety of Medical Products (2005) 2. Regulation Regarding the Implementation and Inspection of the Support for Research and Development Activities (2008) *Access*: http://www.klinikarastirmalar.org.tr/en/documents.php?dok_cat=10	Guideline for Good Clinical Practices (2009) *Access:* http://www.klinikarastirmalar.org.tr/en/documents.php?dok_cat=12

Country	Key Organizations	Legislation	Regulations	Guidelines
	Devices			
	Ministry of Health: www.iegm.gov.tr		Various (Turkish): http://www.klinikarastirmalar.org.tr/en/documents.php?dok_cat=25	
Human Biological Materials		1. Law on Procurement, Preservation, Grafting, and Transplantation of Organs and Tissues, No. 2238 (1979) 2. Law on Blood and Blood Products, No. 2857 (1983)	Regulation on Blood and Blood Products, No. 7314 (1983)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999)
Genetic Research			Regulation on Centers for Diagnosis and Genetic Diseases, No. 23368 (1998)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14 (1999)
Embryos, Stem Cells, and Cloning			1. Regulation on Centers for Medically Assisted Procreation, No. 19551 (1987) 2. Regulation on Organ and Tissue Transplantation Services (2005) 3. Regulation on Cordon Blood Banks (2005)	1. Circular on Research of Embryonic Stem Cells (2005) 2. Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)
Ukraine Note: For an overview of human subject protections in the Ukraine, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 10: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
General	1. Ethical Commission with the Higher Education Committee (EC-HEC) 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)	

Country	Key Organizations	Legislation	Regulations	Guidelines
			(Ukrainian): http://www.moz.gov.ua/ua/main/docs/?docID=7989	
Drugs and Devices	1. State Pharmacological Center: http://www.pharma-center.kiev.ua/view/all_information 2. Ukrainian Ministry of Health, Central Ethics Committee: http://www.moz.gov.ua/en/main/siterubr/	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	1. Ukrainian Ministry of Health Order No. 95 About Approval of Documents Related to the Quality Assurance of Medicines (2009) (Ukrainian): http://www.moz.gov.ua/ua/main/docs/?docID=12796 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	MOH Central Ethics Committee: 1. Information Letters on Ethics Questions of Clinical Trials and Implementation of Medicines (2006) 2. Ethics Expertise of Clinical Trials Medicines (2007) 3. Methodological Aspects of Central EC Activity of Ukrainian Ministry of Health (2007) 4. Ethical Aspects of Placebo Controlled Clinical Trials in Patients with MS (2008) 5. Optimization of Local Ethics Committee Activities (2009)
Privacy/Data Protection		Information Act from the Cabinet of Ministers of the Ukraine (2002)		
Human Biological Materials	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/main/siterubr/		Ukrainian Ministry of Health Order No. 630 About Approval of Procedure for 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	
Genetic Research	Academy of Medical Sciences of the Ukraine			Medical and Ethical Guidelines for Genetic Investigations in Humans
Embryos, Stem Cells, and Cloning	1. National Bioethics Committee of the National Academy of Sciences of the Ukraine (NBC) 2. Ukrainian Ministry of Health: http://www.moz.gov.ua/en/main/siterubr/	1. About the Ban of Human Reproductive Cloning (2004) 2. About Organs and Other Human Materials Transplantology No. 1007-XIV (2007)	1. Recommendation No. 1046, Use of the Human Fetus for the Purpose of Diagnosis, Therapy, Research, Industrial Purchase, and Trading (1986) 2. Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for the Conduct of Clinical Trials of	NBC: Ethical Regulations and Problems of Embryo-Tissue Storage (Recommendations)

Country	Key Organizations	Legislation	Regulations	Guidelines
			Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) (Ukrainian): http://www.moz.gov.ua/ua/main/docs/?docID=8767	
United Kingdom Note: Unless otherwise noted, all laws, regulations, and guidelines listed for England apply to the entire United Kingdom.				
General	*England:*			
	1. Department of Health (DH): http://www.dh.gov.uk/Home/fs/en 2. National Research Ethics Service (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 1 Ethics Committees (AAPEC) http://www.aapec.org.uk/ 7. Economic and Social Research Council (ESRC): http://www.esrc.ac.uk/	Mental Capacity Act 2005, Sections 30-34 (England and Wales): http://www.opsi.gov.uk/acts/acts2005/20050009.htm		DH: 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 NRES: 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): • Building on Improvement • Research Ethics Timeline • Defining Research • Explaining Research Integrated Research Application System (2008): https://www.myresearchproject.org.uk/

Country	Key Organizations	Legislation	Regulations	Guidelines
				MRC: 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 in Developing Societies (2004) 5. Medical Research Involving Children (2004) RCP: Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants (2007) ESRC: Research Ethics Framework
	Northern Ireland:			
	Northern Ireland Health and Personal Social Services: http://www.dhsspsni.gov.uk/			Research Governance Framework for Health and Social Care (2002)
	Scotland:			
	NHSScotland, Chief Scientist Office: http://www.show.scot.nhs.uk/cso/	Adults with Incapacity (Scotland) Act 2000, Section 51: http://www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm	Adults with Incapacity (Ethics Committee) (Scotland) Regulations (2002): http://www.scotland-legislation.hmso.gov.uk/legislation/scotland/ssi2002/20020190.htm	Research Governance Framework for Health and Community Care (2006)
	Wales:			
	Wales Office of Research and Development for Health and Social Care: http://wales.gov.uk/topics/health/research/word/?lang=en			Research Governance Framework for Health and Social Care in Wales (2001)
Drugs and Devices	*Drugs*			
	1. Medicines and Healthcare Products Regulatory Agency (MHRA): http://www.mhra.gov.uk 2. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm 3. National Research Ethics Service (NRES): http://www.nres.npsa.nhs.uk/home	Medicines Act (1968): http://www.legislation.gov.uk/RevisedStatutes/Acts/ukpga/1968/cukpga_19680067_en_1	MHRA: 1. The Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004): http://www.uk-legislation.hmso.gov.uk/si/si2004/20041031.htm 2. Amendment Regulations (SI	MHRA: Consultation Letter on the Medicines for Human Use (Clinical Trials) Regulations (2003) MRC: 1. MRC Guidelines for Good Clinical Practice in Clinical Trials (1998)

Country	Key Organizations	Legislation	Regulations	Guidelines
			2006/1928) http://www.opsi.gov.uk/si/si2006/20061928.htm 3. Amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 and Adults with Incapacity (Scotland) Act 2000 to Facilitate Clinical Research in Emergency Settings (SI 2006/2984): http://www.opsi.gov.uk/si/si2006/20062984.htm	2. MRC Policy on Antiretroviral Therapy for People Infected with HIV and Involved in AIDS Research in Developing Countries (2003) NRES: Memorandum of Understanding between MHRA, COREC, and GTAC (2006) http://www.nres.npsa.nhs.uk/rec-community/guidance/
	Devices			
	1. Medicines and Healthcare Products Regulatory Agency (MHRA): http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/index.htm 2. National Research Ethics Service (NRES): http://www.nres.npsa.nhs.uk/home		Medical Devices Regulations (2002): http://www.opsi.gov.uk/si/si2002/20020618.htm	MHRA: Information for Clinical Investigators (2009): http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON007507&RevisionSelectionMethod=Latest NRES: 1. Communications on Medical Devices Investigations 2. Medical Devices - Questions and Answers 3. NRES Guidance on the Approval of Medical Devices Research 4. Revisions to the European Medical Device Directives (2007/47/EEC): Clinical Evaluation and Investigation *Access:* http://www.nres.npsa.nhs.uk/applications/guidance/guidance-and-good-practice/
Privacy/Data Collection	*England:*			
	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

Country	Key Organizations	Legislation	Regulations	Guidelines
				NHS Information Governance: Security of NHS Patient Data Shared for Research Purposes (2008): http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/whatsnew
	Scotland:			
	NHSScotland: http://www.show.scot.nhs.uk/			Protecting Patient Confidentiality (2002)
Human Biological Materials	1. Royal College of Physicians (RCP): http://www.rcplondon.ac.uk/index.asp 2. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm 3. Department of Health (DH): http://www.dh.gov.uk/Home/fs/en 4. Human Tissue Authority (HTA): http://www.hta.gov.uk/	1. Human Tissue Act (2004): http://www.opsi.gov.uk/acts/acts2004/20040030.htm 2. Statutory Instrument 2006 No. 1260: The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006: http://www.opsi.gov.uk/si/si2006/20061260.htm 3. Statutory Instrument 2006 No. 1659: The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006: http://www.opsi.gov.uk/si/si2006/20061659.htm		RCP: Research Based on Archived Information and Samples (1999) MRC: Human Tissue and Biological Samples for Use in Research (2001) + Annex (2004) DH: The Use of Human Organs and Tissue: An Interim Statement (2003): http://www.nres.npsa.nhs.uk/docs/guidance/MoU.pdf HTA: Codes of Practice 2006
Genetics Research	1. Advisory Committee on Genetic Testing (ACGT): http://www.advisorybodies.doh.gov.uk/genetics/acgt/ 2. Public Health Genetics Unit: http://www.phgu.org.uk/index.php			ACGT: Advice to Research Ethics Committees (1998)
Embryos, Stem Cells, and Cloning	Human Fertilisation and Embryology Authority: http://www.hfea.gov.uk/	Human Fertilisation and Embryology Act (1990): http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm	Human Fertilisation and Embryology (Research Purposes) Regulation (2001)	

Country	Key Organizations	Legislation	Regulations	Guidelines
ASIA/PACIFIC/MIDDLE EAST				
Australia				
General	National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/about/committees/ahec/index.htm Australian Research Council http://www.arc.gov.au/	National Health and Medical Research Council Act (1992): http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/all/search/4AFACF8FAAF9ED97CA25719C0081EF9F	National Health and Medical Research Regulations (2006): http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/all/search/CD6C81A813A14BCCCA257211000E4F9D	1. Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) http://www.nhmrc.gov.au/publications/synopses/e52syn.htm 2. Keeping Research on Track: A Guide for Aboriginal and Torres Strait Islander Peoples about Health Research Ethics (2006) http://www.nhmrc.gov.au/publications/synopses/e65syn.htm 3. National Statement on Ethical Conduct in Human Research (2007) http://www.nhmrc.gov.au/publications/synopses/e72syn.htm 4. Australian Code for the Responsible Conduct of Research (2007) http://www.nhmrc.gov.au/publications/synopses/r39syn.htm
Drugs and Devices	*Drugs*			
	Therapeutic Goods Administration: http://www.tga.gov.au/ct/index.htm	Therapeutic Goods Act (2009): http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/all/search/89DC85FBD2CF7799CA25762C000A762F	Therapeutic Goods Regulations (2009) http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/all/search/AC1C41C98B71506ACA257631002F4B15	1. Human Research Ethics Committees and the Therapeutic Goods Administration (2001) http://www.tga.gov.au/docs/html/hrec.htm 2. Australian Clinical Trial Handbook (2006) http://www.tga.gov.au/ct/cthandbook.htm 3. National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2007)
	Devices			
	Therapeutic Goods Administration: http://www.tga.gov.au/devices/devices.htm			Australian Regulatory Guidelines for Medical Devices (ARGMD): http://www.tga.gov.au/devices/argmd.htm
Privacy/Data Protection Note: All the Australian states and territories have privacy/data protection laws:	Office of the Privacy Commissioner: http://www.privacy.gov.au/	Privacy Act No. 119 (2009): http://www.comlaw.gov.au/comlaw/Legislation/ActCompilation1.nsf/all/search/8039E7AB4B89A16ACA25760700060E24	Privacy (Private Sector) Regulations (2001): http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/all/search/C46A983B1C8AA3DFCA25760A00097BFE	

Country	Key Organizations	Legislation	Regulations	Guidelines
http://www.austlii.edu.au/au/other/alrc/publications/reports/108/vol_3_full.pdf				
Human Biological Materials Note: All the Australian states and territories have laws on the use of human biological materials.	National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/about/committees/ahec/index.htm			National Statement on Ethical Conduct in Human Research (2007): Chapters 3.2 and 3.4
Genetic Research	1. National Health and Medical Research Council, Australian Health Ethics Committee (AHEC): http://www.nhmrc.gov.au/about/committees/ahec/index.htm 2. Office of the Gene Technology Regulator: http://www.ogtr.gov.au/	Gene Technology Act (2000): http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/all/search/51A2449A3EBB9A1CCA257475001ECD9C		AHEC: National Statement on Ethical Conduct in Human Research, Chapter 3.5 (2007)
Embryos, Stem Cells, and Cloning	1. National Health and Medical Research Council, Australian Health Ethics Committee (AHEC): http://www.nhmrc.gov.au/about/committees/ahec/index.htm 2. National Health and Medical Research Council: Embryo Research Licensing Committee http://www.nhmrc.gov.au/about/committees/lc/index.htm	1. Prohibition of Human Cloning Act (2008): http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/all/search/ED63FF59CFEBB728CA2575280008CFC5 2. Research Involving Human Embryos Act (2008): http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/all/search/535F95A0A6D118AACA2575270081D2E	Research Involving Human Embryos Regulations (2003): http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/all/search/53B9DAE14F396A2CCA25744E0005E313	AHEC: 1. National Statement on Ethical Conduct in Human Research, Chapter 3.6 (2007) 2. Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2007): http://www.nhmrc.gov.au/publications/synopses/e78syn.htm
Bangladesh				
General	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			
Drugs and Devices	Bangladesh Directorate of Drug Administration: http://www.ddabd.org	1. The Drugs Act (1964) 2. Drugs (Control) Ordinance 1982, Ordinance No. VIII: http://www.ddabd.org/ordinance_1982.htm		
Human Biological Materials	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			Guidelines for Transfer of Human Biological Materials Abroad for Research Purposes (2004)

Country	Key Organizations	Legislation	Regulations	Guidelines
Burma (Myanmar)				
General	1. Ministry of Health National Ethics Committee on Clinical Research: www.moh.gov.mm 2. Department of Medical Research (DMR) 3. Department of Health, Ethical Review Committee 4. Myanmar Academy of Medical Sciences Ethics Awareness Program		DMR: Operational Guidelines for Institutional Ethical Review Committee (2005)	
Drugs and Devices	Ministry of Health, Food and Drug Administration	National Drug Law (1992)		
China, People's Republic of				
General	1. Ministry of Health (MOH) (Mandarin): http://www.moh.gov.cn/ 2. Ministry of Science and Technology	Law on Practicing Doctors (June 26, 1998), Articles 26 and 37	MOH: Trial Measures for the Ethical Review of Human Related Biomedical Research (2007)	MOH: Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2007) (Mandarin): http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohkjjys/s3581/200804/18816.htm
Drugs and Devices	*Drugs*			
	State Food and Drug Administration: http://www.sfda.gov.cn/	Drug Administration Law (2001)	1. Implementation Bylaws for the Drug Administration Law (2002) (Mandarin) http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohyzs/s3572/200804/18293.htm 2. Chinese Good Clinical Practice (2003) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/24473.html 3. Rules on the Administration of Report and Supervision of Adverse Drug Reactions (2004) 4. Regulation on Drug Registration (2007) (Chinese): http://www.sda.gov.cn/WS01/CL0053/24529.html 5. Qualification and Evaluation of Clinical Trial Sites (2008) (Chinese): http://www.sfda.gov.cn/WS01/CL0121/29571.html	1. Guideline for HIV Vaccine Research Technology (2003) (Mandarin): http://www.sfda.gov.cn/WS01/CL0237/15705.html 2. Guideline for Vaccine Research Technology (2004) (Mandarin): http://www.sfda.gov.cn/WS01/CL0055/10307.html 3. Guidelines for Ethical Review of Clinical Trials of Drugs (2010) (Mandarin): http://www.sfda.gov.cn/WS01/CL0050/55655.html
	Devices			
	State Food and Drug Administration: http://www.sfda.gov.cn/		Rules on Clinical Research for Medical Devices (2004)	

Country	Key Organizations	Legislation	Regulations	Guidelines
Privacy/Data Protection	*Hong Kong:*			
	Privacy Commissioner for Personal Data: www.pco.org.hk	Personal Data (Privacy) Ordinance (1996): http://www.pco.org.hk/english/ordinance/ordfull.html		
Human Biological Materials	Ministry of Health (Mandarin): http://www.moh.gov.cn/			
Genetic Research	1. Ministry of Health (MOH) (Mandarin): http://www.moh.gov.cn/ 2. Ministry of Science and Technology (MOST)		MOH and MOST: Interim Measures for the Administration of Human Genetic Resources (1998)	
Embryos, Stem Cells, and Cloning	1. Ministry of Health (MOH) (Mandarin): http://www.moh.gov.cn/ 2. Ministry of Science and Technology (MOST)		MOH: 1. Ethical Principles and Conduct Norms for Human Assisted Reproductive Technologies. (2003) 2. Regulation on Medical Technique (2009) http://www.moh.gov.cn/publicfiles/business/htmlfiles/zwgkzt/pyzgl/20090 3/39511.htm MOH and MOST: Ethical Guideline for Research on Human Embryo Stem Cells (2004)	
	Hong Kong:			
	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				
General	Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			Ethical Guidelines for Biomedical Research on Human Participants (2006): http://icmr.nic.in/ethical_guidelines.pdf
Drugs and Devices	*Drugs*			
	1. Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): http://cdsco.nic.in 2. Indian Council of Medical Research (ICMR): 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 Participants: Chapter IV. Drug Trials and Vaccine Trials (2006)

Country	Key Organizations	Legislation	Regulations	Guidelines
	Devices			
	1. Central Drugs Standard Control Organization (CDSCO): http://www.cdsco.nic.in/ 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm		CDSCO: Requirements for Conducting Clinical Trial(s) of Medical Devices in India (2010): http://www.cdsco.nic.in/Requirements%20for%20Conducting%20Clinical%20Trial(s)%20of%20Medical%20Devices%20in%20India.PDF	ICMR: Ethical Guidelines for Biomedical Research on Human Participants: Chapter IV. Diagnostic Agents – Use of Radio-Active Materials and X-rays (2006): http://www.icmr.nic.in/ethical_guidelines.pdf
Human Biological Materials	Ministry of Health			Guidelines for Exchange of Human Biological Material for Biomedical Research Purposes (1997): http://www.icmr.nic.in/min.htm
Genetic Research	1. Department of Biotechnology (DBT): http://dbtindia.nic.in/ 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Environmental Protection Act		DBT: 1. Recombinant DNA Safety Guidelines (1990) 2. Ethical Policies on the Human Genome, Genetic Research, and Services (2002) ICMR: Ethical Guidelines for Biomedical Research on Human Subjects: Statement of Specific Principles for Human Genetics and Genomics Research (2006)
Embryos, Stem Cells, and Cloning	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: Guidelines for Stem Cell Research and Therapy (2007): http://icmr.nic.in/stem_cell/Stem_cell_guidelines.pdf
Indonesia				
General	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)
Drugs and Devices	Indonesian FDA		Guidelines on Good Clinical Practice (2001)	
Human Biological Materials			National Guidelines on Use of Stored Biological Materials (2005)	
Iran				
General	Ministry of Health and Medical Education, Office for the Study of Humanistic and Islamic Science in Medicine and Medical Ethics: http://www.mohme.gov.ir/		Protection Code for Human Subjects in Medical Research (1999)	

Country	Key Organizations	Legislation	Regulations	Guidelines
Israel				
General	Ministry of Health: http://www.health.gov.il/english/		Public Health Regulations (Medical Experiments Involving Human Subjects) (1999) (Hebrew): http://www.health.gov.il/pages/default.asp?maincat=11&catid=301&pageid=2203	
Drugs and Devices	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
Privacy/Data Protection	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)		
Genetic Research	Ministry of Health: http://www.health.gov.il/english/	Genetic Information Law (2000) (Hebrew): http://www.moital.gov.il/NR/exeres/66F4DD4E-FA4A-4B76-94BC-DC29543471DE.htm		1. The Instruction of the Supreme Committee for Clinical Studies on Humans Regarding Establishment and Usage of Genetic Samples Reservoir (2005) (Hebrew): http://www.health.gov.il/download/forms/a2658_mk01_05.pdf 2. Amendment (2007) (Hebrew): http://www.health.gov.il/download/forms/a3037_mk17_07.pdf
Embryos, Stem Cells, and Cloning		Genetic Intervention Prohibition Law (Human Cloning and Genetic Changes in Reproduction Cells) (1999)		

Country	Key Organizations	Legislation	Regulations	Guidelines
Japan				
General	1. Ministry of Education, Culture, Sports, Science, and Technology (MEXT): http://www.mext.go.jp/english/ 2. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html			MEXT and MHLW: Ethics Guidelines for Epidemiological Research (2008) (Japanese): http://www.mhlw.go.jp/general/seido/kousei/i-kenkyu/ekigaku/0504sisin.html MHLW: Ethical Guidelines for Clinical Research (2008) (Japanese): http://www.mhlw.go.jp/general/seido/kousei/ikenkyu/rinsyo/dl/shishin.pdfl
Drugs and Devices	*Drugs*			
	1. Ministry of Health, Labor, and Welfare (MHLW) 2. Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html	Pharmaceutical Affairs Law, (2008) (Japanese): http://www.houko.com/00/01/S35/145.HTM	MHLW: Good Clinical Practice Guidelines for Drugs (2009) (Japanese): http://law.e-gov.go.jp/htmldata/H09/H09F03601000028.html	
	Devices			
	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, (2008) (Japanese): http://www.houko.com/00/01/S35/145.HTM	MHLW: Good Clinical Practice Guidelines for Medical Devices (2009) (Japanese): http://law.e-gov.go.jp/htmldata/H17/H17F19001000036.html	
Privacy/Data Protection	Consumer Affairs Agency (Japanese): http://www.caa.go.jp/index.html	Personal Information Protection Act (2009) (Japanese): http://law.e-gov.go.jp/htmldata/H15/H15HO057.html		
Human Biological Materials	Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html			1. On Research and Development Utilizing Human Tissues Removed by Surgery and Other Procedures (1998) (Japanese) http://www1.mhlw.go.jp/shingi/s9812/s1216-2_10.html 2. Guidelines for Quality Assurance and Safety of Medicines Manufactured from Human Cells and Tissues (2008) (Japanese): http://www.kuhp.kyoto-u.ac.jp/~ccmt/files/20080208.pdf
Genetic Research	1. Council for Science and Technology (CST)			CST: Fundamental Principles of Research on the

Country	Key Organizations	Legislation	Regulations	Guidelines
	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)			Human Genome (2000): http://www.lifescience.mext.go.jp/files/pdf/43_137.pdf MEXT, MHLW, and METI: Ethics Guidelines for Human Genome/Gene Analysis Research (2008) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/40_126.pdf MEXT and MHLW: Guidelines for Clinical Research in Gene Therapy (2008) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/6_7.pdf
Embryos, Stem Cells, and Cloning	1. Council for Science and Technology Policy (CSTP): http://www8.cao.go.jp/cstp/english/index.html 2. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html 3. Ministry of Education, Culture, Sports, Science, and Technology (MEXT): http://www.mext.go.jp/english/	Act on Regulation of Human Cloning Techniques (2000): http://www.cas.go.jp/jp/seisaku/hourei/data/htc.pdf	Rules for Enforcement of Act on Regulation of Human Cloning Techniques (2009) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/29_224.pdf	CSTP: Fundamental Philosophy on Handling of Human Embryo (2004) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/6_28.pdf MHLW: Guidelines for Clinical Research Using Human Stem Cells (2006) (Japanese): http://www.mhlw.go.jp/bunya/kenkou/iryousaisei01/pdf/01.pdf MEXT: 1. Guidelines for Handling of a Specified Embryo (2009) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/30_226.pdf 2. Guidelines for Derivation and Distribution of Human Embryonic Stem Cells (2009) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/56_229.pdf 3. Guidelines for Utilization of Human Embryonic Stem Cells (2009) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/57_232.pdf
Jordan				
Drugs and Devices	Jordan Food and Drug Administration: http://www.jfda.jo/en/default/	1. Narcotic and Psychotropic Law No. 11 (1988) 2. Law of Clinical Studies		

Country	Key Organizations	Legislation	Regulations	Guidelines
		(2001): http://www.jfda.jo/custom/law/23.doc 3. Pharmacy and Drug Law No. 80 (2001)		
Kazakhstan Note: For an overview of human subject protections in Kazakhstan, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 5: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
General	Ministry of Health, Central Bioethics Commission			Guidelines on Ethics in Health Research. (2007)
Drugs and Devices	Ministry of Health, Committee of Pharmacy (Kazakh): http://www.mz.gov.kz/	Drug Law (13.01.2004 No. 522-2), Articles 19 and 20 (2004) (Kazakh): http://www.zakon.kz/	1. Order 14.02.2005 No. 53 Instruction on the Conduct of Clinical Trials in Kazakhstan (2005) 2. Order 25.06.2007 # 442 Rules on Preclinical, Medico-Biological Experiments, and Clinical Trials in Kazakhstan (2007)	Guidelines on Clinical Trials in Kazakhstan (2003)
Privacy/Data protection	Ministry of Health (Kazakh): http://www.mz.gov.kz/	Law on the Health Care System (4.06.2003 # 430-II) (2003) (Kazakh): http://www.zakon.kz/		
Korea, South				
Drugs and Devices	Korea Food and Drug Administration (KFDA) (Korean): www.kfda.go.kr/	Pharmaceutical Affairs Act (No. 10324) Articles 10 and 31-34 (2010)	1. Korean Good Clinical Practice. Public Notification of Food and Drug Administration, No. 2009-211 (2009): Translation of 1999 version: http://www.lskglobal.com/english_htm/regulation/kgcp_00.htm 2. Guideline for Investigational New Drug Application: Public Notification No. 2008-32 (2008) 3. Enforcement Rule of Pharmaceutical Affairs Act No. 1, Articles 12, 22, 24, 29, 31-34, 49, 62, 75, 76, and 94 (2010)	
Privacy/Data Protection	1. Ministry of Public Administration and Security: http://www.mopas.go.kr 2. Ministry of Health and Welfare (MOHW) : http://english.mw.go.kr/	1. Act on the Protection of Personal Information Maintained by Public Agencies No. 10012 (2010) 2. Medical Affairs Act No.	Presidential Order of Enforcement Rule of the Protection of Personal Information Maintained by Public Agencies No. 220947 (2008)	Enforcement Rule of the Protection of Personal Information Maintained by Public Agencies No. 1 (2008)

Country	Key Organizations	Legislation	Regulations	Guidelines
		10387 (2010)		
Genetic Research	Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/	Bioethics and Safety Act No. 9932 (2010)	1. Presidential Order of Regulation for Bioethics and Safety No. 22075 (2010) 2. Guidance for Genetic Recombination Research No. 2009-150 (2009)	Guidelines for Bioethics and Safety Act No. 18 (2010)
Embryos, Stem Cells, and Cloning	Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/	Bioethics and Safety Act No. 9932, Articles 2, 18-21, 38, 41, and 45 (2010)	Presidential Order of Regulation for Bioethics and Safety No. 22075(2010)	Guidelines for Bioethics and Safety Act No. 18 (2010)
Kuwait				
General	Ministry of Health, Kuwait Institute for Medical Specialization: http://www.kims.org.kw/			Ethical Guidelines for Biomedical Research (no date): http://www.kims.org.kw/Ethical%202.doc
Kyrgyzstan				
General	1. Ministry of Health (Russian): http://www.med.kg 2. National Bioethics Committee	1. Constitution of Kyrgyz Republic Chapter II, Article 22 (2010): http://www.shailoo2010.kg/us/legislation/adoption-of-the-constitution/54-constitution.html 2. Law on Protection of Citizens Health (09.01.2005 No. 6): Articles 34 and 73 (Russian): http://www.med.kg/MyFiles/Законы/Закон%20КР%20%20Об%20охране%20здоровья%20граждан%20в%20Кыргызской%20Республике%20_1.rtf		
Drugs and Devices	1. Ministry of Health (Russian): http://www.med.kg/ 2. Department of Drug and Medical Devices Provision (Russian): http://pharm.med.kg/ 3. National Bioethics Committee	Drug Law of Kyrgyz Republic (30.04.2003 No. 91) Chapter VII, Articles 25-29 (2003) (Russian): http://www.med.kg/MyFiles/Законы/Закон%20КР%20%20О%20лекарственных%20средствах%20.rtf	Order of the Ministry of Health 16.03.2004 No. 120 on the Conduct of Medical Trials (2004) (Russian): http://www.pharm.kg/ru/legislation/	
Human Biological Materials	1. Ministry of Health (Russian): http://www.med.kg/ 2. National Bioethics Committee	Law on Protection of Citizens Health in the Kyrgyz Republic (09.01.2005 No. 6): Article 39		
Privacy/Data Protection	1. Ministry of Health (Russian): http://www.med.kg/ 2. National Bioethics Committee	Law on Protection of Citizens Health in the Kyrgyz Republic (09.01.2005 No. 6): Article 91		

Country	Key Organizations	Legislation	Regulations	Guidelines
Nepal				
General	Nepal Health Research Council: http://www.nhrc.org.np/			National Ethical Guidelines for Health Research in Nepal (2001): http://www.nhrc.org.np/guidelines/nhrc_ethical guidelines_2001.pdf
Drugs and Devices	Nepal Health Research Council: http://www.nhrc.org.np/			National Guidelines on Clinical Trials with the Use of Pharmaceutical Products (2005): https://webapps.sph.harvard.edu/live/gremap/files/np_pharmaceutical_trial_guidelines.pdf
New Zealand				
General	1. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ 2. National Ethics Advisory Committee (NEAC): http://www.neac.health.govt.nz/ 3. Ministry of Health (MOH): http://www.moh.govt.nz/ 4. Health and Disability 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/	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. Accident Compensation Act 2001 *Access*: All New Zealand laws can be found at: http://www.legislation.govt.nz/act/searchquick.aspx Then search for the name of the law under "Statutes of New Zealand."	HDC: The Code of Health and Disability Services Consumers' Rights (the Code of Rights) (2004): http://www.hdc.org.nz/files/hdc/code-leaflet.pdf	HRC: http://www.hrc.govt.nz/root/Publications/Ethics_Reports_and_Guidelines.html : 1. Guidelines for Researchers on Health Research Involving Māori (2010) 2. Guidelines on Ethics in Health Research (2005) 3. Guidelines on Pacific Health Research (2005) NEAC: 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) 3. Ethical Guidelines for Intervention Studies (2009) MOH: Operational Standard for Ethics Committees: Updated Edition (2006): http://www.moh.govt.nz/moh.nsf/pagesmh/4703/$File/operational-standard-for-ethics-committees-updated-edition.pdf
Drugs and Devices	*Drugs*			
	1. New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz 2. Researched Medicines Industry (RMI): http://www.rmianz.co.nz 3. Health Research Council (HRC),	1. Medicines Act 1981(2005) 2. Accident Compensation Act 2001, Section 32 (2008)	Medsafe: Medicines Regulations 1984 http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM95668.html	Medsafe: New Zealand Regulatory Guidelines for Medicines, Vol. 3: Interim Good Clinical Research Practice Guidelines (1998): http://www.medsafe.govt.nz/regulatory/Guideline/NZRGM%20Volume%203.asp

Country	Key Organizations	Legislation	Regulations	Guidelines
	Standing Committee on Therapeutic Trials: http://www.hrc.govt.nz/root/pages_regulatory/Standing_Committee_on_Therapeutic_Trials.html			RMI: Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial (2008): http://www.rmianz.co.nz/compensation%20guidelines%200808%20final.pdf
	Devices			
	New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz		Medicines (Database of Medical Devices) Regulations (2003): http://www.legislation.govt.nz/regulation/public/2003/0325/latest/DLM224223.html	Operational Standard for Ethics Committees: Updated Edition, Section 3.5 (2006): http://www.moh.govt.nz/moh.nsf/pagesmh/4703/$File/operational-standard-for-ethics-committees-updated-edition.pdf Various: http://www.medsafe.govt.nz/regulatory/MedicalDevices/DevicesCon.asp
Privacy/Data Protection	Privacy Commissioner: http://www.privacy.org.nz/	1. Official Information Act (2009) 2. Public Records Act (2005) 3. Privacy Act (2006): http://www.legislation.govt.nz/act/public/1993/0028/latest/viewpdf.aspx	Health Information Privacy Code 1994: http://www.privacy.org.nz/assets/Files/Codes-of-Practice-materials/Health-Information-Privacy-Code-1994-including-Amendment.pdf	
Human Biological Materials	1. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/root/Ethics/Ethics%20Overview/HRC_Ethics_Committee.html 2. Human Specimen Ethical Guidelines Committee (HPEGC) 3. Te Puni Kokiri (TPK): http://www.tpk.govt.nz/ 4. Office of the Health and Disability Commissioner (HDC): http://www.hdc.org.nz 5. Ministry of Research Science and Technology: http://www.morst.govt.nz/wayfinder/index.asp	1. Health Act 1956 (2005) 2. Human Tissue Act 2008	Standards New Zealand: New Zealand Standard 8135: 2009: Non-Therapeutic Use of Human Tissue: http://www.standards.co.nz/web-shop/?action=basicShopSearch&mod=search&SearchBox1_txtShopName=non+therapeutic+use+of+human+tissue&selStatus=CURRENTANDDRAFT&catalog=NZ	HPEGC: Ethical Guidelines for Human Specimen Collection, Storage, Use and Disposal: A Report to the New Zealand Department of Health (1992) TPK: Guidelines for the Removal, Retention, Return, and Disposal of Maori Body Parts. (1999) MOH: Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (2007): http://www.moh.govt.nz/moh.nsf/pagesmh/6135/$File/guidelines-use-of-human-tissue-may07.pdf
Genetic Research	1. Environmental Risk Management Authority: http://www.ermanz.govt.nz/ 2. Health Research Council (HRC),	Hazardous Substances and New Organisms Act 1996 (2008)		HRC: Ethical Considerations Relating to Research in Human Genetics (2000):

Country	Key Organizations	Legislation	Regulations	Guidelines
	Gene Technology Advisory Committee: http://www.hrc.govt.nz/root/pages_regulatory/Gene_Technology_Advisory_Committee.html			http://www.hrc.govt.nz/assets/pdfs/publications/ethumangen.pdf
Embryos, Stem Cells, and Cloning	1. Advisory Committee on Assisted Reproductive Technology (ACART) http://www.acart.health.govt.nz/ 2. Ministry of Health http://www.moh.govt.nz/ 3. Ethics Committee on Assisted Reproductive Technology (ECART) http://www.ecart.health.govt.nz/ 4. Health and Disability Ethics Committees http://www.newhealth.govt.nz/ethicscommittees/ 5. Health Research Council (HRC), Gene Technology Advisory Committee: http://www.hrc.govt.nz/root/pages_regulatory/Gene_Technology_Advisory_Committee.html	Human Assisted Reproductive Technology Act 2004 (2009)		ACART: http://www.acart.health.govt.nz/moh.nsf/indexcm/acart-resources-guidelines : 1. Guidelines on the Use, Storage, and Disposal of Sperm from a Deceased Man (2000) 2. Guidelines on Preimplantation Genetic Diagnosis (2005) 3. Guidelines on IVF Surrogacy (2005) 4. Guidelines on Within-Family Gamete Donation (2005) 5. Embryo Donation for Reproductive Purposes (2005) 6. Guidelines for Research on Gametes and Non-viable Embryos (Interim) MOH: Guidelines on Using Cells from Established Human Embryonic Stem Cell Lines for Research (2005): http://www.moh.govt.nz/moh.nsf/0/DF32587ABFCA33C5CC2570C800708A24/$File/GuidelinesUsingCells.pdf
Pakistan				
General	Pakistan Medical Research Council, National Bioethics Committee (NBC): http://www.pmrc.org.pk/			Guidelines: http://www.pmrc.org.pk/NBC%20Guidelines.htm
Embryos, Stem Cells, and Cloning				Protocol/Guidelines for Stem Cell Research/Regulation in Pakistan: http://www.pmrc.org.pk/stem_cell_protocol.htm
Philippines				
General	1. Philippine Health Research Ethics Board (PHREB): http://www.pchrd.dost.gov.ph/index.php?option=com_frontpage&Itemid=1 2. Department of Science and Technology (DOST): http://www.dost.gov.ph/ 3. Department of Health		DOST: 1. Administrative Order 001 Series 2007: Requirement for Review of All Research Involving Human Subjects/Participants 2. Administrative Order 001 Series 2008: Registration of all	PHREB: National Ethical Guidelines for Health Research (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf This document includes the following: a. Ethical Guidelines for International Collaborative Research

Country	Key Organizations	Legislation	Regulations	Guidelines
	4. Commission of Higher Education (CHED)		Ethics Review Committee at the PHREB CHED: Memo 34 Series 2007: Endorsement of DOST Administrative Order 001, Series 2007	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
Drugs and Devices	*Drugs*			
	Food and Drug Administration: 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
	Devices			
	Food and Drug Administration: http://www.bfad.gov.ph/			Various: http://www.bfad.gov.ph/default.cfm?page_id=826&parent=633
Genetic Research	Philippine Health Research Ethics Board (PHREB)			Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf
Embryos, Stem Cells, and Cloning	Philippine Health Research Ethics Board (PHREB)			Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf
Qatar				
General	Health Research Ethics Committee			Guidelines, Regulations, and Policies for Research Involving Human Subjects (2009): http://qatar-weill.cornell.edu/research/pdf/Ministry%20Guidelines.doc

Country	Key Organizations	Legislation	Regulations	Guidelines
Singapore				
General	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Ministry of Health National Medical Ethics Committee (NMEC) 3. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org 4. Singapore Medical Council (SMC): http://www.smc.gov.sg	Medical Registration Act (Cap. 174) (1985): http://statutes.agc.gov.sg/	MOH: Directive of June 25, 1998: Hospital Ethics Committees	NMEC: Ethical Guidelines on Research Involving Human Subjects (1997) BAC: Research Involving Human Subjects: Guidelines for IRBs (2004) MOH: 1. Governance Framework for Human Biomedical Research (2007) 2. Operational Guidelines for IRBs (2007) 3. Code of Ethical Practice in Human Biomedical Research (2009)
Drugs and Devices	*Drugs*			
	1. Health Sciences Authority of Singapore (HSA): http://www.hsa.gov.sg 2. Ministry of Health National Medical Ethics Committee (NMEC)	Medicines Act (1975): http://statutes.agc.gov.sg/	Medicines (Clinical Trials) Regulations (1998): http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/legislation.html#Medicine	HSA: 1. Singapore Guideline for Good Clinical Practice (1998) 2. Various Guidelines on Clinical Trials: http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials/guidelines.html NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)
	Devices			
	1. National Environment Agency, Centre For Radiation Protection And Nuclear Science 2. Health Sciences Authority: http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/about_medical_device.html	Radiation Protection Act: http://statutes.agc.gov.sg/	Radiation Protection Regulations: http://app2.nea.gov.sg/legislation.aspx	
Privacy/Data Protection	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	Computer Misuse Act (Cap. 50A) (1993): http://statutes.agc.gov.sg/		MOH: Advisory on Data Protection Standards for Electronic Medical Records (EMR) Systems (2002) BAC: Personal Information in Biomedical Research (2007)

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Health Sciences Authority 3. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	1. Medical (Therapy, Education, and Research) Act (1973): http://statutes.agc.gov.sg/ 2. Medicines Act (1975): http://statutes.agc.gov.sg/	Medicines (Clinical Trials) Regulations (1998): http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/legislation.html#Medicine	BAC: 1. Human Tissue Research (2002) 2. Human-Animal Combinations in Stem-Cell Research (2010)
Genetic Research	1. Ministry of Health National Medical Ethics Committee (NMEC) 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org			NMEC: Ethical Guidelines for Gene Technology (2001) BAC: Genetic Testing and Genetic Research (2005): http://www.bioethics-singapore.org/uploadfile/55211%20PMGT%20Research.pdf
Embryos, Stem Cells, and Cloning	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org/	Human Cloning and Other Prohibited Practices Act (2004): 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: 1. Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning (2002) 2. Donation of Human Eggs for Research (2008)
Taiwan				
General	Department of Health: http://www.doh.gov.tw/EN2006/index_EN.aspx	Medical Care Act, Articles 8, 78, 79, 80, and 98 (2009): http://www.doh.gov.tw/ufile/doc/Medical_Care_Act98.pdf	1. Enforcement Rules of the Medical Care Act (2006) (Chinese): http://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT0202.asp 2. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162	1. Ethical Guidelines for the Announcement of New Medical Knowledge or Research Report by Medical Institutes or Members (2001) http://www.doh.gov.tw/ufile/doc/10-醫療機構及醫事人員發布醫學新知或研究報告倫理守則.doc 2. Healthcare Institution Institutional Review Board Organization and Operations (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 Expedited Review (2006) (Chinese): http://www.doh.gov.tw/CHT2006/DM/DM2_p01.aspx?class_no=1&now_fod_list_no=4356&level_no=3&doc_no=43680 4. Human Research Ethics Policy Guidelines (2007): http://www.doh.gov.tw/ufile/doc/Human%20R

Country	Key Organizations	Legislation	Regulations	Guidelines
				esearch%20Ethics%20Policy%20Guidelines.pdf
Drugs and Devices	1. Department of Health: http://www.doh.gov.tw/EN2006/index_EN.aspx 2. Taiwan Food and Drug Administration: http://www.fda.gov.tw/	1. DOH: Medical Care Act, Articles 8, 78, 79, 80, and 98 (2009): http://www.doh.gov.tw/ufile/doc/Medical_Care_Act98.pdf 2. FDA: Pharmaceutical Affairs Act (2005): http://www.doh.gov.tw/EN2006/DM/DM1_p01.aspx?class_no=247&now_fod_list_no=247&level_no=1&doc_no=39739	DOH: 1. Enforcement Rules of the Medical Care Act (2006) (Chinese): http://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT0202.asp 2. Regulations on human trials (2009) http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162 FDA: 1. Guideline for Good Clinical Practice (2005) (Chinese): http://www.doh.gov.tw/CHT2006/DM/DM2_p01.aspx?class_no=2&now_fod_list_no=6726&level_no=3&doc_no=39852 2. Enforcement Rules of the Pharmaceutical Affairs Act (2006) (Chinese): http://www.doh.gov.tw/CHT2006/DM/DM2_p01.aspx?class_no=2&now_fod_list_no=8108&level_no=3&doc_no=454	FDA: 1. Operational Guidelines for Drug Clinical Trials (2002) 2. Guidelines for Informed Consent in Clinical Trials (2007) (Chinese): http://www.doh.gov.tw/ufile/doc/%e5%8f%97%e8%a9%a6%e8%80%85%e5%90%8c%e6%84%8f%e6%9b%b8%e5%85%a7%e5%ae%b9%e5%8f%83%e8%80%83%e7%af%84%e6%9c%ac.pdf
Privacy/Data Protection	Ministry of Justice: http://www.moj.gov.tw/mp095.html	Computer-Processed Personal Data Protection Law (1995): http://www.privacyexchange.org/legal/nat/omni/taiwan.html		
Human Biological Materials	Department of Health: http://www.doh.gov.tw/EN2006/index_EN.aspx	1. Medical Care Act (2009): http://www.doh.gov.tw/ufile/doc/Medical_Care_Act98.pdf 2. Human Biobank Management Act (2010): http://dohlaw.doh.gov.tw/Chi/ChiContent.asp?msgid=252&KeyWord	Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162	1.Good Tissue Practice (2002) (Chinese): http://www.doh.gov.tw/CHT2006/DM/DM2_p01.aspx?class_no=1&now_fod_list_no=4356&level_no=3&doc_no=40875 2. Guidelines for Collection and Use of Human Specimens for Research (2006): http://www.doh.gov.tw/ufile/doc/Human%20Research%20Ethics%20Policy%20Guidelines.pdf
Genetic Research	1. Department of Health: http://www.doh.gov.tw/EN2006/index_EN.aspx 2. Taiwan Food and Drug Administration: http://www.fda.gov.tw/	DOH: Human Biobank Management Act (2010): http://dohlaw.doh.gov.tw/Chi/ChiContent.asp?msgid=252&KeyWord	DOH: Regulations on Commercial Benefit Feedback of Human Biobank (Chinese): http://dohlaw.doh.gov.tw/Chi/NewsContent.asp?msgid=2977&KeyWord=	DOH: Guidance for Information Safety of Human Biobank (2010) (Chinese): http://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT0202.asp

Country	Key Organizations	Legislation	Regulations	Guidelines
	3. National Science Council: http://web.nsc.gov.tw/default.asp?mp=7			FDA: 1. Guidance for Informed Consent Forms for Pharmacogenetic Research (2005) (Chinese): http://www.doh.gov.tw/ufile/doc/200511_%e8%97%a5%e7%89%a9%e5%9f%ba%e5%9b%a0%e5%ad%b8%e7%a0%94%e7%a9%b6%e4%b9%8b%e5%8f%97%e6%aa%a2%e8%80%85%e5%90%8c%e6%84%8f%e6%9b%b8%e5%85%a7%e5%ae%b9%e5%8f%83%e8%80%83%e6%8c%87%e5%bc%95.pdf
Embryos, Stem Cells, and Cloning	Department of Health: http://www.doh.gov.tw/EN2006/index_EN.aspx	Artificial Reproduction Act (2007): http://dohlaw.doh.gov.tw/Chi/EngContent.asp?msgid=102&KeyWord=%A4H%A4u%A5%CD%B4%DE%AAk		Policy Instructions on the Ethics of Human Embryo and Embryonic Stem Cell Research (2007): http://www.doh.gov.tw/ufile/doc/Policy%20Instructions%20on%20the%20Ethics%20of%20Human%20Embryos.pdf
Tajikistan Note: For an overview of human subject protections in Tajikistan, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 9: http://www.unesco.ru/files/docs/shs/2007/publications/ethical_review_cis_book_kubar_english.pdf				
General	1. Ministry of Public Health 2. Republic Committee on Medical Ethics		1. Order of the Ministry of Public Health of the Republic Tajikistan of 10 March, 2005 No. 118: About the Assertion of the Normative Documents of Republic Committee on Medical Ethics (Russian) 2. Position of the Republic Committee on Medical Ethics, Affirmed by the Order of the Ministry of Public Health of Republic Tajikistan of March 10, 2005, No. 118 (Russian)	
Thailand				
General	1. National Research Council of Thailand (NCRT) (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 the Observance of Medical Ethics (2006)	MCT: 1. National Guideline for Ethical Research on Human Subjects (2002) 2. The Ethical Guidelines for Research on Human Subject in Thailand (2007)
Drugs and Devices	*Drugs*			
	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)

Country	Key Organizations	Legislation	Regulations	Guidelines
	Devices			
	Food and Drug Administration, Medical Device Control Division: http://www.fda.moph.go.th/eng/medical/pre.stm	1988 Medical Device Act: http://www2.fda.moph.go.th/Exporters/law/Document/Mdc/36-MEDICAL%20DEVICE%20ACT.htm		
Privacy/Data Protection	Office of the Information Commission	1. Official Information Act, B.E. 2540 (1997) 2. National Health Act, B.E. 2549 (2006)		
Vietnam				
General	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)	
Drugs and Devices	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 the CARIBBEAN				
Pan American Health Organization				
Drugs and Devices	Pan American Health Organization: http://www.paho.org/			Good Clinical Practices: Document for the Americas (2004): http://www.paho.org/english/ad/ths/ev/GCP-Eng-doct.pdf
Argentina				
General Note: Several provinces have their own regulations pertaining to human subjects research.	Ministry of Health: http://www.msal.gov.ar		1. Ministerial Resolution 1490/2007 Approving the Good Clinical Practice Guideline for Clinical Research with Human Beings 2. Ministerial Resolution 102/09: National Register for Clinical Trials	
Drugs and Devices Note: Several provinces have their own regulations pertaining to drug research.	*Drugs*			
	National Administration of Medications, Foods, and Medical Technology (ANMAT) (Spanish): http://www.anmat.gov.ar/index.asp		Provision 5330/97 on Good Research Practices in Clinical Pharmaceutical Studies (1997) (Spanish): http://infoleg.mecon.gov.ar/infolegInternet/anexos/45000-49999/46745/norma.htm	
	Devices			
	National Administration of Medications, Foods, and Medical Technology (ANMAT) (Spanish): http://www.anmat.gov.ar/index.asp		Provision 969/97 on the Regulation of Good Clinical Practice with Medical Technology Products (1997) (Spanish): http://www.anmat.gov.ar/Legislacion/ProductosMedicos/Disposicion_ANMAT_969-1997.pdf	
Privacy/Data Protection	National Personal Data Protection Authority (Spanish): http://www.jus.gov.ar/datospersonales/index.html	Personal Data Protection Act No. 25.326 (2000): http://www.protecciondedatos.com.ar/law25326.htm		
Bolivia				
General	1. Ministry of Health and Sport (MHS): http://www.sns.gov.bo/ 2. National Bioethics Committee (NBC)	1. Legal Decree No. 15.629 of July 18, 1978, Articles 147 and 148. 2. New Political Constitution of the State, Article 44 (2009): http://www.repac.org.bo/documento	Regulations on Public Health Research, Chapter V (1978)	MHS: Guidelines for the Development of Health Research and Ethical Norms (2002) NBC: Requirements for the Evaluation of

Country	Key Organizations	Legislation	Regulations	Guidelines
		s/NUEVA%20CPE.pdf		Research Projects
Drugs and Devices	1. Ministry of Health and Sport (MHS): http://www.sns.gov.bo/ 2. National Bioethics Committee (NBC)			MHS: Rule on Clinical Studies with Medicines or Products in the Clinical Investigation Stage (2005) NBC: Projects that Involve Drugs or Therapeutic Products
Brazil				
General	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html	CNS: Decree 98 830: Collection by Foreigners of Data and Scientific Materials in Brazil (1990) (Portuguese): http://ibama2.ibama.gov.br/cnia2/renima/cnia/lema/lema_texto/HTM-ANTIGOS/98830-90.HTM	CONEP: 1. Resolution 196/96: Rules on Research Involving Human Subjects (1996): http://conselho.saude.gov.br/docs/Resolucoes/reso_196_english.doc 2. Resolution 304/2000: On Complimentary Rules for Research Involving Indigenous People (2000): http://www.conselho.saude.gov.br/resolucoes/2000/Reso304.doc 3. Internal CONEP Regulation (2001) (Portuguese): http://www.conselho.saude.gov.br/Web_comissoes/conep/aquivos/conep/regimento.doc 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 5. Resolution 346/2005: On Multicenter Research (2005) (Portuguese): http://www.conselho.saude.gov.br/docs/Resolucoes/Reso346.doc	
Drugs and Devices	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Healthcare Surveillance Agency (Portuguese): http://www.anvisa.gov.br		CNS: Resolution 251/1997: On Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Diagnostic Tests (1997): http://www.ensp.fiocruz.br/etica/docs/cns/Res251i.pdf Resolution 404/2008: On Helsinki Declaration (2000) (Portuguese): http://conselho.saude.gov.br/resolucoes/reso_08.htm	
Human Biological Materials	National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html		CONEP: CNS Resolution 347/05 Approval Guidelines for Ethical Analysis of Research Projects Involving Storage of Materials or Use of Materials Stored by Previous Research (Portugese): http://conselho.saude.gov.br/docs/Reso347.doc	CONEP: Approval Guidelines for Ethical Analysis of Research Projects Involving Storage of Materials or Use of Materials Stored by Previous Research: Resolution 347/05 (2005)
Genetic Research	1. National Commission on Research Ethics (CONEP) (Portuguese): http://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/12847.html	CONEP: Resolution 340/2004 : On Research on Human Genetics (2004) (Portuguese): http://conselho.saude.gov.br/resolucoes/2004/Reso340.doc CTNBio: Decree No. 5,591, of November 22, 2005: http://www.ctnbio.gov.br/index.php/content/view/12848.html	CONEP: Approval Guidelines for Ethical Analysis and Conduct of Research Projects in the Special Thematic Area of Human Genetics: Resolution 340/04 (2004)
Embryos, Stem Cells, and Cloning	National Biosafety Technical Commission (Portuguese): http://www.ctnbio.gov.br	Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/12847.html	CTNBio: Decree No. 5,591, of November 22, 2005: http://www.ctnbio.gov.br/index.php/content/view/12848.html	
Chile				
General	Ministry of Health (Spanish): http://www.minsal.cl		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)	

Country	Key Organizations	Legislation	Regulations	Guidelines
			7. Resolution No. 2.085 of the Ministry of Health (2001)	
Drugs and Devices	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): http://www.ispch.cl/formularios/norma_tec/norm_tec_n_57.pdf	Ethical Guidelines for Clinical Trials with Pharmaceutical and Biological Products (2001)
Privacy/Data Protection		Law for the Protection of Private Life No. 19.628 (1999) (Spanish): http://www.bcn.cl/leyes/141599		
Genetic Research		1. Law No. 26.027 (2005): http://www.lyd.com/programas/legislativo/proyecto_ley_genoma_humano.pdf 2. Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2007)		
Embryos, Stem Cells, and Cloning		Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2007)		
Colombia				
General	Ministry of Social Protection (Spanish): www.minproteccionsocial.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430 (1993): http://www.unal.edu.co/dib/normas/etica_res_8430_1993.pdf	
Drugs and Devices	*Drugs*			
	National Institute of Drug and Food Surveillance (Spanish): http://www.invima.gov.co/		Resolution No. 2378 of 2008, Adapting Good Clinical Practices for Institutions that Conduct Research with Medicines in Human Beings	
	Devices			
	National Institute of Drug and Food Surveillance (Spanish):	Various: http://web.invima.gov.co/portal/faces/index.jsp?id=2283	Various: http://web.invima.gov.co/portal/faces/index.jsp?id=2284	Various: http://web.invima.gov.co/portal/faces/index.jsp?id=2285

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.invima.gov.co/			
Privacy/Data Protection		Constitution of Colombia, Article 15 (2003)		
Human Biological Materials	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter VI (1993)	
Genetic Research	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapter II (1993)	
Costa Rica				
General	Ministry of Health: http://www.ministeriodesalud.go.cr/	Law 5395, General Health Law, Articles 64-68 (1973) (Spanish): http://www.netsalud.sa.cr/leyes/libro1.htm		
Drugs and Devices	Ministry of Health (Spanish): www.ministeriodesalud.go.cr		Executive Decree 36068-S, 2010: Suspension of Filing Requirement *in vivo* Equivalence Studies	
Dominica				
General	Ministry of Health: http://www.dominica.gov.dm/cms/index.php?q=node/21			Guidelines for the Conduct of Research on Human Subjects (2005)
Grenada				
General	Windward Islands Research and Education Foundation (WINDREF)/St. George's University: http://www.sgu.edu/school-of-medicine/institutional-review-board.html			Guidelines for the Conduct of Research of WINDREF
Guatemala				
Drugs and Devices	Ministry of Public Health and Social Assistance		Ministerial Accord SP-M-466-2007, For the Regulation of Clinical Trials in Humans (2007)	
Honduras				
General			Health Code, Decree No. 65-91, Articles 175 and 176	
Jamaica				
General	Ministry of Health: http://www.moh.gov.jm			Ministry of Health Guidelines for the Conduct of Research on Human Subjects

Country	Key Organizations	Legislation	Regulations	Guidelines
				(2002)
Drugs and Devices	Ministry of Justice: http://www.moj.gov.jm/law	Food and Drugs Act: http://www.moj.gov.jm/laws/statutes/The%20Food%20and%20Drugs%20Act.pdf	Food and Drugs Regulations (1975): http://www.moj.gov.jm/laws/subsidiary/Food%20and%20Drugs%20Act.pdf and http://www.moj.gov.jm/laws/subsidiary/Food%20and%20Drugs%20Regulations,%201975.pdf	
Mexico				
General	Secretariat of Health: http://www.salud.gob.mx/ General Health Council: www.csg.salud.gob.mx/	General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2007): http://www.salud.gob.mx/unidades/cdi/legis/lgs/index-t5.htm As amended (2008): http://www.diputados.gob.mx/LeyesBiblio/ref/lgs/LGS_ref36_14jul08.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	
Drugs and Devices	*Drugs*			
	Federal Commission for Protection Against Health Risks: www.cofepris.gob.mx/	General Health Law, Title V, Chapter I, Articles 96-103: Health Research (2005): http://www.salud.gob.mx/unidades/cdi/legis/lgs/index-indice.htm	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	
	Devices			
	Federal Commission for Protection Against Health Risks: www.cofepris.gob.mx/		Regulation on the General Health Law in the Matter of Health Research, Title Four, Chapter III (1984) (Spanish): www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html	
Privacy/Data Protection	Federal Institute on Access to Public Information (Spanish): www.ifai.org.mx/	Federal Law for the Protection of Personal Data in the Possession of Private Individuals (2010) (Spanish): http://www.diputados.gob.mx/LeyesBiblio/pdf/LFPDPPP.pdf		
Human Biological Materials	Secretariat of Health: http://www.salud.gob.mx/	General Health Law, Title XIV, Articles 313-342 (2005): www.consejomexicano.org.mx/documents/lgs.pdf		
Genetic Research	National Institute of Genomic Medicine: http://www.inmegen.gob.mx/	1. Biosafety Law on Genetically Modified Organisms (2008	Regulation on the General Health Law in the Matter of Health	

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		(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	Research, Title Four, Chapter Two (1984) (Spanish): www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html	
Panama				
General	National Research Bioethics Committee (Spanish): http://www.gorgas.gob.pa/index.php?option=com_content&view=article&id=54&Itemid=103&lang=en		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%C2%BA%2024%20938%20%20Resolucion390.doc	Informed Consent (2006) (Spanish): http://www.gorgas.gob.pa/images/bioetica/Elementos%20del%20Consentimiento%20Informado.pdf
Human Biological Materials		Law 52 of 1995, Official Gazette 22,929		
Embryos, Stem Cells, and Cloning		Law 3 of 2004, Official Gazette 24,969		
Peru				
General	1. National Institute of Health (Spanish): http://www.ins.gob.pe/ 2. National Network of Research Ethics Committees	General Health Law No. 26842, Article 28 (1997) (Spanish)		
Drugs and Devices	1. 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 2. National Directorate of Drugs and Medical Devices: www.digemid.minsa.gob.pe		1. Supreme Decree No. 017-2006-SA: Regulation on Clinical Trials in Peru (2006): http://www.digemid.minsa.gob.pe/normatividad/DS017-2006SA.pdf 2. Supreme Decree No. 006-2007-SA: Modification of the Regulation on Clinical Trials in Peru (2007): http://www.digemid.minsa.gob.pe/normatividad/DS006-2007EP.pdf	
Privacy/Data Protection	National Directorate of Drugs and Medical Devices: www.digemid.minsa.gob.pe		Supreme Decree No. 002-2009-SA: Regulation on Legislative Decree No. 1072, Data Protection http://www.digemid.minsa.gob.pe/normatividad/DS%20002-2009-SA09.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
Uruguay				
Human Biological Materials	Ministry of Public Health (Spanish): http://www.msp.gub.uy/index_1.html		Circular No. 40/95 Establishing Rules Regarding the Donation of Organs and Tissues for Scientific and Therapeutic Purposes (1995)	
Venezuela				
General	1. National Fund on Science and Technology, Commission on Bioethics and Biosecurity (FONACIT) (Spanish): http://www.fonacit.gov.ve/bioetica.asp 2. Venezuelan Institute of Scientific Research, Bioethics Commission (IVIC)	Constitution, Article 46 (Spanish)	Resolution No. 48 (1998)	FONACIT: Code on Bioethics and Biosecurity (2002) IVIC: 1. Annex 1: General Ethical Issues in Research Involving Living Persons 2. Annex 2: Necessity of Establishing a Clear and Precise Study Protocol Before Starting Research 3. Informed Consent
Drugs and Devices	National Institute of Hygiene "Rafael Rangel" (Spanish)	Medicines Act, Articles 72 and 73		
Genetic Research	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				
General	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)
Drugs and Devices	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)
Egypt				
General	Medical Profession Union	Constitution of the Arab Republic of Egypt, Article 43: http://www.sis.gov.eg/En/Politics/Constitution/Text/0407030000000000001.htm	Professional Ethics Regulations: Conducting Medical Research on Human Beings Articles 52-61 (2003) *Access*: Scroll to bottom of page, click Download Code of Ethics: http://www.ems.org.eg/2_4/2_4_4/2_4_4.htm	
Drugs and Devices	Egyptian Drug Authority: http://www.eda.mohp.gov.eg/			
Human Biological Materials			Professional Ethics Regulations: Conducting Medical Research on Human Beings Articles 49-51 (2003): http://www.ems.org.eg/2_4/2_4_4/2_4_4.htm	
Ethiopia				
General	Ethiopian Science and Technology Commission, Health Department	Proclamation 60/1999, Section 21		National Health Research Ethics Review Guideline, Fourth Edition (2005): www.most.gov.et/Ethics%20Guideline.pdf
Drugs and Devices	Drug Administration and Control Authority		Drug Administration and Control Proclamation No. 176/1999, Article 21	
Human Biological Materials	Ethiopian Science and Technology Commission, Health Department			National Health Research Ethics Review Guideline, Fourth Edition, Chapter 9 (2005): www.most.gov.et/Ethics%20Guideline.pdf
Gambia				
Genetic Research	Medical Research Council (UK) The Gambia: http://www.mrc.gm/			Guidelines of the National DNA Bank (2001)
Kenya				
General	1. National Council for Science and Technology (NCST)	1. Science and Technology Act (2001)	NCST: Guidelines for Ethical Conduct of	

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	2. Ministry of Health (MOH)	2. HIV and AIDS Prevention and Control Act, Chapter 14 (2006)	Biomedical Research Involving Human Subjects in Kenya (2004): https://webapps.sph.harvard.edu/live/gremap/files/ke_NCST_guidelines.pdf	
Drugs and Devices	Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/	Pharmacy and Poisons Act, Chapter 244 (2001): http://www.pharmacyboardkenya.org/assets/files/cap_244_revised_2002_Latest.pdf	MOH: Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005)	
Human Biological Materials	Ministry of Health (MOH)		Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, page 44 (2005)	
Malawi				
General	1. National Research Council of Malawi (NRCM) 2. National Health Sciences Research Committee (NHSRC) 3. College of Medicine Research and Ethics Committee (COMREC): http://www.medcol.mw/ 4. Ministry of Health	1. Presidential Decree on 30th March 1974 2. Malawi Government Gazette, June 11, 1976, General Notice No. 398 3. Constitution of Malawi, Article 19(5) (1994)	NRCM: Procedures and Guidelines for the Conduct of Research in Malawi (2002)	NHSRC: 1. Operational Guidelines (2001) 2. Summary Guidelines for Writing Research Proposals (2001) COMREC: Research Guidelines (2004): http://www.medcol.mw/comrec/res.guidelines.php
Drugs and Devices	Pharmacy, Medicines, and Poisons Board of Malawi	Pharmacy, Medicines, and Poisons Act, Act 15 of 1988)		
Genetic Research	National Research Council of Malawi (NRCM)		Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002)	
Nigeria				
General	National Health Research Ethics Committee: http://nhrec.net/	National Health Bill 2009		National Code of Health Research Ethics (2007): http://www.nhrec.net/nhrec/NCHRE_10.pdf
Drugs and Devices	National Agency for Food, Drug Administration and Control (NAFDAC): http://www.nafdac.gov.ng/	Decree No. 15 of 1993	Good Clinical Practice Regulations (2009): http://apps.who.int/medicinedocs/documents/s17103e/s17103e.pdf	
Rwanda				
General	Ministry of Health, National Ethics Committee			Standard Operating Procedures (2009): http://www.moh.gov.rw/index.php?option=com_docman&task=doc_download&gid=126&Itemid=81

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South Africa				
General	1. Department of Health (DH): http://www.doh.gov.za 2. Medical Research Council of South Africa (MRC): http://www.mrc.ac.za 3. National Health Research Ethics Council: http://www.doh.gov.za/nhrec/	1. Constitution of South Africa, Article 12(2) (1996) 2. National Health Act No. 61, Chapter 9 (2003): http://www.doh.gov.za/docs/legislation-f.html		DH: Ethics in Health Research: Principles, Structures, and Processes (2004): http://www.doh.gov.za/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)
Drugs and Devices	1. Department of Health (DH): http://www.doh.gov.za 2. Medicines Control Council: http://www.mccza.com	Medicines and Related Substances Control Act, 101 of 1965 http://www.info.gov.za/view/DownloadFileAction?id=68096		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
Human Biological Materials	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		
Genetic Research	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za			MRC: Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.sahealthinfo.org/ethics/book2.htm
Embryos, Stem Cells, and Cloning	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za	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				
General	Federal Ministry of Health: http://www.fmoh.gov.sd/English/index.php			National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): http://sites.google.com/site/healthresearchlibrary/national-guidelines
Drugs and Devices	Federal Ministry of Health: http://www.fmoh.gov.sd/English/index.php	Act on Pharmaceuticals and Poisons (2001)		
Human Biological Materials	Federal Ministry of Health: http://www.fmoh.gov.sd/English/index.php	Human Organs and Tissues Transplant Legislation, Chapter 2, Articles 3 and 4 (1978)		

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Genetic Research	University of Khartoum, Institute of Endemic Diseases			Guidelines for Genetics Research on Sudanese Subjects (2005)
Tanzania				
General	1. Ministry of Health (MOH) 2. National Institute for Medical Research (NIMR), National Health Research Ethics Committee (NHREC): http://www.nimr.or.tz/ethical_guidelines.html 3. Tanzania Commission for Science and Technology (COSTECH): www.costech.or.tz	1. National Institute for Medical Research, Act of Parliament No. 23, of 1979: http://www.parliament.go.tz/Polis/PAMS/Docs/23-1979.pdf 2. Tanzania Commission for Science and Technology, Act No. 7 of 1986 3. Amendment of NIMR Act 1997, Tanzania Government Gazette, No. 675	NIMR: 1. Coordination of Health Research in Tanzania 2. Coordination of Formation of Institutional Health Research Committees to Formally Approve for Local Health Research 3. Coordination of Research in Tanzania	NHREC: 1. Guidelines on Ethics for Health Research in Tanzania (2001) 2. Brochure for Health Researchers in Tanzania (2006) COSTECH: COSTECH Guidelines on Research Permits and Clearance (2006)
Drugs and Devices	*Drugs*			
	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003): http://www.tfda.or.tz/tfdaact.pdf		
	Devices			
	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Medical Device Act (1988)		
Tunisia				
Drugs and Devices	Ministry of Public Health, Institut Pasteur: www.pasteur.tn		Conditions of Contract and Specifications Related to Medical or Scientific Experimentation of Medicines Intended for Humans	Disposals and Director's Principles Related to Good Practices in Clinical Trials
Uganda				
General	Uganda National Council on Science and Technology (UNCST): http://www.uncst.go.ug/			National Guidelines for Research Involving Humans as Research Participants (2007): http://uncst.go.ug/site/documents/rihp_guide.pdf
Drugs and Devices	National Drug Authority: http://www.nda.or.ug/	National Drug Authority Statute (1993)		
Zimbabwe				
General	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw	1. Government Notice Act (1974) 2. Research Act (1986)		1. Guidelines for Researchers and Ethics Review Committees in Zimbabwe (2004) 2. Conducting Health Research in Zimbabwe: What Researchers Need to Know (2004)

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Drugs and Devices	*Drugs*			
	Medicines Control Authority of Zimbabwe: http://www.mcaz.co.zw/	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 (2010): http://www.mcaz.co.zw/trials/GUIDELINES%20FOR%20GCP%202010%20Zimbabwe.pdf
	Devices			
	Medicines Control Authority of Zimbabwe: http://www.mcaz.co.zw/devices.html		Medicines and Allied Substances Control (Condom) Regulations (2005): http://www.mcaz.co.zw/Condom%20Regulations.pdf	
Human Biological Materials	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw			Ethical Guidelines on the Collection of Blood Samples for Research (1999)