International Compilation of Human Research Standards

2013 Edition

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

PURPOSE

The International Compilation of Human Research Standards enumerates over 1,000 laws, regulations, and guidelines that govern human subjects research in 104 countries, as well as the standards from a number of international and regional organizations. This Compilation was developed for use by researchers, IRBs/Research Ethics Committees, sponsors, and others who are involved in human subjects research around the world.

As in the past, in-country authorities around the world provided updates or confirmations of the accuracy of existing listings – see page 123. One new country is featured in the 2013 edition: Ecuador.

ORGANIZATION

The Table of Contents is found on page 3. For each country, the standards are categorized by rows as:

1. General, i.e., applicable to most or all types of human subjects research
2. Drugs and Devices
3. Research Injury
4. Privacy/Data Protection (also see Privacy International reports: https://www.privacyinternational.org/reports)
5. Human Biological Materials
6. Genetic (also see the HumGen International database: http://www.humgen.umontreal.ca/int/)
7. Embryos, Stem Cells, and Cloning

These seven categories often overlap, so it may be necessary to review all standards to obtain a necessary 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 – encompasses statutes, statutory instruments, and legislative decrees, as well as any pertinent constitutional provisions.
3. Regulations – refer to instruments that are created and issued in the name of governmental administrative bodies.
4. Guidelines – pertain to non-binding instruments.

The year of the document's most recent version (or date initial approval, if never amended) is indicated in parenthesis when that information is available, unless the date is part of the document's title, e.g., Act 46/2012.

HOW TO ACCESS A DESIRED DOCUMENT

Documents can be accessed in five possible ways:

1. Link to the web address (URL).
2. Search for document at the website of the agency listed in the Key Organizations column.
3. Perform an Internet search on the document title.
4. Request a 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 International Compilation of Human Research Standards does not include standards from the state or local levels. Nor does the Compilation cover:

1. Laws, regulations, or guidelines specific to research integrity, clinical bioethics, 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, drafts, 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: 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 requested to review listings to assure their accuracy and completeness, researchers and other individuals should check with local authorities and/or research ethics committees before commencing 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: 1. Operational Guidelines for Ethics Committees that Review Biomedical Research (2000): http://whqlibdoc.who.int/hq/2000/TDR_PRD_ETHICS_2000.1.pdf 2. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants: http://whqlibdoc.who.int/publications/2011/9789241502948_eng.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/products/guidelines/efficacy/article/efficacy-guidelines.html

Country	Key Organizations	Legislation	Regulations	Guidelines
				WHO: 1. Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation (2002): http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf 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 14155:2011: http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=45557
Research Injury	1. International Conference on Harmonization (ICH): http://www.ich.org/ 2. Council for International Organizations of Medical Sciences: http://www.cioms.ch/			ICH: E6 Good Clinical Practice: Consolidated Guidance, Section 5.8 (1996): http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html CIOMS: International Ethical Guidelines for Biomedical Research Involving Human Subjects, Guideline 19 (2002)
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

Country	Key Organizations	Legislation	Regulations	Guidelines
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: 1. Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens (1997): www.who.int/csr/emc97_3.pdf 2. Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research (2003): http://www.who.int/reproductive-health/hrp/tissue.pdf IATA: Infectious Substances and Diagnostic Specimens Shipping Guidelines (2005) ISBER: Best Practices for Repositories I: Collection, Storage and Retrieval of Human Biological Materials for Research (2005)
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.	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 2. National Defence 3. Correctional Service of Canada			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition (2010): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/ 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
Drugs and Devices	*Drugs*			
	1. Health Canada, Therapeutic Products Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index		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	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 11: Clinical Trials (2010)
	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	
Research Injury	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, 2nd Edition, Article 3.2(j) (2010):

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Privacy/Data Protection Note: Each of the Canadian provinces and territories has also enacted privacy legislation.	1. Office of the Privacy Commissioner of Canada (OPC): http://www.privcom.gc.ca/index_e.asp 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 3. Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html	1. Privacy Act, Sections 7-8 (1983): http://www.privcom.gc.ca/legislation/02_07_01_e.asp 2. Personal Information Protection and Electronic Documents Act, Articles 5 and 7 (2001): http://www.privcom.gc.ca/legislation/02_06_01_e.asp	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, 2nd Edition, Chapter 5: Privacy and Confidentiality (2010) 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, 2nd Edition, Chapter 12: Human Tissue (2010)
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, 2nd Edition, Chapter 13: Human Genetic Research (2010)
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, 2nd Edition, Chapter 12, Section F (2005) CIHR: Updated Guidelines for Human Pluripotent Stem Cell Research (2007): http://www.cihr-irsc.gc.ca/e/34460.html

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United States Note: All of the following departments and agencies subscribe to subpart A, often referred to as the Common Rule (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
	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	
	Department of Defense, Human and Animal RDT&E Protection Programs: 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 (2011): http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf *Army:* Army Regulation 70-25: http://ahrpo.amedd.army.mil/Regulations/armyregs.cfm *Navy:* 1. SECNAVINST 3900.39 series: http://www.fas.org/irp/doddir/navy/secnavinst/3900_39d.pdf 2. Marine Corps Order: 3900.18 series: http://www.med.navy.mil/bumed/humanresearch/Documents/HRPP/Resources/ReferenceMaterial/MCO%203900.18%20-%2021%20Jan%202011.pdf	

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			Air Force: AFI 40-402 (2005): http://www.e-publishing.af.mil/shared/media/epubs/AFI40-402.pdf *Office of the Under Secretary of Defense for Personnel and Readiness:* Research Regulatory Oversight Office, Human Research Protection Program Operating Instruction: http://home.fhpr.osd.mil/resources/policies/policies.aspx *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.humansubjects.energy.gov		1. 10 CFR 745 (1991), Subpart A 2. DOE Order 443.1B 3. DOE 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		
	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	

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	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	
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 (2010): http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm	1. 21 CFR 50 (2011) 2. 21 CFR 312 (2011) 3. 21 CFR 56 (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. Drug-Specific: Numerous: http://www.fda.gov/Drugs/GuidanceCompliance

Country	Key Organizations	Legislation	Regulations	Guidelines
		Provisions added by the FDA Safety and Innovation Act of 2012: http://www.gpo.gov/fdsys/pkg/BILLS-112s3187enr/pdf/BILLS-112s3187enr.pdf 2. Public Health Service Act, 42 USC Section 262 (1998): http://www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm		eRegulatoryInformation/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 (2010): http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm	1. 21 CFR 50 (2011) 2. 21 CFR 56 (2011) 3. 21 CFR 807, Subpart E (2010) 4. 21 CFR 812 (2010) 5. 21 CFR 814 (2011)	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
Research Injury	Same as "General," listed above.		Sections 116(a)(6) and (7) of Subpart A, listed above under "General."	
	Department of Defense, Regulatory Affairs: www.dtic.mil/biosys/org/regulatory.html		DoD Directive 3216.02, paragraph 5.3.4 (2002) *Air Force Instruction 40-402*, Protection of Human Subjects in Biomedical and Behavioral Research (2000)	
	Department of Veterans Affairs: 1. Office of Research Oversight (ORO): www1.va.gov/oro/ 2. Office of Research and Development: www.research.va.gov	38 CFR 17.85: Treatment of Research-Related Injuries to Human Subjects	Handbook 1200.5, Appendix F, Paragraph 2a(11)	
Privacy/Data Protection	Department of Health and Human Services: 1. National Institutes of Health (NIH): http://privacyruleandresearch.nih.gov/ 2. 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	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:	DHHS: Various on the Privacy Rule: http://privacyruleandresearch.nih.gov/

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Confidential Information Protection and Statistical Efficiency Act (2002): http://www.eia.doe.gov/oss/CIPSEA.pdf	http://www.hhs.gov/ocr/privacy/hipaa/administrative/index.html	
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 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			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 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://oba.od.nih.gov/rdna/nih_guidelines_oba.html

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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 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: 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) *Access:* http://stemcells.nih.gov/policy

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: http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1289 3. Ethics Review process under FP7 http://cordis.europa.eu/fp7/ethics_en.html 4. European Commission Group on Ethics in Science and New Technologies (EGE): http://ec.europa.eu/european_group_ethics/index_en.htm			European Commission Ethics Review: Various: http://cordis.europa.eu/fp7/ethics_en.html EGE: Ethical Aspects of Clinical Research in Developing Countries (2003): http://ec.europa.eu/bepa/european-group-ethics/docs/avis17_en.pdf 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 to the Convention on Human Rights and Biomedicine 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
Drugs and Devices	*Drugs*			
	1. European Commission, SANCO Pharmaceuticals Unit: http://ec.europa.eu/health/index_en.htm 2. European Medicines Agency (EMA): http://www.ema.europa.eu/	EC: 1. Directive 2001/20/EC: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF 2. Directive 2005/28/EC: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_091/l_09120050409en00130019.pdf	EC: EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/health/documents/eudralex/vol-10/index_en.htm	EMA: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997) EC: EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/health/documents/eudralex/vol-10/index_en.htm
	Devices			
	European Commission, SANCO Cosmetics and Medical Devices: http://ec.europa.eu/health/medical-	1. Directive 93/42/EEC Concerning Medical Devices: http://eur-		Various: http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
	devices/index_en.htm	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=OJ:L:1998:331:0001:0037:EN:PDF 3. Directive 2007/47/EC of the European Parliament and of the 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		
Research Injury	1. Council of Europe, Bioethics Division (CoE): http://www.coe.int/bioethics 2. European Medicines Agency (EMA): http://www.emea.europa.eu/	Clinical Trials Directive 2001/20/EC, Articles 3.2.f, 6.3.h, and 6.3.i: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF		CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, 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 to the Convention on Human Rights and Biomedicine concerning Biomedical Research, Article 13, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG
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://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf		CoE, Public and Private Law Division: 1. Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=108&CL=ENG 2. Recommendation No. R (97) 5 on the Protection of Medical Data (1997)

Country	Key Organizations	Legislation	Regulations	Guidelines
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://ec.europa.eu/bepa/european-group-ethics/welcome/index_en.htm 4. European Medicines Agency (EMEA): http://www.ema.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://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0023:EN:HTML		EGE: Ethical Aspects of Human Tissue Banking (1998) EMA: Concept Paper on the Development of a Guideline on Biobanks Issues Relevant to Pharmacogenetics (2005) CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Recommendation Rec (2006) 4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin (2006): http://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75
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 3. 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 4. Recommendation Rec (2006)4 of the Committee of Ministers to Members States on Research on Biomedical

Country	Key Organizations	Legislation	Regulations	Guidelines
				Materials of Human Origin (2006)4: 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/bepa/european-group-ethics/welcome/index_en.htm	EC: Decision No. 1982/2006/EC: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_412/l_41220061230en00010041.pdf		EGE: 1. Opinion No. 15 - Ethical Aspects of Human Stem Cell Research and Use (2000): http://ec.europa.eu/bepa/european-group-ethics/docs/avis15_en.pdf 2. Opinion No. 22 - The Ethics Review of hESC FP7 Research Projects (2007): http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_22_final_follow_up_en.pdf 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
Commonwealth of Independent States				
General	Interparliamentary Assembly: http://www.iacis.ru/html/index-eng.php			1. 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 2. Recommendations on Ethical and Legal Regulation and Safety of Genetic Medical Technologies in the CIS Member Nations (2007) (Russian): http://www.bankzakonov.com/republic_pravo_by_2010/blockj3/rtf-e8k3w4.htm 3. Declaration on Ethical Principles of Science Activity (2012): -- Final version in Russian: http://www.iacis.ru/html/index.php?id=22&nid=4&pag=806&find=%C4%E5%EA%EB%E0

Country	Key Organizations	Legislation	Regulations	Guidelines
				%F0%E0%F6%E8%FF%20%EE%E1%20%FD%F2%E8%F7%E5%F1%EA%E8%F5%20%EF%F0%E8%ED%F6%E8%EF%E0%25 -- English version with slight differences from final version: http://unesdoc.unesco.org/images/0021/002116/211662m.pdf
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.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/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 (2011): http://www.ris.bka.gv.at/Dokumente/Erv/ERV_2002_1_120/ERV_2002_1_120.pdf 2. Hospitals Act (2011) (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: http://www.ethikkommissionen.at
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/en/ages-austrian-agency-for-health-and-food-safety/ 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/
	Devices			
	Same as for Drugs.	Medical Devices Act (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen		Various: http://www.basg.at/medizinprodukte/formulare/klinische-pruefung/

Country	Key Organizations	Legislation	Regulations	Guidelines
		&Gesetzesnummer=10011003		
Research Injury	1. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/en/ages-austrian-agency-for-health-and-food-safety/ 2. Austrian Federal Office for Safety in Health Care: http://www.basg.at/en/austrian-federal-office-for-safety-in-health-care/	Austrian Drug Law, Article 32 (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True Austrian Medical Devices Law, Article 47 (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003&ShowPrintPreview=True		
Privacy/Data Protection Note: The Austrian states also 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		
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 3. Biobanks for Medical Research - Amendments to the Bioethics Commission Report of May 2007 (2011): http://www.bka.gv.at/DocView.axd?CobId=42719
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	1. Ministry of Health (German):	Reproductive Medicine Act		Bioethics Commission:

Country	Key Organizations	Legislation	Regulations	Guidelines
Cells, and Cloning	http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	(2010) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10003046&ShowPrintPreview=True		Research on Human Embryonic Stem Cells (2009) (German): http://www.bundeskanzleramt.at/DocView.axd?CobId=34240
Belarus 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.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/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 3. Methodological Guidelines of Health Ministry (2000)
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

Country	Key Organizations	Legislation	Regulations	Guidelines
	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): 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	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
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 (SSFM)	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 SSFM: 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)	
Research Injury		Law Relating to Experimentation on Humans, Chapter XVII (Responsibility and Insurance) Article 29 (French) (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		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/INSTITUTIONSAPPARE

Country	Key Organizations	Legislation	Regulations	Guidelines
		Allocation of Organs of Human Origin 3. Act on the Removal and Transplantation of Organs (2006) (French): http://www.staatsbladclip.be/lois/2006/08/28/loi-2006022815.html 4. 2007 Amendment (French): http://www.staatsbladclip.be/lois/2007/04/13/loi-2007022504.html		NTEES1_MENU/HOGEGEZONDHEIDSRAAD1_MENU/ADVIEZENENAANBEVELINGEN1_MENU/ADVIEZENENAANBEVELINGEN1_DOCS/7691_SQ_COMMUNS_2007_FR.PDF
Embryos, Stem Cells, and Cloning	1. Federal Public Service: www.health.fgov.be 2. Federal Commission for Medical and Scientific Research on Embryos in Vitro	1. Royal Decree Fixing the Criteria for the Program Applicable to the Care Programs 'Reproductive Medicine' (15/02/1999) 2. Act on Research on Embryos in Vitro (2003): 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				
General		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (2007): 2. Additional Protocol Concerning Biomedical Research, CETS No. 195 (2007)		
Drugs and Devices	*Federation of Bosnia and Herzegovina:* 1. Ministry of Health: http://www.fmoh.gov.ba/ 2. Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Law on Drugs No. 51/01: http://www.almbih.gov.ba/_doc/regulative/fbih/Zakon_o_lijekovima-sluzbene_novine_FBiH_broj_51-01.pdf 2. Law on Changes and Amendments of the Law on Drugs No. 29/05:	1. Regulation about Clinical testing of IMP and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf 2. Regulation about Medical Devices (2010): http://www.almbih.gov.ba/_doc/regul	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.almbih.gov.ba/_doc/regulative/fbih/Zakon_o_lijekovima-sluzbene_novine_FBiH_broj_29-05.pdf	ative/pravilnik_ms_bos.pdf 3. Standards of GCP in Conducting CTs (2012): http://www.almbih.gov.ba/_doc/regulative/Smjernice_dobre_klinicke_prakse-bo.pdf	
	Republic of Srpska: 1. Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx 2. Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Law on Drugs No. 19/01: http://www.almbih.gov.ba/_doc/regulative/rs/Zakon_o_lekovima.pdf 2. Law on Changes and Amendments of Law on Drugs No. 34/08: http://www.almbih.gov.ba/_doc/regulative/rs/ID_Zakona_o_lijekovima_34_08.pdf	1. Regulation about Clinical testing of IMP and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf 2. Regulation about Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_ms_bos.pdf 3. Standards of GCP in Conducting CTs (2012): http://www.almbih.gov.ba/_doc/regulative/Smjernice_dobre_klinicke_prakse-bo.pdf	
Research Injury	*Federation of Bosnia and Herzegovina:* Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.al.rs.ba	Medicinal Products and Medicinal Devices Act, Article 116: http://www.almbih.gov.ba/_doc/regulative/zakon_o_lijekovima_bih_bos.pdf	Rules on Clinical Trials and Medical Devices	
	Republic of Srpska: Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/	Law on Health Insurance of the Republic of Srpska, Official Gazette Republic of Srpska No. 51/01, 70/01, 51/03, 17/08, 1/09		
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.azlp.gov.ba/images/PropisiBOS/Zakon_o_%20zastiti_licnih_podataka_u_BiH_BOS.pdf		
Embryos, Stem Cells and Cloning		Law on Blood and Blood Products (2010): http://www.fbihvlada.gov.ba/bosanski/zakoni/2010/zakoni/8bos.htm Law on Transplantation of Organs and Tissues (2009): http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-		

Country	Key Organizations	Legislation	Regulations	Guidelines
		transplantaciji-organa-i-tkiva-u-svrhu-lijecenja		
Bulgaria				
General	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	1. Constitution of the Republic of Bulgaria, Article 29 (2007) 2. Oviedo Convention on Human Rights and Biomedicine (2001) 3. Law Ratifying the Additional Protocol on Biomedical Research (2006) 4. Law on Medicinal Products in Human Medicine (2011) 5. Healthcare Act, Articles 199 and 200 (2012)		
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 (2011), Chapter 4	MOH: Regulation No. 31 on the Rules for GCP (2012)	
	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
Research Injury	Bulgarian Drug Agency: http://en.bda.bg/index.php	Law on Medicinal Products in Human Medicine, Chapter 4, Articles 91 and 92 (2011): http://en.bda.bg/images/stories/documents/legal_acts/213566177121620 1147.pdf	Regulation 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice, Section 5.8 (2012): http://bda.bg/images/stories/documents/regulations/naredbi/naredba31_pril 1.pdf	
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	

Country	Key Organizations	Legislation	Regulations	Guidelines
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)		
Croatia				
General		1. Patient Protection Act, Article 20 (Croatian): http://narodne-novine.nn.hr/clanci/sluzbeni/313593.html 2. Oviedo Convention on Human Rights and Biomedicine (2003)		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
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: 1. Ordinance on Clinical Trials and Good Clinical Practice (2007) (Croatian): http://narodne-novine.nn.hr/clanci/sluzbeni/329774.html 2. Rule Book on Amendments to Ordinance on CTs and GCP: http://narodne-novine.nn.hr/clanci/sluzbeni/2010_11_127_3314.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		
Research Injury	1. Agency for Medicinal Products and Medical Devices of Croatia: http://www.almp.hr/ 2. Ministry of Health: http://www.zdravlje.hr/	1. Law on Drugs (2007) 2. Law on Mandatory Health Insurance from 2008: http://www.zdravlje.hr/ministarstvo/zakonodavstvo	Rules about Clinical Trials and Good Clinical Practice, Articles 12 and 13: http://narodne-novine.nn.hr/clanci/sluzbeni/329774.html	
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	Ministry of Health: http://www.zdravlje.hr/	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)		

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (2007) 3. Medical Fertilization Act: http://narodne-novine.nn.hr/clanci/sluzbeni/2009_07_88_2150.html 4. Law about Blood and Blood Products from 2006: http://www.zdravlje.hr/ministarstvo/zakonodavstvo/		
Cyprus				
General		1. The Safeguarding and Protection of Patients' Rights Law (2004): http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/6960B7A5AA76C4A3C22571C9002B99F0?OpenDocument 2. Law No. 31 (III)/2001: Oviedo Convention on Human Rights and Biomedicine		
Drugs and Devices	1. Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/moh/moh.nsf/pharm_en/pharm_en?OpenDocument 2. Ministry of Health, National Bioethics Committee: http://www.moh.gov.cy	Law for Good Clinical Practice (2004)		
Research Injury	Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/moh/moh.nsf/pharm_en/pharm_en?OpenDocument	Legislation Concerning Medicinal Products of Human Use (Good Clinical Practice) No. 452/2004, Regulation No. 11 (8)		
Privacy/Data Protection	Commissioner's Office for the Protection of Personal Data: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/index_en/index_en?opendocument	1. Processing of Personal Data (Protection of Individuals) Law of 2001: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/138(I)-2001_en.pdf 2. Amended in 2003: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697		

Country	Key Organizations	Legislation	Regulations	Guidelines
		e70c0046f7759c2256e8c004a0a49/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. Oviedo Convention on Human Rights and Biomedicine (2001) 2. Act No. 130/2002 Collection on the Research and Development Support as Amended 3. Act No. 372/2011 on Healthcare Services 4. Act. No. 373/2011 on Specific Healthcare Services		
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
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
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. Act of 26 April 2006 on Research on Human Embryonic Stem Cells No. 227/2006 Sb. (Coll.): http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Czech-Rep/page.aspx/165		
Denmark 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 Medicinal Products in Humans (2004)	Guideline on Informed Consent from Patients in Biomedical Trials (2000)
Research Injury	Danish Patient Insurance Association: http://www.patientforsikringen.dk/en.aspx	1. Liability for Damages Act (2007): http://www.patientforsikringen.dk/en/Love-og-Regler/Lov-om-klage-og-erstatningsadgang/Behandlingsskad		

Country	Key Organizations	Legislation	Regulations	Guidelines
		er.aspx 2. Danish Act on the Right to Complain and Receive Compensation within the Health Service (2009): http://www.patientforsikringen.dk/en/Love-og-Regler/Lov-om-klage-og-erstatningsadgang/Lægemiddelskader.aspx		
Privacy/Data Protection	1. Danish Council of Ethics (DCE): http://www.etiskraad.dk/sw293.asp 2. Danish Data Protection Agency (DPA): http://www.datatilsynet.dk/english/	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)		
Genetic Research		Act on the DNA Profile Register, Act No. 434 of 31 May 2000		
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				
General	Estonian Council on Bioethics	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

Country	Key Organizations	Legislation	Regulations	Guidelines
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.sam.ee/en/clinical-trials-medicinal-products-estonia	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) 2. Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 (2005): http://www.sam.ee/627	
Research Injury	1. Minister of Social Affairs (MSA): http://www.sm.ee/eng.html 2. Estonian Health Insurance Fund: http://www.haigekassa.ee/eng/	Medicinal Products Act, Section 90: http://www.legaltext.ee/et/andmebaas/tekst.asp?loc=text&dok=X90009k2&keel=en&pg=1&ptyyp=RT&tyyp=X&query=ravimiseadus	Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 of the Minister of Social Affairs of (2005): http://www.sam.ee/en/clinical-trials-medicinal-products-estonia	
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. National Committee on Medical Research Ethics (TUKIJA):	Medical Research Act No. 488/1999 (amended 295/2004 and 794/2010): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488	MSAH: 1. Decree on the National Committee on Medical Research Ethics No. 820/2010	TUKIJA: 1. Checklist for Researchers and Members of Ethics Committees (2009) (Finnish): http://www.tukija.fi/fi/julkaisut/ohjeet_ja_suositukset

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	http://www.tukija.fi/en 3. National Advisory Board on Research Ethics (TENK): http://www.tenk.fi/en/index.html		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. 841/2010 5. Decree on Fees, No. 840/2010	2. Operating Procedures of National Committee on Medical Research Ethics (2010): http://www.tukija.fi/en/publications
Drugs and Devices	*Drugs*			
	1. Finnish Medicines Agency (FIMEA): http://www.fimea.fi/ 2. Ministry of Social Affairs and Health (MSAH): http://www.stm.fi	Medicines Act No. 395/1987 (several amendments) http://www.finlex.fi/fi/laki/smur/1987/19870395	FIMEA: 1. Several Decrees: http://www.finlex.fi/fi/laki/smur/1987/19870395#nojalla 2. Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 1/2007 http://www.fimea.fi/healthcare_professionals/clinical_drug_trials	
	Devices			
	National Supervisory Authority for Welfare and Health (VALVIRA): http://www.valvira.fi/en/licensing/medical_devices	Medical Devices Act No. 629/2010: http://www.finlex.fi/fi/laki/kokoelma/2010/20100085.pdf	VALVIRA Various: http://www.valvira.fi/en/licensing/medical_devices/legislation	
Research Injury	1. Finnish Patient Insurance Centre (Finnish): http://www.potilasvakuutuskeskus.fi/www/page/pvk_www_2181 2. Finnish Pharmaceutical Insurance Pool (Finnish): http://www.laakevahinkovakuutuspooli.fi/www/page/lvp_www_2090	Patient Injuries Act No. 585/1986 (amended several times): http://www.finlex.fi/fi/laki/ajantasa/1986/19860585		Pharmaceutical Injuries Insurance: General Terms and Conditions (2007) http://www.laakevahinkovakuutuspooli.fi/www/page/lvp_www_3194
Privacy/Data Protection	Office of the Data Protection Ombudsman: http://www.tietosuoja.fi/1560.htm	Personal Data Act No. 523/1999: http://www.finlex.fi/fi/laki/ajantasa/1999/19990523		
Human Biological Materials	National Supervisory Authority for Welfare and Health (Finnish): http://www.valvira.fi/luvat/kudosluvat	Act on the Medical Use of Human Organs ,Tissues and Cells No. 101/2001 (amended 547/2007): http://www.finlex.fi/fi/laki/ajantasa/2001/20010101		National Supervisory Authority for Welfare and Health (Finnish): http://www.valvira.fi/luvat/kudosluvat/lupa_elimien_kudoksien_ja_solujen_laaketieteelliseen_kayttoon

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research	1. National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en 2. Board for Gene Technology http://www.geenitekniikanlautakunta.fi/en	1. Medical Research Act No. 488/1999 (amended 295/2004 and 794/2010): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488 2. Gene Technology Act No. 377/1995		
Embryos, Stem Cells, and Cloning	1. National Supervisory Authority for Welfare and Health: http://www.valvira.fi/luvat/ 2. National Advisory Board on Research Ethics (TENK): http://www.tenk.fi/en/index.html 3. National Committee on Medical Research Ethics (TUKIJA) http://www.tukija.fi/en 4. National Advisory Board on Social Welfare and Health Care Ethics (ETENE): http://www.etene.fi/en	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002) 2. Medical Research Act No. 488/1999 (amended 295/2004 and 749/2010): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488 3. Act on Assisted Fertility Treatments No. 1237/2006 http://www.finlex.fi/fi/laki/ajantasa/2006/20061237		Report on Stem Cells, Cloning, and Research (2005): http://www.tukija.fi/en/publications/publications

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. Law No. 2012-300 of 5 March 2012 Regarding Research Involving Humans (French): http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025441587&dateTexte=&categorieLien=id	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
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)

Country	Key Organizations	Legislation	Regulations	Guidelines
Research Injury	French Health Products Safety Agency (AFSSAPS): http://agmed.sante.gouv.fr/ang/indang.htm	Law No. 2012-300 of 5 March 2012 Regarding Research Involving Humans (French): http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025441587&dateTexte=&categorieLien=id		
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 "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)		CCNE: Commercialization of Human Stem Cells and Other Cell Line (2006)

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Law No. 2012-300 of 5 March 2012 Regarding Research Involving Humans (French): http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025441587&dateTexte=&categorieLien=id		
Georgia 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.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf				
General		1. Oviedo Convention on Human Rights and Biomedicine ETS No.164 (2001) 2. Additional Protocol to the Convention's on Human Rights and Biomedicine, concerning Biomedical Research, ETS No. 195 (2010) 3. Law on Health Care, Chapter XIX (1997)		
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) Law of Drug and Pharmaceutical Activity (2008)	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)
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
Embryos, Stem Cells, and Cloning		1. Law on Health Care, Article 142 (1997) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning ETS No. 168 (2001)		
Germany 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			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
	2. Central Ethics Commission of the BÄK (German): www.zentrale-ethikkommission.de/ 3. Working Group of the Medical Ethics Committees in Germany (German): http://www.ak-med-ethik-komm.de/ 4. German Ethics Council (NER): http://www.ethikrat.org/en_index.php 5. Federal Ministry of Health (BMG): http://www.bmg.bund.de/cln_041/nn_600110/EN/Home/homepage__node,param=.html__nnn=true			
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 (2009): http://www.bmg.bund.de/fileadmin/redaktion/pdf_gesetze/amg-engl.pdf	BfArM : 1. Promulgation on the Principles of the Conduct of Clinical Trials of Drugs According to the Rules (1987) 2. Second Promulgation on the Clinical Trial of Drugs in Human (1997) 3. Regulation for the Application of Good Clinical Practice of Clinical Medications for Human Use (2006) BMBF: Principles and Responsibilities Related to Clinical Studies (2003): 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	
Research Injury		Medicinal Products Act, Sections Section 40, Sub-section 3 (2009):		

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.bmg.bund.de/fileadmin/redaktion/pdf_gesetze/amg-engl.pdf		
Privacy/Data Protection Note: The 16 German states also have data protection laws (German): http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html	Federal Commissioner for Data Protection and Freedom of Information: http://www.bfdi.bund.de/cln_030/nn_533554/EN/Home/homepage__node.html__nnn=true	Federal Data Protection Act, as Amended (2003): http://www.bfdi.bund.de/cln_029/nn_535764/EN/DataProtectionActs/DataProtectionActs__node.html__nnn=true		
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):	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)

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.pei.de/cln_048/nn_159030/EN/institute-en/institut-node-en.html?__nnn=true			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/infos-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				
General	National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3			1. Template Code of Research Ethics for Biological Sciences (2008): http://www.bioethics.gr/media/pdf/recommendations/research_ethics_code.pdf 2. A Guide for Research Ethics Committees for Biological Research (2008):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.bioethics.gr/media/pdf/recommendations/guide.pdf
Drugs and Devices	1. National Organization for Medicines (NOM): http://www.eof.gr/web/guest/home, then click on "EN" in upper left hand section for English 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. 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) 2. Act 3418/2005 Code on Medical Ethics (Greek): http://www.bioethics.gr/media/pdf/biolaw/human/code_of_practice_new_gr.pdf	1. Ministerial Decision ΔΥΓ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC: http://www.bioethics.gr/media/pdf/biolaw/human/clinical_trials_directive_gr.pdf 2. Ministerial Decision ΔΥΓ 3 α/79602/2007: Harmonization of the Greek Legislation with EU Legislation, according to the Directive 2005/28/EC: http://www.bioethics.gr/media/pdf/biolaw/human/DYG3a-79602.pdf	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
Research Injury	National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. 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) 2. Act 3418/2005 Code on Medical Ethics (Greek): http://www.bioethics.gr/media/pdf/biolaw/human/code_of_practice_new_gr.pdf	1. Ministerial Decision ΔΥΓ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC: http://www.bioethics.gr/media/pdf/biolaw/human/clinical_trials_directive_gr.pdf 2. Ministerial Decision ΔΥΓ 3 α/79602/2007 Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2005/28/EC: http://www.bioethics.gr/media/pdf/biolaw/human/DYG3a-79602.pdf	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 Various: http://www.eof.gr/web/guest/clinicalmedical
Privacy/Data Protection	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. Act 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		

Country	Key Organizations	Legislation	Regulations	Guidelines
		4. Act 3418/2005 Code on Medical Ethics (Greek): http://www.bioethics.gr/media/pdf/biolaw/human/code_of_practice_new_gr.pdf		
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: 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. Act 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 on Medical Ethics (Greek): http://www.bioethics.gr/media/pdf/biolaw/human/code_of_practice_new_gr.pdf		HDPA: Opinion No. 15/2001 NBC: 1. Recommendation on Banks of Biological Material of Human Origin (Biobanks) in Biomedical Research:" http://www.bioethics.gr/media/pdf/recommendations/biobanks_recom_eng.pdf 2. Recommendation on the Collection and Use of Genetic Data: http://www.bioethics.gr/media/pdf/recommendations/recom_genetic_data_eng.pdf 3. Opinion on Prenatal and Pre-implantation Diagnosis and Embryo Treatment: http://www.bioethics.gr/media/pdf/recommendations/1_pd_pgd_opin_eng2.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. 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) 2. Civil Code (Act 3089/2002, Medically Assisted Reproduction): http://www.bioethics.gr/media/pdf/biolaw/human/assisted_reproduction_gr.pdf 3. Act 3305/2005 Application of Medically Assisted Reproduction: http://www.bioethics.gr/media/pdf/biolaw/human/fertility_clinics_regulation.pdf		NBC: 1. Recommendation on the Use of Stem Cells in Biomedicine and Clinical Medicine: http://www.bioethics.gr/media/pdf/recommendations/recom_stem_cells_eng.pdf 2. Recommendation on Human Reproductive Cloning: http://www.bioethics.gr/media/pdf/recommendations/recom_cloning_eng.pdf 3. Opinion on Prenatal and Pre-implantation Diagnosis and Embryo Treatment: http://www.bioethics.gr/media/pdf/recommendations/1_pd_pgd_opin_eng2.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Hungary 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 Human Resources (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Scientific and Research Ethics Committee	1. Fundamental Law of Hungary, Articles II-III 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	1. Decree No. 235/2009 (X.20.) from the Hungarian Government on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products, and for the Clinical Studies of the Medical Devices (Hungarian): http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900235.KOR&celpara=#xcelparam 2. Decree 23/2002 (V. 9.) of the Minister of Health on Biomedical Research on Human Beings (Hungarian): http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam	
Drugs and Devices	*Drugs*			
	1. National Institute for Quality and Organizational Development in Healthcare and Medicines: http://www.ogyi.hu/main_page/ 2. Medical Research Council, Ethics Committee for Clinical Pharmacology: http://www.ett.hu/kfeb/kfeb.htm 3. European Union: http://ec.europa.eu/health/index_en.htm	*Clinical Trials:* Act XCV of 2005 on Medicinal Products for Human Use, Section 3: http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=a0500095.tv&dbnum=62 *Non-Interventional Trials:* Act CLIV of 1997 on Health Care, Chapter VIII: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV	*Clinical Trials:* 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://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM&celpara=#xcelparam *Non-Interventional Trials:* Decree 23/2002. (V. 9) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam	Rules Governing Medicinal Products in the European Union, Volume 10: http://ec.europa.eu/health/documents/eudralex/vol-10/

Country	Key Organizations	Legislation	Regulations	Guidelines
	Devices			
	1. Authority for Medical Devices: http://www.eekh.hu/en/index.php?option=com_content&task=blogcategory&id=14&Itemid=28 2. Medical Research Council, Ethics Committee for Clinical Pharmacology: http://www.ett.hu/kfeb/kfeb.htm	Act CLIV of 1997 on Health Care, Chapter VIII: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV	*Clinical Trials:* Decree 4/2009. (III. 17.) of the Minister of Health on Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900004.EUM&celpara=#xcelparam *Non-Interventional Trials:* 1. Government Decree 235/2009. (X.20.) on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products and for the Clinical Studies of the Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900235.KOR&celpara=#xcelparam 2. Decree 23/2002. (V. 9.) of the Minister of Health on Biomedical Research on Human Beings http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam	
Research Injury	National Institute for Quality and Organizational Development in Healthcare and Medicines: http://www.ogyi.hu/main_page/	Act XCV of 2005 on Medicinal Products for Human Use, Section 3, Paragraph 5: http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=a0500095.tv&dbnum=62		
Privacy/Data Protection	Hungarian National Authority for Data Protection and Freedom of Information: http://www.naih.hu/general-information.html	1. Act CXII of 2011 on Informational Self-Determination and Freedom of Information: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A1100112.TV&celpara=#xcelparam 2. Act XLVII of 1997 on the Handling of Medical and Other Related Data: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700047.TV&celpara=#xcelparam		

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma	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: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0600080.TV&celpara=#xcelparam	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: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam	
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: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0800021.TV&celpara=#xcelparam		Decree 60/2003. (X. 20.) of the Minister of Health, Social and Family Affairs on the Minimum Professional Requirements Necessary for Providing Health Services: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0300060.ESC&celpara=#xcelparam
Embryos, Stem Cells, and Cloning	1. Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 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: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200006.TV&celpara=#xcelparam	Decree 30/1998. (VI. 24.) of the Minister of Welfare on Regulations on Specific Procedures for Human Reproduction: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800030.NM&celpara=#xcelparam	Decree 18/1998. (XII. 27.) of the Minister of Health on Implementing Act CLIV of 1997 on Health Care as Regards Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam
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, Article 10 (2009): http://eng.velferdarraduneyti.is/acts-of-Parliament/nr/20100 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):	Medicinal Products Act No. 93 (2009):	MCA: Regulation on Clinical Trials of	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.imca.is/ 2. National Bioethics Committee (NBC): www.visindasidanefnd.is	http://eng.heilbrigdisraduneyti.is/laws-and-regulations/laws//nr/3128	Medicinal Products in Humans No. 443 (2004): http://eng.heilbrigdisraduneyti.is/media/Reglugerdir-enska/Regulation_on_clinical_trials_of_medicinal_products_in_humans_No443-2004.pdf	
	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	
Research Injury	Icelandic Medicines Control Agency (MCA): http://www.imca.is/	Act 112/2008 (Icelandic): http://www.althingi.is/lagas/nuna/20080112.html	Regulation on Clinical Trials of Medicinal Products in Humans No. 443 (2004): http://eng.heilbrigdisraduneyti.is/media/Reglugerdir-enska/Regulation_on_clinical_trials_of_medicinal_products_in_humans_No443-2004.pdf	
Privacy/Data Protection	Data Protection Authority: http://www.personuvernd.is/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
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	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
		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		
Ireland				
General	Irish Council for Bioethics (ICB): http://www.bioethics.ie			Operational Procedures for Research Ethics Committees: Guidance 2004: http://www.bioethics.ie/uploads/docs/guide.pdf
Drugs and Devices	*Drugs*			
	Irish Medicines Board: http://www.imb.ie/	European Communities (Clinical Trials on Medicinal Products for Human Use) Amendment 2004 (S.I. No. 878 of 2004): http://www.dohc.ie/legislation/statutory_instruments/?year=2004&number=878	1. European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004): http://www.dohc.ie/legislation/statutory_instruments/?year=2004&number=190 2. European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment No. 2) Regulations 2006 (S.I. 374 of 2006): http://www.dohc.ie/legislation/statutory_instruments/?year=2006&number=374	IMB: Guide to Clinical Trials (2004)
	Devices			
	Irish Medicines Board: http://www.imb.ie/			Various: http://www.imb.ie/EN/Medical-Devices/PreMarket-Activities/Clinical-Investigations.aspx
Research Injury	Irish Medicines Board: http://www.imb.ie/		European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, Section 13(6)(k) and Schedule 1, Part 2, Paragraph 4 (S.I. No. 190 of 2004): http://www.dohc.ie/legislation/statutory_instruments/?year=2004&number=190	
Privacy/Data Protection	Data Protection Commissioner: http://www.dataprotection.ie/docs/Home/	Data Protection Act (1988), as amended (2003):		

Country	Key Organizations	Legislation	Regulations	Guidelines
	4.htm	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
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
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://ricerca-	Italy has numerous regulations that govern drug research: http://ricerca-clinica.agenziafarmaco.it/en/node/26 The following are the most important: 1. Ministerial Decree 21 December 2007: Directions for Submitting the Request for Authorisation of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authority, for Communicating Substantial Amendments, for Declaring the End of the Trial and for the Request of an Opinion to the Ethics Committee	

Country	Key Organizations	Legislation	Regulations	Guidelines
		clinica.agenziafarmaco.it/en/node/26 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	2. Ministerial Decree 31 March 2008: Definition of the Minimum Requirements that Contract Research Organisations (CROs) Shall Satisfy in Order to Work within Clinical Trials on Medicinal Products	
	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
Research Injury	Ministry of Health, Employment, and Social Policies		Ministerial Decree 14 of July 2009: Minimum Requirements for Insurance Policies which Safeguard Participants to Clinical Trials of Medicinal Products: http://ricerca-clinica.agenziafarmaco.it/it/node/3	
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): http://ricerca-clinica.agenziafarmaco.it/it/node/506 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)	

Country	Key Organizations	Legislation	Regulations	Guidelines
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.biobanknetwork.org/documents/GUIDELINES.pdf
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 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				
General			Statutes of Central Medical Ethics Committees (1998) (Latvian): http://www.likumi.lv/doc.php?id=46597	
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.vza.gov.lv/index.php?id=355&sa=355&top=333 2. Law on the Rights of Patients, Section 11 (2010) http://www.vvc.gov.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: http://www.zva.gov.lv/doc_upl/MK_not_289_English_02062010.pdf	
	Devices			
	State Agency of Medicines: http://www.vza.gov.lv/index.php?setlang=en&large=	Medical Treatment Law, Section 34 (2009): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Medical_Treatment_Law.doc	Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for Human Use (2010): http://www.vvc.gov.lv/export/sites/de	

Country	Key Organizations	Legislation	Regulations	Guidelines
			fault/docs/LRTA/MK_Noteikumi/Cab._Reg._No._891_-_Procedures_for_the_Clinical_Trial_of_Medical_Devices.doc	
Research Injury	State Agency of Medicines: http://www.vza.gov.lv/index.php?setlang=en&large=		*Drugs:* Cabinet Regulation No. 289: Regulations on Conducting Clinical Trials and Non-Interventional studies and Labeling of Investigational Medicinal Products, and Procedure for Conducting Inspections on Compliance with the Requirements of Good Clinical Practice, Sections 22, 31.6, 54.10, 55.9, and 61.14 (2010): http://www.zva.gov.lv/doc_upl/MK_not_289_English_02062010.pdf *Devices:* Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for Human Use, Sections 42.7 and 62.5 (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._891_-_Procedures_for_the_Clinical_Trial_of_Medical_Devices.doc	
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.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Law_On_the_Rights_of_Patients.doc		
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.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/On_the	Cabinet Regulation No. 208: Procedures for Banking, Storage and Utilisation of Human Tissues and Organs (2008): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Ca	

Country	Key Organizations	Legislation	Regulations	Guidelines
		_Protection_of_the_Body_of_Deceased_Human_Beings_and_the_Use_of_Human_Tissues_and_Organs_in_Medicine.doc	b._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.vvc.gov.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.vvc.gov.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.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Sexual_and_Reproductive_Health_Law.doc	Cabinet Regulation No. 716: Order of Medically-Assisted Procreation, Donor Registry, and Donor Bank (2003) (Latvian) http://www.likumi.lv/doc.php?id=82281&from=off	
Lithuania 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 2. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-381039724	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 (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446	Government of the Republic of Lithuania: Decree Nr. 1458 on State Fees (2000, last amended in 2012) MOH: 1. Decree No. 23 on the Procedure for the Estimation and Covering of Expenses Incurred by Research Subjects (2011) 2. Decree No. V-405 on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage, and Providing Information on Biomedical Research (2010) LBEC: 1. Decree No. V-14 on the	LBEC: Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical Research of the LBEC (2010)

Country	Key Organizations	Legislation	Regulations	Guidelines
			Requirements for the Biomedical Research Protocol, Patient Information Sheet, and Informed Consent Form, and for the CV of Investigator (2010). 2. The Decree No.V-28 on Biomedical Research on Health Data (2011)	
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?-381039724 3. Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Law on Ethics of Biomedical Research (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446 2. Law on Pharmacy (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=426291	MOH: 1. Decree No. 435 on the Procedure for Issuing Favorable Opinion to Conduct Clinical Trial on Medicinal Product, Approval for Clinical Trial on Medicinal Product, Conducting and Controlling Clinical Trials (2011) 2. Decree No. 320 on the Rules of Good Clinical Practice (2006) LBEC: 1. Decree No. V-11 on the Documents Required by the Lithuanian Bioethics Committee to be Presented by the Sponsor of Biomedical Research and (or) by the Principal Investigator in Order to be Authorized to Conduct a Clinical Trial on Medicinal Products, and on the Procedure on the Submission of the Documents to be presented to the Lithuanian Bioethics Committee (2004) 2. Decree No. V-10 on the Procedure for Issuing a Favorable Opinion for Substantial Amendment (2008)	LBEC: Guidelines to Advertise clinical trials, adopted by the Group of Experts on Biomedical Research of the LBEC (2007) SMCA: Detailed Guidance No. 1A-396 for the Request for Authorisation of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authorities, Notification of Substantial Amendments, and Declaration of the End of the Trial, (2006)
	Devices			
	1. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-381039724 2. State Health Care Accreditation Agency Under the Ministry of Health	Law on Ethics of Biomedical Research (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446	MOH: Decree No. V-2 on the Procedure to Issue Approvals to Conduct Biomedical Research (2011)	

Country	Key Organizations	Legislation	Regulations	Guidelines
	(SHCA): http://www.vaspvt.gov.lt/en		SHCA: Decree No. T1-1064 on the Procedure to Issue Recommendation to Conduct Clinical Trial on Medical Device (2010)	
Research Injury	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	Law on Ethics of Biomedical Research (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446	MOH: Decree No. 745 on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor (2012)	
Privacy/Data Protection	State Data Protection Inspectorate: http://www.ada.lt/index.php?lng=en	Law on Legal Protection of Personal Data (2011): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=400103		
Human Biological Materials	1. Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG 2. Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-381039724	Law on Ethics of Biomedical Research (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446	LBEC: Decree No.V-28 on Biomedical Research on Health Data (2011)	
Embryos, Stem Cells, and Cloning	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Law on Ethics of Biomedical Research (2012): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=414446 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 (2002): http://conventions.coe.int/Treaty/EN/Treaties/Html/168.htm	MOH: 1. Decree No. V-660 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 (2007) 2. Decree No. V-659 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 Therefrom (2007)	

Country	Key Organizations	Legislation	Regulations	Guidelines
Luxembourg				
General		Hospitals Act of 1998, Article 25 (French): http://www.legilux.public.lu/leg/a/archives/2011/0103/a103.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 (French and German): http://www.cnpd.public.lu/fr/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.public.lu/fr/legislation/droit-lux/doc_loi02082002_en.pdf	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*			
	1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Macedonian Drug Agency http://www.reglek.com.mk/	Law on Medicinal Products and Medical Devices (2007): http://www.reglek.com.mk/dokumenti/18_zakon_za_lekovi.doc	1. Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2009) http://www.reglek.com.mk/dokumenti/186_801411036.doc 2. Rulebook for the Changes in the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2010): http://www.reglek.com.mk/dokumenti/183_541952251.doc 3. Rulebook for the Changes in the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2012): http://www.reglek.com.mk/dokument	1. Guideline for the Clinical Trial Applicant in Accordance with the Law on Medicinal Products and Medical Devices 2. Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents and GCP Guidelines (2012): http://www.reglek.com.mk/dokumenti/279_334042412.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			i/273_106026555.doc 4. Regulation on the Manner of Reporting, Contents of the Reporting Form for Adverse Reactions to Medicinal Products and the Manner of Organisation of Pharmaco-vigilance System: http://www.reglek.com.mk/dokumenti/190_553132198.doc	
	Devices			
	1. Macedonian Drug Agency http://moh.gov.mk/index.php?category=39 2. Macedonian Drug Agency: http://www.reglek.com.mk/	Law for Drugs and Medical Devices (2007): http://www.reglek.com.mk/dokumenti/18_zakon_za_lekovi.doc	Same as above.	Same as above.
Research Injury	1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Macedonian Drug Agency http://www.reglek.com.mk/	Law on Medicinal Products and Medical Devices (2007): http://www.reglek.com.mk/dokumenti/18_zakon_za_lekovi.doc	Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and Documentation, Article 12 (7) (2009): www.reglek.com.mk/dokumenti/186_801411036.doc	
Privacy/Data Protection	Directorate for Personal Data Protection (Macedonian): www.dzlp.mk	Law on Personal Data Protection (2005): http://www.ceecprivacy.org/pdf/Law%20on%20Personal%20Data%20Protection.pdf	Decree for Enacting the Law for Changing and Amending the Law on Personal Data Protection: a. 19 August 2008 b. 20 September 2010 c. 03 October 2011	
Human Biological Materials	1. Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/ 2. Health Insurance Fund of Republic of Macedonia: http://www.fzo.org.mk	1. Law on Health Protection http://www.fzo.org.mk/WBStorage/Files/ZAKON%20ZA%20ZDRAVSTVENATA%20ZASTITA%2043%20od%2029.03.2012.pdf 2. Law on Taking and Transplanting of Human Body Organs: http://moh.gov.mk/files.php?file=Zakon_zemanje_i_presaduvanje_na_delovi_od_coveckoto_telo_781856183.pdf Sub-law Acts : http://www.fzo.org.mk/default.asp?ItemID=6541AC10FFC3C5498F0887C57131D996		Guideline on How to Perform Health Care that Relates to Procedures Regarding the Transfer and Transport of Biological Materials and the Method of Packing and Labeling of Biological Materials: http://moh.gov.mk/upatuvanje/images/Laboratorii%20-%20Upatstvo%20za%20TRANSPORT%20na%20materijal%20(rabotna%20verzija%202).doc

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Law on 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, With Additional Protocol on the Prohibition of Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin: http://www.pravo.org.mk/download.php?id=5543		
Genetic Research	Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/	Law on Patients Rights Protection, Article 21: Action on Human Genome: http://www.miahealth.mk/dokumentacija/80_648801981.pdf		
Embryos, Stem Cells, and Cloning	Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/	Law on 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, With Additional Protocol on the Prohibition of Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin: http://www.pravo.org.mk/download.php?id=5543		
Malta 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: https://ehealth.gov.mt/HealthPortal/others/regulatory_councils/health_ethics_committee/health_ethics_committee.aspx			
Drugs and Devices	*Drugs*			
	Medicines Authority: http://medicinesauthority.gov.mt/	1. Medicines Act, 2003: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8924&l=1 2. Subsidiary Legislation, 458.43, Clinical Trials Regulations, 2004:		Guidance Notes on Good Clinical Practice (2010): http://medicinesauthority.gov.mt/clinicaltrials.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11281&l=1 3. Subsidiary Legislation, 458.47, Good Clinical Practice and Requirements for Manufacturing or Import Authorisation of Investigational Medicinal Products (Human Use) Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11285&l=1		
	Devices			
	1. Medicines Authority: http://medicinesauthority.gov.mt/ 2. Malta Competition and Consumer Affairs Authority, Technical Regulations Division, Regulatory Affairs Directorate: http://www.mccaa.org.mt/en/regulatory-affairs-directorate	1. Product Safety Act, 2001: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8893&l=1 2. Subsidiary Legislation, 427.44, Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10781&l=1 3. Subsidiary Legislation, 427.16, *In Vitro* Diagnostic .Medical Devices Regulations, 2003 http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10756&l=1 4. Subsidiary Legislation, 427.10, Active Implantable Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10753&l=1		
Privacy/Data Protection	Office of the Information and Data Protection Commissioner: http://idpc.gov.mt/index.aspx	Data Protection Act, 2002: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8906&l=1		

Country	Key Organizations	Legislation	Regulations	Guidelines
Moldova 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.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf				
General	National Committee of Bioethics of the Ministry of Health: http://www.ms.gov.md/en/	Oviedo Convention on Human Rights and Biomedicine (2002)		
Drugs and Devices	1. National Committee of Ethics for Clinical Study of Drugs and New Methods of Treatment of the 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 (Moldovian): http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311586 Law No. 263 of 27.10.2005 on Rights and Responsibilities of Patient. Articles 9, 10, 11, 12, 13 and 14 (Moldovian): http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=313060	MOH: 1. Ordnance No. 10: On Performance of Clinical Trials in the Republic of Moldova (2002) 2. Order No. 22 of 12.01.2006 "Regarding Modification of the Order No. 10 on Performance of Clinical Trials"	
Research Injury	Ministry of Health (MOH): http://www.ms.gov.md/en/	1. Annex No.1 to the Oder No.10 from 14.01.2002 of the Ministry of Health, Sections 5.8 and 8: http://www.amed.md/ordine_MS.html 2. Law No. 411-XIII of 28.03.1995 "Regarding Health Protection"		
Privacy/Data Protection	National Center for Personal Data Protection of the Republic of Moldova: http://www.datepersonale.md/en/start/	1. Law No.133 of 08.07.2011 on the Protection of Personal Data: http://lex.justice.md/md/340495/ 2. Law No. 982 of 11.05.2000 on Access to Information: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311759	Decision of Government No. 1123 of 14.12.2010: On the Approval of the Requirements for the Assurance of Personal Data Security at their Processing within the Information Systems of Personal Data: http://www.datepersonale.md/file/hotariri/cerinte_securitate%20eng_101228.pdf	
Human Biological Materials	1. Ministry of Health (MOH): http://www.ms.gov.md/en/ 2. Transplant Agency http://lex.justice.md/md/334622	Law No. 42 of 06.03.2008 on Transplantation of Organs, Tissues and Human Cells: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=32	MOH: Ordnance No. 10: On Performance of Clinical Trials in the Republic of Moldova (2002)	

Country	Key Organizations	Legislation	Regulations	Guidelines
		7709		
Embryos, Stem Cells, and Cloning	1. Ministry of Health (MOH): http://www.ms.gov.md/en/ 2. National Commission on Biological Security http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=303353	1. 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) 2. Law No. 42 of 06.03.2008 on Transplantation of Organs, Tissues and Human Cells: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=327709		
Montenegro				
Drugs and Devices	Ministry of Health of Montenegro: www.mz.cg.yu	Law for Drugs and Pharmacies of Montenegro, Articles 37-39		
Research Injury	Medicines and Medical Devices Agency: http://calims.me/	Law on Medicinal Products, Article 48: http://calims.me/images/docs/zakon%20o%20ljekovima.pdf		
Netherlands				
General	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl	1. Population Screening Act (1996): http://www.gr.nl/en/about-us/council/committees-standing-committees/ciebvo 2. Medical Research Involving Human Subjects Act (2006 version - minor changes implemented in 2012 have not yet been translated to English): http://www.ccmo-online.nl/hipe/uploads/downloads_catw/Medical%20Research%20involving%20Human%20Subjects%20Act%20March%2001%202006.pdf	1. Concerning the Use of a Special Form (2002) 2. Concerning Requirements of Expertise of Accredited Review Board Members (2002) 3. Concerning the Organization and Working Method of Accredited Review Board Members (2003) 4. External Review Guideline (2004) 5. Research Contract Review Guideline (2009)	Manual for the Review of Medical Research Involving Human Subjects (2002)
Drugs and Devices	1. Ministry of Health, Welfare, and Sport (MHWS): http://www.government.nl/ministries/vws#ref-minvws 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%20	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

Country	Key Organizations	Legislation	Regulations	Guidelines
			Geneesmiddelenwet	
Research Injury	Ministry of Health, Welfare and Sport: http://www.government.nl/ministries/vws#ref-minvws	Medical Research Involving Human Subjects Act, Article 7 (2006): http://www.ccmo-online.nl/hipe/uploads/downloads_catw/Medical%20Research%20involving%20Human%20Subjects%20Act%20March%2001%202006.pdf	Regulation on Mandatory Insurance Regarding Medical Research Involving Human Subjects (2003): http://www.ccmo-online.nl/hipe/uploads/downloads/Verzekeringsbesluit_2003-ENG.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/Pages/home.aspx	Personal Data Protection Act (2004) (Dutch): http://www.cbpweb.nl/downloads_wetten/WBP.PDF		FMWV: 1. Code for Adequate Secondary Use of Data (2004): http://www.federa.org/sites/default/files/bijlagen/coreon/code_of_conduct_for_medical_research_1.pdf 2. Explanatory Report Accompanying the Code: http://www.federa.org/sites/default/files/bijlagen/coreon/explanatory_report1.pdf
Human Biological Materials	Federation of Biomedical Scientific Societies (Dutch): http://www.federa.org/	Civil Code, Article 467 (1994) (Dutch): http://www.dutchcivillaw.com/legislation/dcctitle7777.htm		Code for Proper Secondary Use of Human Tissue in the Netherlands (2002): http://www.federa.org/sites/default/files/bijlagen/coreon/codeproperseconderyuseofhumantissue1_0.pdf
Genetic Research	1. Ministry of Housing, Spatial Planning, and Environment (VROM): http://english.verkeerenwaterstaat.nl/english/ 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://bggo.rivm.nl/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) (Dutch): http://wetten.overheid.nl/BWBR0012983/ 2. Embryos Act (2002) (Dutch): http://wetten.overheid.nl/BWBR0013797/		
Norway				
General	1. National Committee for Medical and Health Research Ethics (NEM): http://www.etikkom.no/en/In-English/Committee-for-Medical-and-Health-Research/	1. Oviedo Convention on Human Rights and Biomedicine (2006) 2. Law regarding Ethics and		NEM: 1. Research Ethical Review in Norway (1998) 2. NEM: Standard Operating Procedures

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. National Committee for Research Ethics in the Social Sciences and the Humanities (NESH): http://www.etikkom.no/en/In-English/ 3. National Committee for Research Ethics in Science and Technology (NENT): http://www.etikkom.no/English/NENT	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*&&		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
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2007)		
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 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, Chapter 2a (2008): www.gif.gov.pl/?aid=173 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. 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/	
Research Injury		Pharmaceutical Law, Chapter 36b(2)(6) (2008): www.gif.gov.pl/?aid=173	1. Order of the Minister of Finance Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2004) 2. Order of the Minister of Finance Amending the Regulation Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2005)	
Privacy/Data Protection	Inspector General for the Protection of Personal Data: http://www.giodo.gov.pl/168/j/en/	Act on the Protection of Personal Data (2006): http://www.giodo.gov.pl/data/filemanager_en/61.doc		
Human Biological Materials		1. Act of 26 October 1995 on the Collection and Transplantation of Cells 2. Act of 22 August 1997 on the Public Blood Service 3. July 1, 2005 Act Regarding Sampling, Storage and Transplanting of Cells, Tissues and Organs		

Country	Key Organizations	Legislation	Regulations	Guidelines
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: http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH 2. Ethics Commission for Clinical Research (CEIC): http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/CEIC	1. Approval of the Applicable Legal Standards for the Conduct of Clinical Trials of Medicines for Human Use, Law No. 46/2004 2. Approval of the Composition, Operations, and Financing of the Ethics Commission for Clinical Research, Decree No. 57/2005 (Portuguese): http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/portaria_57-2005.pdf	Decree-Law No. 102/2007 of April 2	
	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
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
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		

Country	Key Organizations	Legislation	Regulations	Guidelines
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
Romania 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. Order 904/25Jul2006 on Approval of Rules Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use -- Transposition of 2001/20/EC Directive 2. Order 905/25Jul2006 on Approval of the Principles and Guidelines for Good Manufacturing Practice in Respect of Medicinal Products for Human Use and Investigational Medicinal Products for Human Use -- Transposition of the 2003/94/CE Directive *Access:* http://www.anm.ro/en/html/legislation_minister_orders.html	MOH: Guideline for Clinical Trials in Pediatric Populations (CPMP/ICH/2711/99) (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
Research Injury	National Medicines Agency: http://www.anm.ro/en/home.html	Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
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		
Human Biological Materials	Ministry of Health (MOH) (Romanian): http://www.ms.ro/	Law No. 95/2006 Regarding the Reform in Health Field. Title VI. Performing of Sampling and Transplant of Organs, Tissues and Human Origin Cells with Therapeutic Purpose: http://www.transplant.ro/Lege/TitlulVI_Legea_95_2006.html	Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on Standards of Quality and Safety of Human Organs Intended for Transplantation: http://europa.eu/legislation_summaries/public_health/threats_to_health/sp0008_ro.htm	
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 (2001) 2. Law No. 301 from 2004 Penal Code – Chapter IV – Crimes and Felonies Regarding Genetic Manipulation: http://www.codpenal.ro/legislatie/document/lege-301-din-2004-codul-penal-capitol-4-crime-si-delicte-privind-manipularea-genetica-1260-63259.html		
Russia				
General	1. Ministry of Healthcare of the Russian Federation: http://www.rosminzdrav.ru 2. Federal Service on Surveillance in Healthcare (Roszdravnadzor): (Russian): http://www.roszdravnadzor.ru/	1. Constitution of the Russian Federation, Article 21 (1993): http://www.constitution.ru/en/10003000-03.htm 2. Federal Law #FZ 323 "On Foundations of Protection of Citizen's Health in the Russian		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Federation" (2011) (Russian): http://www.rosminzdrav.ru/docs/laws/104		
Drugs and Devices	Council of Ethics of the Ministry of Healthcare of the Russian Federation: http://www.roszdravnadzor.ru/etika/et/norm	Federal Law #61FZ "On circulation of Medicines" (2011): http://www.consultpharma.ru/index.php?option=com_content&view=article&id=152:61fz&catid=31:drugs&Itemid=36&lang=en	MOH: 1. Ministry of Health Order No. 753n (August 26, 2010) "On Assertion of Order of Organization and Carrying out of Ethical Review…" (Russian): http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=104353 2. Ministry of Health Order No. 774n (August 31, 2010) "On Council of Ethics" (Russian): http://www.businesspravo.ru/Docum/DocumShow_DocumID_171302.html GOST: Good Clinical Practice. GOST-R 52379-2005 (September 27, 2005)	
Research Injury		Federal Law #61FZ "On Circulation of Medicines" (2011), Art. 38-44: http://www.consultpharma.ru/index.php?option=com_content&view=article&id=152:61fz&catid=31:drugs&Itemid=36&lang=en		
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	Inter-Departmental Commission on Genetic-Engineering Activity	Federal Law of July 5, 1996, N OF 8'-FZ "About the State Control in the Area of Genetic-Engineering Activity" (With changes of July 12, 2000)	Order of the Ministry of Education and Science of the Russian Federation #154 (2005): "Statute of the Inter-Departmental Commission on Genetic-	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Engineering Activity" (Russian): http://www.zakonprost.ru/content/base/part/438157	
Embryos, Stem Cells, and Cloning		Federal Law #30-FZ "On Introduction of Change in Art. 1 of the Federal Law "On Temporary Ban on Human Cloning" (2010) (Russian): http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=98895;fld=134;dst=100008;rnd=0.5044818258109531		
San Marino				
General		Oviedo Convention on Human Rights and Biomedicine (1998)		
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1999)		
Serbia				
Drugs and Devices	1. Ministry of Health (MOH): http://www.zdravlje.gov.rs/ 2. Serbian Drug Agency http://www.alims.gov.rs	Law on Medicines and Medical Devices, Official Gazette No. 30/2012: http://www.alims.gov.rs/download/o_agenciji/Zakon_o_lekovima_30-2010.pdf	MOH: Regulation on Content of Requests and Documents for Approval of Clinical Trials and Procedures for Conducting Clinical Trials, Official Gazette of RS, 64/2011, 31 Aug 2011: http://www.alims.gov.rs/download/regulativa/Pravilnici/Pravilnik%20o%20klinickom%20ispitvanju/pravilnik%20klinicka_2011.pdf	
Research Injury	1. Ministry of Health (MOH): http://www.zdravlje.gov.rs/ 2. Serbian Drug Agency http://www.alims.gov.rs	Law on Medicines and Medical Devices, Article 72: http://www.alims.gov.rs/download/o_agenciji/Zakon_o_lekovima_30-2010.pdf	MOH: Regulation on Content of Requests and Documents for Approval of Clinical Trials and Procedures for Conducting Clinical Trials, Official Gazette of RS, 64/2011, 31 Aug 2011: http://www.alims.gov.rs/download/regulativa/Pravilnici/Pravilnik%20o%20klinickom%20ispitvanju/pravilnik%20klinicka_2011.pdf	
Privacy/Data Protection		Law on the Protection of Personal Data, Official Gazette 68/12, Page 41 (18 July 2012)		

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning		Law on Organ Transplantation, Official Gazette No. 72/2009: http://zakon.co.rs/zakon-o-transplantaciji-organa.html		
Slovakia For an overview of human subject protections in Slovakia, see "National Regulations on Ethics and Research in Slovak Republic:" ec.europa.eu/research/science-society/pdf/sk_eng_lr.pdf				
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: http://www.sukl.sk/en	Act No. 140/1998 Coll. on Drugs and Medical Devices, as amended by Acts No. 9/2004 and 542/2006, 489/2008, and 402/2009 Coll.	Ministerial Regulation No. 239/2004 Coll. on Requirements for Clinical Trials and Good Clinical Practice, as amended by Ministerial Regulation No. 148/2009 Coll.	
Research Injury		Law 277/1994 on Health Care, Section 44		
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		

Country	Key Organizations	Legislation	Regulations	Guidelines
		the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998)		
Slovenia 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	Bylaw on Clinical Trials, Official gazette, No. 54/06	NMEC: 1. Ministerial Decree No. 30 (1995) 2. Statutory Notes (1998) 3. Slovenian Directive on Clinical Drug Testing No. 67.8372-8385 (2000) 4. On the Ethical Review of Phase IV Clinical Studies (2003) (Slovenian): http://www.mf.uni-lj.si/kme-nmec/Docu/Ocenjevanje_klin_studij_IV_faze.pdf	
	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
Research Injury		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1999) 2. Additional Protocol Concerning Biomedical Research, Article 13, CETS No. 195 (2007)		
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		On Interventions into the Human Corpse Which are not Part of the Routine Autopsy and on Handling	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
	Medical Devices (JAZMP): http://www.jazmp.si/index.php?id=56		with Biologic Material of Human Origin (2004)	
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 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): http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/ETS164Spanish.pdf 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 regulations pertaining to drug research.	*Drugs* Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/investigacionClinica/medicamentos/home.htm	1. Royal Decree 223/2004: Regulation of Medication Clinical Trials: www.cerc-europe.org/documents/Royal_decree_223.2004.pdf 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	1. Order SCO/256/2007 That Establishes the Principles and Detailed Directives on Good Clinical Practice, and the Requirements to Approve the Manufacture and Import of Research Medications for Human Use (Spanish): http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rcl_2007_270.pdf 2. Order SCO/362/2008 that Modifies Order SCO/256/2007 (Spanish): http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rcl_2008_410.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Devices			
	Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/investigacionClinica/productosSanitarios/home.htm	Various (Spanish): http://www.aemps.gob.es/legislacion/espana/productosSanitarios/docs/Directiva_93-42-CEE/rcl_2009_2105.pdf	Various (Spanish): http://www.aemps.es/actividad/pschb/implantables1.htm#circulares	
Research Injury	Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/home.htm	Royal Decree 223/2004: Regulation of Medication Clinical Trials, Article 8: www.cerc-europe.org/documents/Royal_decree_223.2004.pdf Law 14/2007 on Biomedical Research, Article 18: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
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	1. Royal Decree 1720/2007 (Spanish): https://www.agpd.es/portalwebAGPD/canaldocumentacion/legislacion/estatal/common/pdfs/RD_1720_2007.pdf 2. Royal Decree of 19 January 2008 (Spanish): https://www.agpd.es/portalwebAGPD/canaldocumentacion/legislacion/estatal/common/pdfs/RD_1720_2007.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/Spani	Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples (2006) (Spanish): http://www.boe.es/boe/dias/2006/02/07/pdfs/A04626-04636.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
		shLawonBiomedicalResearchEnglish.pdf		
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 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. 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):	CEPN: Information for Research Participants SRC: 1. Guidelines for the Ethical Evaluation of Medical Research on Humans (2003) 2. Policy Statement Regarding the Assessment of Scientific Studies in which Patients or Healthy Subjects are to Undergo Invasive Operations (2003) 3. Good Research Practice: http://www.cm.se/webbshop_vr/pdfer/2011_03.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.epn.se/start/regulations/the-statute-(20071068).aspx SRC: Regulations and General Counsel VRFS 2012:1 on Ethical Vetting of Human Subjects Research: http://www.epn.se/media/48216/vrfs_2012_1.pdf	
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	MPA Regulations on Clinical Trials in Humans -- LVFS 2011:19 (Swedish): http://www.lakemedelsverket.se/upload/lvfs/LVFS_2011_19.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	1. Swedish Data Inspection Board: http://www.datainspektionen.se/in-english/ 2. Swedish Research Council (SRC): http://www.vr.se/english	SFS 2009:400 - Public Access to Information and Secrecy Act: http://www.notisum.se/rnp/sls/lag/20090400.htm	SFS 2009:641 - Public Access to Information and Secrecy Ordinance: http://www.notisum.se/rnp/sls/lag/20090641.htm	Swedish Data Inspection Board Report 2004:2 SRC: Policy Document: Handling Personal Data (Swedish): http://www.vr.se/download/18.6b2f98a910b3e260ae28000342/Personuppgifter_7.pdf
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. Consolidated regulations (Swedish): http://www.socialstyrelsen.se/sosfs/2002-11/Sidor/2002-11.aspx	SRC: Research Ethics Guidelines for Using Biobanks (Swedish) (2003) http://www.vr.se/download/18.6b2f98a910b3e260ae28000350/Riktlinjer_Biobanker_11.pdf
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	SRC: Guidelines for Ethical Vetting of Human Stem Cell Research (Swedish): http://www.vr.se/download/18.6b2f98a910b3e260ae28000362/human_stamcellsforskning_16.pdf
Switzerland 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 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		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 (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	
Research Injury		Federal Law on Medicinal Products and Medical Devices, RS 812.21, Article 54 (2002, French): http://www.admin.ch/ch/f/rs/c812_21.html	Ordinance on Clinical Trials of Therapeutic Products, Article 7 (French) (2001): http://www.admin.ch/ch/f/rs/812_214_2/a7.html	
Privacy/Data Protection Note: Most Swiss cantons have enacted laws regarding data collection in the	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		

Country	Key Organizations	Legislation	Regulations	Guidelines
public sector.		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 (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*			
	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr	Turkish Penal Law, Article 90 (2005)	1. Fundamental Law #3359 on Health Services, Supplemental Article 10 (2011):	1. Guideline for Good Clinical Practice (2011): http://www.titck.gov.tr/Folders/TheLaws/Clini

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=1&thelawId=347 2. Regulation on Clinical Trials (2011): http://www.titck.gov.tr/Default.aspx?sayfa=regulations&lang=en&thelawtype=14&thelawId=398	cal%20Drug%20Research%20Department/GOOD_CLINICAL_PRACTICES_August_2011_PO_70c96bf.pdf 2. Guidance on the Ethics of Pediatric Clinical Research (2011): http://www.titck.gov.tr/Folders/TheLaws/Clinical%20Drug%20Research%20Department/GUIDANCE_ON_ETHICAL_APPROACHES_FOR_CLINICAL_TRIALS_CONDUCTED_WITH_THE_PEDIATRIC_POPULATION9_9_2011-PO-_2227a90.pdf 3. Drug Observational Studies Guide (2011): http://www.titck.gov.tr/Folders/TheLaws/Clinical%20Drug%20Research%20Department/GUIDELINE_FOR_OBSERVATIONAL_STUDIES_CONDUCTED_ON_DRUGS__August_2011_PO_96aad43.pdf
	Devices			
	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr		Various (Turkish): http://www.klinikarastirmalar.org.tr/en/documents.php?dok_cat=25	
Research Injury	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr	Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2004)		Guidance on Insuring Volunteers in a Clinical Trial (2011): http://www.titck.gov.tr/Folders/TheLaws/Clinical%20Drug%20Research%20Department/GUIDANCE_ON_INSURING_VOLUNTEERS_IN_A_CLINICAL_TRIAL_August__2011_rev_PO__47a0c5b.pdf
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)	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999) 2. Good Clinical Practice Guidelines for Advanced Therapy Medicinal Products (2011): http://www.titck.gov.tr/Folders/TheLaws/Klinik%20Araştırmalar%20Şube%20Müdürlüğü/Ileri%20tedavi%20Kılavuzu%20Eylül%202011_21a9d11.pdf
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	1. Circular on Research of Embryonic Stem Cells (2005) 2. Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)

Country	Key Organizations	Legislation	Regulations	Guidelines
			Tissue Transplantation Services (2005) 3. Regulation on Cordon Blood Banks (2005)	
Ukraine All listed documents are in Ukrainian.				
General	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	1. Criminal Code of Ukraine 2001, Article 142 2. Health Care Law, Article 45 (1992)	Order HEC Ukraine from 29.05.2007 No. 342, with Changes from 03.03.2008 No. 147	
Drugs and Devices	Ministry of Health of Ukraine State Expert Center: http://www.dec.gov.ua	1. 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 2. Ministry of Health Act 23.09/2009 No. 690, with Changes 12.07.2012 No. 523: http://zakon1.rada.gov.ua/laws/show/z1010-09	1. Ukrainian Ministry of Health Order No. 95 About Approval of Documents Related to the Quality Assurance of Medicines (2009): http://www.moz.gov.ua/ua/main/docs/?docID=12796 With changes 03.10.2011 No. 634: http://www.moz.gov.ua/ua/portal/dn_20111003_634.html 2. Ukrainian Ministry of Health Order No. 690 About Approval of Procedure for Conducting Clinical Trials of Medical Products and Expertise of Materials of Clinical Trials and Model Statute of the Ethics Commission (2009) with changes from 12.07.2012 No. 523: http://zakon1.rada.gov.ua/laws/show/z1010-09	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)
Research Injury		On Medicines, Article 8 No. 123/96BP (1996): http://www.pharma-center.kiev.ua/site/file_uploads//en/new_doc/law_en.doc		
Privacy/Data Protection	State Service of Ukraine on Personal Data Protection: http://zpd.gov.ua/dszpd/en/index	1. Information Act from the Cabinet of Ministers of the Ukraine (2002) 2. On Protection Personal Data Act, 01.06.2010 with changes from 23.02.2012 http://zakon3.rada.gov.ua/laws/show/2297-17	1. Ministry of Justice of Ukraine Order 30.12.2011 N 3659/5 About Approval Model Procedures for Processing of Personal Data in Databases with Personal Data: http://zakon3.rada.gov.ua/laws/show/z0001-12 2. Cabinet of Ministry of Ukraine	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Resolution of 25.05.2011 No. 616 On the Approval of the State Register of Personal Data and the Order of Keeping: http://zakon3.rada.gov.ua/laws/show/616-2011-%D0%BF	
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 the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007): http://www.moz.gov.ua/ua/main/docs/?docID=8767	
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 Council of Europe 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 Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) with Changes from 23.09.2009 No. 690: http://zakon1.rada.gov.ua/laws/show/z1206-07	NBC: Ethical Regulations and Problems of Embryo-Tissue Storage (Recommendations)

Country	Key Organizations	Legislation	Regulations	Guidelines
United Kingdom 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. Health Research Authority (HRA): http://www.hra.nhs.uk/ 3. National Research Ethics Service (NRES): http://www.nres.nhs.uk/ 4. Medical Research Council (MRC): http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm	Department of Health: http://www.dh.gov.uk/health/category/publications/legislation/		DH: 1. Governance Arrangements for NHS Research Ethics Committees (2011): http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474 2. Research Governance Framework for Health and Social Care (2005) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962 NRES: 1. Directory of NRES Guidance: http://www.nres.nhs.uk/applications/guidance/ 2. Integrated Research Application System: https://www.myresearchproject.org.uk/ Medical Research Council: 1. Personal Information in Medical Research (2000) 2. Research Involving Human Participants in Developing Societies (2004) 3. MRC Guidelines for Good Clinical Practice in Clinical Trials (2006) 4. Medical Research Involving Children (2007) 5. Good Research Practice: Principles and Guidelines (2012) *Access:* http://www.mrc.ac.uk/Newspublications/Publications/Ethicsandguidance/index.htm
	Scotland:			
	1. NHSScotland, Chief Scientist Office (CSO): http://www.cso.scot.nhs.uk/Resources/sitemap.htm 2. NHS Research Scotland: http://www.cso.scot.nhs.uk/SuppScience/NRS/NRS.html	Adults with Incapacity (Scotland) Act 2000, Section 51: http://www.scotland.gov.uk/Topics/Justice/law/awi/legislation	Adults with Incapacity (Ethics Committee) (Scotland) Regulations (2002): http://www.scotland-legislation.hmso.gov.uk/legislation/scotland/ssi2002/20020190.htm	CSO: 1. Research Governance Framework for Health and Community Care (2006) 2. Governance Arrangements for NHS Research Ethics Committees (2011): http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidan

Country	Key Organizations	Legislation	Regulations	Guidelines
				ce/DH_126474
	Wales:			
	National Institute for Health and Social Care, Welch Government: http://wales.gov.uk/topics/health/research/nischr/?lang=en			Governance Arrangements for NHS Research Ethics Committees (2011): http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474
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.nhs.uk/ 4. Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk/Pages/default.aspx	Medicines Act (1968): http://www.legislation.gov.uk/ukpga/1968/67/contents	MHRA: 1. Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004): http://www.legislation.gov.uk/uksi/2004/1031/contents/made 2. Amendment Regulations (SI 2006/1928) http://www.legislation.gov.uk/uksi/2006/1928/contents/made 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.legislation.gov.uk/uksi/2006/2984/pdfs/uksi_20062984_en.pdf	MHRA: Consultation Letter on the Medicines for Human Use (Clinical Trials) Regulations (2003): https://www.google.com/url?q=http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con007629.pdf&sa=U&ei=A0qAUM_hHs_J0AGu84GwDw&ved=0CBoQFjAH&client=internal-uds-cse&usg=AFQjCNFuVjyMnPXGv46_3pLxM36SSDmGYQ MRC: 1. MRC Guidelines for Good Clinical Practice in Clinical Trials (1998) 2. MRC Policy on Antiretroviral Therapy for People Infected with HIV and Involved in AIDS Research in Developing Countries (2003) ABPI: Guidelines for Phase I Clinical Trials (2012): http://www.abpi.org.uk/our-work/library/guidelines/Pages/phase-1-trials-2012.aspx
	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.nhs.uk/		Medical Devices Regulations (2002): http://www.opsi.gov.uk/si/si2002/20020618.htm	MHRA: Clinical Trials for Medical Devices: http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/index.htm NRES: Medical Devices Guidance : http://www.nres.nhs.uk/applications/guidance/guidance-and-good-practice/#medical
Research Injury	1. Medicines and Healthcare Products Regulatory Agency (MHRA):		Medicines for Human Use (Clinical Trials) Regulations,	DH: Research in the NHS: Indemnity and

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.mhra.gov.uk 2. Department of Health (DH): http://www.dh.gov.uk/Home/fs/en 3. Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk 4. Association of the British Healthcare Industry (ABHI): http://www.abhi.org.uk/		Statutory Instrument No. 1031, Regulation 15(5)(i)(j)(k) and Schedule 3 Part 1, Paragraphs 1(g) and 3(c) (2004): http://www.mhra.gov.uk/HowHowweregul/Devices/index.hth	Arrangements (2005): http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4125284.pdf ABPI: Clinical Trial Compensation Guidelines (1994): http://www.abpi.org.uk/our-work/library/guidelines/Pages/ct-compensation.aspx ABHI: Clinical Investigations Compensation Guidelines (1995): http://www.abhi.org.uk/multimedia/groups/clinical-investigations/ci_compensationguidelines.doc
Privacy/Data Collection	*England:*			
	1. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm 2. Information Commissioner's Office: http://www.informationcommissioner.gov.uk/ 3. National Research Ethics Service (NRES): http://www.nres.nhs.uk/ 4. National Information Governance Board for Health and Social Care: http://www.nigb.nhs.uk/	Data Protection Act (1998): http://www.legislation.gov.uk/ukpga/1998/29/contents		MRC: Personal Information in Medical Research (2000) NRES: Ethical Review of Research Databases: http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-databases/ NHS: Security of NHS Patient Data Shared for Research Purposes (2008): http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/links/infosecresearchdata.pdf/view?searchterm=data%20shared%20for%20research
Human Biological Materials	1. Royal College of Physicians (RCP): http://www.rcplondon.ac.uk/ 2. Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm 3. Human Tissue Authority (HTA): http://www.hta.gov.uk/	1. Human Tissue Act (2004): http://www.legislation.gov.uk/ukpga/2004/30/contents 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.legislation.gov.uk/uksi/		RCP: Research Based on Archived Information and Samples (1999) MRC: Human Tissue and Biological Samples for Use in Research (2001) + Annex (2004) HTA: Codes of Practice:

Country	Key Organizations	Legislation	Regulations	Guidelines
		2006/1260/contents/made 3. Statutory Instrument 2006 No. 1659: The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006: http://www.legislation.gov.uk/uksi/2006/1659/contents/made		http://www.hta.gov.uk/legislationpoliciesandcodesofpractice.cfm
Genetics Research	1. Human Genetics Commission: http://www.hgc.gov.uk/Client/index.asp?ContentId=1 2. Public Health Genetics Foundation: http://www.phgu.org.uk/index.php			Human Genetics Commission: http://www.hgc.gov.uk/Client/index.asp?ContentId=1
Embryos, Stem Cells, and Cloning	Human Fertilisation and Embryology Authority: http://www.hfea.gov.uk/	Human Fertilisation and Embryology Act (1990): http://www.legislation.gov.uk/ukpga/1990/37/contents The HFE Act (2008): http://www.hfea.gov.uk/134.html	Human Fertilisation and Embryology Regulation and Chronology: http://www.hfea.gov.uk/1319.html	

Country	Key Organizations	Legislation	Regulations	Guidelines
ASIA/PACIFIC/MIDDLE EAST				
Australia				
General	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Australian Research Council (ARC): http://www.arc.gov.au/ 3. Universities Australia (UA): http://www.universitiesaustralia.edu.au/ 4. Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS): http://www.aiatsis.gov.au/index.html	National Health and Medical Research Council Act 1992 (2011): http://www.comlaw.gov.au/Details/C2012C00255	National Health and Medical Research Regulations (2006): http://www.comlaw.gov.au/Details/F2006L03519	NHMRC: 1. Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) http://www.nhmrc.gov.au/guidelines/publications/e52 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 NHMRC, ARC, and UA: 1. National Statement on Ethical Conduct in Human Research (2009): http://www.nhmrc.gov.au/publications/synopses/e72syn.htm 2. Australian Code for the Responsible Conduct of Research (2007): http://www.nhmrc.gov.au/publications/synopses/r39syn.htm AIATSIS: Guidelines for Ethical Research in Australian Indigenous Studies (2012): http://www.aiatsis.gov.au/research/ethics/GERAIS.html
Drugs and Devices	*Drugs*			
	Therapeutic Goods Administration (TGA): http://www.tga.gov.au	Therapeutic Goods Act 1989 (2012): http://www.comlaw.gov.au/Details/C2012C00355	Therapeutic Goods Regulations 1990 (2012): http://www.comlaw.gov.au/Details/F2012C00455	TGA: 1. Human Research Ethics Committees and the Therapeutic Goods Administration (2001): http://www.tga.gov.au/hp/access-hrec.htm 2. Australian Clinical Trial Handbook (2006): http://www.tga.gov.au/pdf/clinical-trials-handbook.pdf NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2009): http://www.nhmrc.gov.au/publications/synopses/e72syn.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
	Devices			
	Therapeutic Goods Administration: http://www.tga.gov.au/industry/devices.htm	Therapeutic Goods Act 1989: http://www.comlaw.gov.au/Details/C2012C00355	Therapeutic Goods (Medical Devices) Regulations 2002 (2012): http://www.comlaw.gov.au/Details/F2012C00424	Australian Regulatory Guidelines for Medical Devices (ARGMD) (2011): http://www.tga.gov.au/industry/devices-argmd.htm
Research Injury	1. Therapeutic Goods Administration (TGA): http://www.tga.gov.au/ 2. Medicines Australia http://medicinesaustralia.com.au/ 3. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au			TGA: Guidance on Good Clinical Practice (CPMP/ICH-135/95). Paragraphs 5.8.1, 5.11.1, 8.2.5 , 8.2.7 (2000): http://www.tga.gov.au/pdf/euguide/ich13595.pdf Medicines Australia: Industry Standard Compensation Guidelines, Section 4 (2012): http://medicinesaustralia.com.au/issues-information/clinical-trials/indemity-and-compensation-guidelines/ NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research. Paragraphs 3.3.24 and 3.3.25 (2009): http://www.nhmrc.gov.au/guidelines/publications/e72
Privacy/Data Protection Note: All Australian states and territories have privacy/data protection laws: http://www.austlii.edu.au/au/other/alrc/publications/reports/108/vol_3_full.pdf	Office of the Australian Information Commissioner: http://www.privacy.gov.au/	Privacy Act 1988 (2012): http://www.comlaw.gov.au/Details/C2012C00414	Privacy (Private Sector) Regulations 2001 (2012): http://www.comlaw.gov.au/Details/F2011C00438	1. Guidelines under Section 95 of the Privacy Act 1988 (2000): http://www.nhmrc.gov.au/guidelines/publications/e26 2. Guidelines Approved under Section 95A of the Privacy Act 1988 (2001): http://www.nhmrc.gov.au/guidelines/publications/e43 3. Guidelines Approved under Section 95AA of the Privacy Act 1988 (2009): http://www.nhmrc.gov.au/guidelines/publications/e96
Human Biological Materials Note: All Australian states and territories have laws on human biological materials.	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Therapeutic Goods Administration: http://www.tga.gov.au/			NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research (2009): Chapters 3.2 and 3.4: http://www.nhmrc.gov.au/publications/synopses/e72syn.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
				TGA: Australian Regulatory Guidelines for Biologicals (2011): http://www.tga.gov.au/industry/biologicals-argb.htm
Genetic Research	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Office of the Gene Technology Regulator: http://www.ogtr.gov.au/	Gene Technology Act 2000 (2011): http://www.comlaw.gov.au/Details/C2012C00172		NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research, Chapter 3.5 (2009): http://www.nhmrc.gov.au/publications/synopses/e72syn.htm
Embryos, Stem Cells, and Cloning	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 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 2002 (2011): http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/all/search/ED63FF59CFEBB728CA2575280008CFC5 2. Research Involving Human Embryos Act 2002 (2008): http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/all/search/535F95A0A6D118AACA25752700811D2E	Research Involving Human Embryos Regulations (2008): http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/all/search/53B9DAE14F396A2CCA25744E0005E313	NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research, Chapter 3.6 (2009): http://www.nhmrc.gov.au/publications/synopses/e72syn.htm NHMRC: 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)
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)	

Country	Key Organizations	Legislation	Regulations	Guidelines
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: http://www.most.cn/	Law on Practicing Doctors (June 26, 1998), Articles 26 and 37 (Mandarin): http://www.gov.cn/banshi/2005-08/01/content_18970.htm		MOH: Interim Measures for 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 of the People's Republic of China (2001) (English): http://eng.sfda.gov.cn/WS03/CL0766/61638.html	1. Regulations for Implementation of the Drug Administration Law of the People's Republic of China (2002) (English): http://eng.sfda.gov.cn/WS03/CL0767/61640.html 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 (2010) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/62621.html 4. Provisions for Drug Registration (2007) (English): http://eng.sfda.gov.cn/WS03/CL0768/61645.html 5. Qualification and Evaluation of Clinical Trial Sites (2008) (Mandarin): http://www.sfda.gov.cn/WS01/CL0121/29571.html 6. Good Manufacturing Practice for Drugs (2010 Revision): http://eng.sfda.gov.cn/WS03/CL0768/65113.html 7. Special Review and Approval Procedure for Drug Registration of the State Food and Drug Administration (2005) (English):	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 on Ethical Review of Drug Clinical Trials (2010) (Mandarin): http://www.sfda.gov.cn/WS01/CL0050/55655.html

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://eng.sfda.gov.cn/WS03/CL0768/61646.html	
	Devices			
	State Food and Drug Administration: http://www.sfda.gov.cn/		Provisions for Clinical Trials of Medical Devices (2004) (English): http://eng.sfda.gov.cn/WS03/CL0768/61644.html	
Privacy/Data Protection	*Hong Kong:*			
	Privacy Commissioner for Personal Data: www.pco.org.hk	Personal Data (Privacy) Ordinance (2012): http://www.pcpd.org.hk/english/review_ordinance/reviewordinance.html		
Research Injury	1. Ministry of Health (MOH) (Mandarin): http://www.moh.gov.cn/ 2. State Food and Drug Administration (SFDA): http://www.sfda.gov.cn/	Chinese Good Clinical Practice, Article 43 (2003) (Mandarin): http://www.sda.gov.cn/WS01/CL0053/24473.html	MOH: 1. Interim Measures for Guidelines on Ethical Review of Biomedical Research Involving Human Subjects, Article 20 (2007) (Mandarin): http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohkjjys/s3581/200804/18816.htm 2. Regulations on Recall of Medical Devices (Interim), Article 37 (2011) (Mandarin): http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohzcfgs/s3576/201106/51998.htm	SFDA: 1. Provisions for Clinical Trials of Medical Devices, Article 8 (2004) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/24475.html 2. Guideline on Vaccine Clinical Trials, Part 6 (2004) (Mandarin): http://www.sda.gov.cn/WS01/CL0844/10307.html 3. Guideline on Ethical Review of Drug Clinical Trials, Appendix 1, Section 6.10 (2010) (Mandarin): http://www.sda.gov.cn/WS01/CL0058/55613.html
Genetic Research	1. Ministry of Health (MOH) (Mandarin): http://www.moh.gov.cn/ 2. Ministry of Science and Technology (MOST): http://www.most.cn/		MOH and MOST: Interim Measures for the Administration of Human Genetic Resources (1998) (Mandarin): http://www.most.gov.cn/bszn/new/rlyc/wjxz/200512/t20051226_55327.htm	
Embryos, Stem Cells, and Cloning	1. Ministry of Health (MOH) (Mandarin): http://www.moh.gov.cn/ 2. Ministry of Science and Technology (MOST): http://www.most.cn/		MOH: 1. Ethical Principles and Conduct Norms for Human Assisted Reproductive Technologies. (2003) (Mandarin): http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohbgt/pw10303/200804/18593.htm 2. Regulation on the Clinical Application of Medical Technique (2009)	MOH and MOST: Ethical Guidelines for Research on Human Embryo Stem Cells (2003) (Mandarin): http://www.most.gov.cn/fggw/zfwj/zfwj2003/200512/t20051214_54948.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.moh.gov.cn/publicfiles/business/htmlfiles/zwgkzt/pyzgl/200903/39511.htm	
	Hong Kong:			
	Legislative Council of the Hong Kong Special Administrative Region of the People's Republic of China: http://www.legco.gov.hk/index.html		Human Reproductive Technology Ordinance, Chapter 561 (2007): http://www.legislation.gov.hk/blis_pdf.nsf/6799165D2FEE3FA94825755E0033E532/795C7496522C8237482575EF001B5A45?OpenDocument&bt=0	
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	Revised Schedule Y of the Drugs & Cosmetics Act (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)
	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			ICMR: Ethical Guidelines for Biomedical Research on Human Participants: Clinical Trials with Surgical Procedures/Medical Devices: http://www.icmr.nic.in/ethical_guidelines.pdf
Research Injury	Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			Ethical Guidelines for Biomedical Research on Human Participants: Chapter III, Section VI (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 (1986)		DBT: 1. Recombinant DNA Safety Guidelines (1990) 2. Ethical Policies on the Human Genome, Genetic Research, and Services (2002)

Country	Key Organizations	Legislation	Regulations	Guidelines
				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)	
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	Guidelines for Clinical Trials in Human Subjects (2006) (English): http://www.health.gov.il/Download/pages/GuidelinesforClinicalTrials.doc

Country	Key Organizations	Legislation	Regulations	Guidelines
			4. 2005 Amendment (Hebrew): http://www.health.gov.il/download/forms/a2672_mk07_05.pdf	
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)		
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/i-kenkyu/rinsyo/dl/shishin.pdf
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, (2011) (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	

Country	Key Organizations	Legislation	Regulations	Guidelines
	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, (2011) (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: http://www.caa.go.jp/en/index.html	Personal Information Protection Act (2009) Japanese: http://law.e-gov.go.jp/htmldata/H15/H15HO057.html English (2003 version, chapters 1, 4-1, and 5 only): http://www.cs-trans.biz/Personal_Information.htm		
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) 2. Ministry of Education, Culture, Sports, Science, and Technology (MEXT) 3. Ministry of Health, Labor, and Welfare (MHLW) 4. Ministry of Economy, Trade, and Industry (METI)			CST: Fundamental Principles of Research on the Human Genome (2000): http://www.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.mhlw.go.jp/general/seido/kousei/i-kenkyu/genome/0504sisin.html MEXT and MHLW: Guidelines for Clinical Research in Gene Therapy (2008) (Japanese):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.mhlw.go.jp/general/seido/kousei/i-kenkyu/idenshi/0504sisin.html
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 (2010) (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 MEXT and MHLW: Ethical Guidelines for Research on Assisted Reproductive Technology to Develop Human Fertilized Embryos (2010) (Japanese): http://www.mhlw.go.jp/general/seido/kousei/i-kenkyu/dl/9_01.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 (2001): http://www.jfda.jo/custom/law/23.doc 3. Pharmacy and Drug Law No. 80 (2001)		

Country	Key Organizations	Legislation	Regulations	Guidelines
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.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/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. 10387 (2010)	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)
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	Guidelines for Bioethics and Safety Act No. 18 (2010)

Country	Key Organizations	Legislation	Regulations	Guidelines
			Recombination Research No. 2009-150 (2009)	
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. Government of the Kyrgyz Republic (Russian): http://www.gov.kg 2. Ministry of Health (Russian): http://www.med.kg	1. Constitution of Kyrgyz Republic, Chapter II, Article 22 (2010): http://www.gov.kg/?page_id=263 2. Law on Protection of Citizens Health (Sept. 1, 2005, No. 6): Articles 34 and 73 (Russian): http://www.pharm.kg/ru/legislation		
Drugs and Devices	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP) (Russian): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Drug Law of Kyrgyz Republic (30.04.2003 No. 91) Chapter VII, Articles 25-29 (2003) (Russian): http://www.pharm.kg/ru/legislation	DDMDP: An Order on the Conduct of Clinical Trials, Trials on Bioequivalence of Medical Drugs, N 26, Paragraphs 18 and 19 (1999) (Russian): http://pharm.kg/ru/legislation	DDMDP: 1. National Standard KMC 1195:2010: Medical Devices: Rules of Preparing Clinical Testing (2010) 2. About Safety of Medical Products for Medical Application, Governmental Order No. 137 of June 4, 2011: http://www.pharm.kg/ru/legislation/
Research Injury	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP) (Russian): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Drug Law of Kyrgyz Republic (30.04.2003 No. 91) Chapter VII, Article 28 (2003) (Russian): http://www.pharm.kg/ru/legislation	DDMDP: An Order on the Conduct of Clinical Trials, Trials on Bioequivalence of Medical Drugs, N 26, Paragraphs 18 and 19 (1999) (Russian): http://pharm.kg/ru/legislation	DDMDP: 1. About the Safety of Drugs for Medical Application, Governmental Order No. 137 of June 4, 2011, Chapter 4, Paragraphs 65 and 68: http://www.pharm.kg/ru/legislation/ 2. National Standard KMC 1195:2010: Medical Devices, Rules of Preparing for Clinical Testing, Paragraphs 3, 4, and 6 (2010)
Human Biological Materials	1. Ministry of Health, Department of Drug and Medical Devices Provision (Russian): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on Protection of Citizens Health in the Kyrgyz Republic (09.01.2005 No. 6): Article 39		

Country	Key Organizations	Legislation	Regulations	Guidelines
Privacy/Data Protection	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP) (Russian): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on Protection of Citizens Health in the Kyrgyz Republic (09.01.2005 No. 6): Article 91		DDMDP: 1. About the Safety of Drugs for Medical Application, Governmental Order No. 137 June 4, 2011, Chapter 4, Paragraph 68: http://www.pharm.kg/ru/legislation/ 2. National Standard KMC 1195:2010: Medical Devices, Rules of Preparing for Clinical Testing Paragraph s 14-15 (2010)
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.ethics.health.govt.nz/ 6. Ministry of Business, Innovation and Employment: http://www.msi.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 acts, bills, and regulations can be found at: http://www.legislation.govt.nz/default.aspx	HDC: The Code of Health and Disability Services Consumers' Rights (the Code of Rights) (2004): http://www.hdc.org.nz/the-act--code/the-code-of-rights	HRC: 1. Guidelines for Researchers on Health Research Involving Māori (2010) 2. Guidelines on Pacific Health Research (2005) *Access:* http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval 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 (2012) 3. Ethical Guidelines for Intervention Studies (2012) *Access:* http://www.neac.health.govt.nz/moh.nsf/indexcm/neac-resources-publications MOH: Standard Operating Procedures for Health and Disability Ethics Committees (2012): http://www.ethics.health.govt.nz/operating-procedures

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	*Drugs*			
	1. New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz 2. Medicines New Zealand: http://www.medicinesnz.co.nz/ 3. Health Research Council (HRC), Standing Committee on Therapeutic Trials: http://www.hrc.govt.nz/about-us/committees/standing-committee-therapeutic-trials-scott	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://medsafe.govt.nz/regulatory/clinicaltrials.asp RMI: Medicines New Zealand: Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial (2008): http://www.medicinesnz.co.nz/assets/Uploads/compensation-guidelines-0808-final.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	1. 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 2. Various guidelines: http://medsafe.govt.nz/regulatory/DevicesNew/13ConductingClinicalTrials.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/ethics-and-regulatory/applying-ethical-approval 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.msi.govt.nz/	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

Country	Key Organizations	Legislation	Regulations	Guidelines
				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), Gene Technology Advisory Committee: http://www.hrc.govt.nz/about-us/committees/gene-technology-advisory-committee-gtac	Hazardous Substances and New Organisms Act 1996 (2008)		HRC: Ethical Considerations Relating to Research in Human Genetics (2000): http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval/specific-considerations
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.ethicscommittees.health.govt.nz/ 5. Health Research Council (HRC), Gene Technology Advisory Committee: http://www.hrc.govt.nz/about-us/committees/gene-technology-advisory-committee-gtac	Human Assisted Reproductive Technology Act 2004 (2009)		ACART: 1. Guidelines on the Use, Storage, and Disposal of Sperm from a Deceased Man (2000) 2. Guidelines on Preimplantation Genetic Diagnosis (2005) 3. Guidelines on IVF Surrogacy (2005) 4. Guidelines on Within-Family Gamete Donation (2005) 5. Embryo Donation for Reproductive Purposes (2005) 6. Guidelines for Research on Gametes and Non-viable Embryos (Interim) *Access:* http://www.acart.health.govt.nz/moh.nsf/indexcm/acart-resources-guidelines Health and Disability Ethics Committees: Guidelines on Using Cells from Established Human Embryonic Stem Cell Lines for Research (2005): http://www.ethicscommittees.health.govt.nz/moh.nsf/indexcm/ethics-resources-consultation-guidelines-stem-cell-use
Pakistan				
General	Pakistan Medical Research Council, National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Guidelines: http://nbcpakistan.org.pk/?page_id=61
Drugs and Devices	Pakistan Medical Research Council, National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Guidelines For Healthcare Professionals Interaction with Pharmaceutical Trade and Industry (PPI Guidelines): http://nbcpakistan.org.pk/?page_id=61

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	Pakistan Medical Research Council, National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Protocol/Guidelines for Stem Cell Research/Regulation in Pakistan: http://nbcpakistan.org.pk/?page_id=61
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 4. Commission of Higher Education (CHED)		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 Ethics Review Committee at the PHREB CHED: Memo 34 Series 2007: Endorsement of DOST Administrative Order 001, Series 2007	PHREB: National Ethical Guidelines for Health Research (2006), which includes: a. Ethical Guidelines for International Collaborative Research b. Ethical Guidelines for Herbal Research c. Ethical Guidelines for Complementary and Alternative Medicine Research d. Ethical Guidelines for Epidemiological Research e. Ethical Guidelines for Social and Behavioral Research f. Ethical Guidelines for the Conduct of Research on Populations Traumatized in Emergencies and Disasters g. Ethical Guidelines for HIV/AIDS Research h. Ethical Guidelines for Research on Assisted Reproductive Technology *Access:* https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf
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 guidelines: http://www.bfad.gov.ph/default.cfm?page_id=826&parent=633
Research Injury	1. Department of Science and Technology (DOST): http://www.dost.gov.ph/ 2. Philippine Health Research Ethics			DOST: National Guidelines for Biomedical/Behavioral Research, page 14 (2000):

Country	Key Organizations	Legislation	Regulations	Guidelines
	Board (PHREB): http://www.pchrd.dost.gov.ph/index.php?option=com_frontpage&Itemid=1			www.nus.edu.sg/irb/Articles/PCHRD_DOST_NEC%20Guidelines.pdf PHREB: National Ethical Guidelines for Health Research, pages 19-20 (2006): https://webapps.sph.harvard.edu/live/gremap/files/ph_natl_ethical_gdlns.pdf
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
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/hea

Country	Key Organizations	Legislation	Regulations	Guidelines
				lth_products_regulation/clinical_trials/guidelines.html NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)
	Devices			
	1. Health Sciences Authority of Singapore (HSA): http://www.hsa.gov.sg 2. National Environment Agency, Centre For Radiation Protection And Nuclear Science	1. Health Products Act (2007): http://statutes.agc.gov.sg/ 2. Radiation Protection Act (2007): http://statutes.agc.gov.sg/	1. Health Products (Medical Device) Regulations (2010): http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/legislation.html#Health%20Products%20Act 2. Radiation Protection Regulations: http://app2.nea.gov.sg/legislation.aspx	
Research Injury	1. Health Sciences Authority 2. National Environment Agency, Centre For Radiation Protection And Nuclear Science 3. Ministry of Health National Medical Ethics Committee (NMEC)	1. Medicines Act (1975): http://statutes.agc.gov.sg/ 2. Radiation Protection Act (2007): http://statutes.agc.gov.sg/	1. Medicines (Clinical Trials) Regulations (1998) http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/legislation.html#Medicine 2. Radiation Protection Regulations: http://app2.nea.gov.sg/legislation.aspx	HSA: Singapore Guideline for Good Clinical Practice (1998) NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)
Privacy/Data Protection	1. Ministry of Information, Communications, and the Arts (MICA) 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	1. Computer Misuse Act (Cap. 50A) (1993): http://statutes.agc.gov.sg/ 2. Personal Data Protection Bill (2012) http://www.parliament.gov.sg/sites/default/files/Personal%20Data%20Protection%20Bill%2024-2012.pdf		BAC: Personal Information in Biomedical Research (2007)
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)

Country	Key Organizations	Legislation	Regulations	Guidelines
				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/	Licensing Terms and Conditions on Assisted Reproduction Services (2011): http://www.moh.gov.sg/mohcorp/publications.aspx?id=16042	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	1. Medical Care Act, Articles 8, 78, 79, 80, and 98 (2009): http://www.doh.gov.tw/ufile/doc/Medical_Care_Act98.pdf 2. Human Subjects Research Act (2011): http://www.doh.gov.tw/EN2006/DM/DM1_p01.aspx?class_no=246&now_fod_list_no=246&level_no=1&doc_no=84985	The following regulations are available in Chinese at http://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT0202.asp : 1. Enforcement Rules of the Medical Care Act (2006) 2. Regulations for Organization and Operation of Ethics Review Board (2012) 4. Exempt Review Categories for Human Research (2012) 5. Informed Consent Exemptions for Human Research (2012) 6. Expedited Review Categories for Human Research (2012) 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. Human Research Ethics Policy Guidelines (2007): http://www.doh.gov.tw/ufile/doc/Human%20Research%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 (FDA): 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. 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

Country	Key Organizations	Legislation	Regulations	Guidelines
			FDA: 1. Guideline for Good Clinical Practice (2010) (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	
Research Injury	1. Department of Health (DOH): http://www.doh.gov.tw/EN2006/index_EN.aspx 2. Taiwan Food and Drug Administration: http://www.fda.gov.tw/	Medical Care Act, Article 79 (2009): http://www.doh.gov.tw/ufile/doc/Medical_Care_Act98.pdf	FDA: Guideline for Good Clinical Practice, Article 22 (2010) (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	DOH: Human Research Ethics Policy Guidelines, Article 4 (2007): http://www.doh.gov.tw/ufile/doc/Human%20Research%20Ethics%20Policy%20Guidelines.pdf
Privacy/Data Protection	Ministry of Justice: http://www.moj.gov.tw/mp095.html	Personal Information Protection Act (2010): http://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=I0050021		
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 3. Human Subjects Research Act (2011): http://www.doh.gov.tw/EN2006/DM/DM1_p01.aspx?class_no=246&now_fod_list_no=246&level_no=1&doc_no=84985	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/ 3. National Science Council: http://web.nsc.gov.tw/default.asp?mp=7	DOH: Human Biobank Management Act (2010): http://dohlaw.doh.gov.tw/Chi/ChiContent.asp?msgid=252&KeyWord	DOH: 1. Regulations on Commercial Benefit Feedback of Human Biobank (2010) (Chinese): http://dohlaw.doh.gov.tw/Chi/NewsContent.asp?msgid=2977&KeyWord= 2. Administrative Regulations on	DOH: Guidance for Information Safety of Human Biobank (2010) (Chinese): http://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT0202.asp FDA:

Country	Key Organizations	Legislation	Regulations	Guidelines
			the Establishment of Human Biobanks (2011): http://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT0202.asp	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, Bureau of Health Promotion (DOH): http://www.bhp.doh.gov.tw/BHPnet/English/index.aspx	Artificial Reproduction Act (2007): http://dohlaw.doh.gov.tw/Chi/EngContent.asp?msgid=102&KeyWord=%A4H%A4u%A5%CD%B4%DE%AAk		DOH: 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.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/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	Medical Professions Act (2009), Articles 47-51: http://www.fercit.org/SIDCER-FERCAP/Handout_10/4.%20Accreditation-update_surveyor_aj.Sopit.pdf	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)		
Embryos, Stem Cells, and Cloning		Medical Professions Act (2009), Articles 2-3		Guidelines for Genetics and Stem Cell Research in Humans and Guidelines for Material Transfer Agreements (2002)
Vietnam				
General	1. Ministry of Public Health (MOPH) (Vietnamese): http://vbqppl.moj.gov.vn/vbpq/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=26689 2. Ministry of Health (MOH) (Vietnamese): http://vbqppl.moj.gov.vn/vbpq/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=25876		MOPH: 1. Circular No. 03/2012/TT-BYT: Guidelines on Clinical Trials 2. Decision No. 458/QD-BYT, 460/QD-BYT on Promulgation of the "Procedure of Organizing and Functioning Ethical Review Committee for Bio-Medical research, Mission 2012-2017" MOH: 1. Circular No. 37/2010/TT-BYT on Management of Scientific Research and Testing Production Project at the MOH Level (2010) 2. Decision No. 2626/QD-BYT on Promulgation of the "Procedure of Organizing and Functioning Ethical Committee for Bio-Medical research, Mission 2008 – 2012" (2008)	
Drugs and Devices	Ministry of Health: http://vbqppl.moj.gov.vn/vbpq/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=25876		1. Circular No. 08/2010/TT-BYT on the Guidance to Report Data from the Research of Bioequivalence of Drug Registration (2010) 2. Regulation on Clinical Trials (2007)	Guidelines on Good Clinical Practice of Clinical Trials (2008)

Country	Key Organizations	Legislation	Regulations	Guidelines
			3. Decision No. 799/QD-BYT of the Minister of Health on the Promulgation of the "Guidelines on Good Clinical Practice of Clinical Trials" (2008) 4. 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)	

Country	Key Organizations	Legislation	Regulations	Guidelines
LATIN AMERICA and the CARIBBEAN				
Pan American Health Organization				
Drugs and Devices	*Drugs*			
	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
	Devices			
	Pan American Health Organization: http://www.paho.org/			A Model Regulatory Program for Medical Devices: An International Guide (2001): http://www.paho.org/English/HSP/HSE/medical_devices.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 1480/2011 Approving the Guidelines for Human Health Research and Creating the National Register for Human Health Research: http://www.anmat.gov.ar/webanmat/legislacion/medicamentos/Resolucion_1480-2011.pdf 2. Ministerial Resolution 102/09: National Register for Clinical Trials	Resolution 1480/2011: Guidelines for Investigators Working with Human Beings: http://www.fecicla.org/archivos/regulaciones/Resolucion1480-11.pdf
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		1. Provision 2247/09: Guide for the Study of Clinical Trials of Type II Diabetes (2009) (Spanish): http://www.anmat.gov.ar/webanmat/Legislacion/Medicamentos/Disposicion_ANMAT_2247-2009.pdf 2. Provision ANMAT 6677/10 on Good Research Practices in Clinical Pharmaceutical Studies (2010) (Spanish): http://www.anmat.gov.ar/Comunicados/Dispo_6677-10.pdf	
	Devices			
	National Administration of Medications, Foods, and Medical Technology (ANMAT) (Spanish):		Provision 969/97 on the Regulation of Good Clinical Practice with Medical	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.anmat.gov.ar/index.asp		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		
Barbados				
	University of the West Indies – Cave Hill / Ministry of Health: http://www.cavehill.uwi.edu/researchethics/home.aspx			Research Ethics Policy and Guidelines
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/documentos/NUEVA%20CPE.pdf	1. Regulations on Public Health Research, Chapter V (1978) 2. Rules and Regulations of the National Bioethics Committee (Spanish)	MHS: Guidelines for the Development of Health Research and Ethical Norms (2002) NBC: 1. Requirements for the Evaluation of Research Projects 2. Code of Ethics and Medical Deontology
Drugs and Devices	1. Ministry of Health and Sport, National Pharmacological Commission (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://www.cnpq.br/programas/aex/docs/aex_16.pdf	CONEP: 1. Resolution 196/96: Rules on Research Involving Human Subjects (1996): http://conselho.saude.gov.br/resolucoes/1996/Res196_en.pdf 2. Resolution 304/2000: On Complimentary Rules for Research Involving Indigenous People (2000): http://www.conselho.saude.gov.br/resolucoes/2000/Reso304.doc	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf	
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 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/2008/Reso_404.doc	
Human Biological Materials	National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html	Ordinance No. 2.201/11: Establishing the National Guidelines for Biobanks of Human Biological Material for Research Purposes (2011) (Portugese): http://www2.inca.gov.br/wps/wcm/connect/59b03d80485acdbc8570b563a415c32e/portaria_2201_de_14_de_set_2011.pdf?MOD=AJPERES&CACHEID=59b03d80485acdbc8570b563a415c32e	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/resolucoes/2005/Res347_en.pdf	CONEP: Approval Guidelines for Ethical Analysis of Research Projects Involving Storage of Materials or Use of Materials Stored by Previous Research: Resolution 441/11 (2011): http://conselho.saude.gov.br/resolucoes/2005/Res347_en.pdf
Genetic Research	1. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html	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):	CONEP: Approval Guidelines for Ethical Analysis and Conduct of Research Projects in the Special Thematic Area of Human

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. National Biosafety Technical Commission (CTNBio) (Portuguese): http://www.ctnbio.gov.br		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	Genetics: Resolution 340/04 (2004): http://conselho.saude.gov.br/resolucoes/2004/Res340_en.pdf
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	Law Nº 20584. Regulating the Rights and Duties Incumbent upon Persons in Connection with Actions Linked to their Health Care (2012) (Spanish): http://www.leychile.cl/Navegar?idNorma=1039348	1. Supreme Decree No. 42 (1986) 2. Supreme Decree No. 1.935 (1993) 3. General Technical Rule No. 2 of the Ministry of Health (1993) 4. Exemption Resolution No. 134 (1994) 5. Supreme Decree No. 494 (1999) 6. Exemption Resolution No. 1.856 (1999) 7. Resolution No. 2.085 of the Ministry of Health (2001)	
Drugs 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)
Research Injury	Ministry of Health: 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	
Privacy/Data Protection		Law for the Protection of Private Life No. 19.628 (1999) (Spanish): http://www.bcn.cl/leyes/141599		

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research		Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2006): http://www.leychile.cl./Navegar?idNorma=253478		
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 Health and Social Protection (Spanish): http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430 (1993): http://www.minsalud.gov.co/Normatividad/RESOLUCION%208430%20DE%201993.pdf	
Drugs and Devices	*Drugs*			
	National Institute of Drug and Food Surveillance (Spanish): http://www.invima.gov.co/		1. Resolution No. 2378 of 2008, Adapting Good Clinical Practices for Institutions that Conduct Research with Medicines in Human Beings: http://web.invima.gov.co/portal/documents/portal/documents/root//resolucion2378_2008.pdf 2. Resolution No. 2011020764 June 10th, 2011: Regulation Related to the Content and Frequency of Adverse Event Reports in Clinical Investigation in Humans: http://web.invima.gov.co/portal/documents/portal/documents/root/normatividad/Institucional/2011/Resolucion%202011020764.pdf	
	Devices			
	National Institute of Drug and Food Surveillance (Spanish): http://www.invima.gov.co/	Various: http://web.invima.gov.co/portal/faces/index.jsp?id=2283	Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapters I and III (1993)	Various guidelines: http://web.invima.gov.co/portal/faces/index.jsp?id=2285

Country	Key Organizations	Legislation	Regulations	Guidelines
Research Injury	Ministry of Health and Social Protection (Spanish): http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Art. 13 (1993)	
Privacy/Data Protection	Ministry of Health and Social Protection (Spanish): http://www.minsalud.gov.co	Constitution of Colombia, Article 15 (2003)	Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Art. 8 (1993)	
Human Biological Materials	Ministry of Health and Social Protection (Spanish): http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter VI (1993)	
Genetic Research	Ministry of Health and Social Protection (Spanish): http://www.minsalud.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	Regulation for the Approval of Observational Studies in the CCSS: http://www.cendeisss.sa.cr/etica/06-REGULACa.html	
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)
Ecuador				
General	Ministry of Public Health: http://www.msp.gov.ec/	Organic Health Law, Articles 207-208, of 22 December 2006: http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf		1. National Policy on Scientific Research. 2. Ministerial Accord 209 RO 87 of 23 August 2005
Drugs and Devices	Ministry of Public Health: http://www.msp.gov.ec/		1. Regulation on Research, RO 292 2. Regulation for the Approval, Monitoring, Follow-up, and Evaluation of Health Research	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Projects	
Biological Materials	Ministry of Public Health: http://www.ontot.gob.ec/ontotweb	Organic Health Law, Articles 81-86, of 22 December 2006: http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf	Regulation for the Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells of 24 August 2011: http://www.ontot.gob.ec/ontotweb/index.php/descargas/reglamento?download=66:reglamento-general-a-la-ley-organica-de-donacion-y-trasplantes-de-organos-tejidos-y-celulas	
Genetic Research	Ministry of Public Health: http://www.msp.gov.ec/	Organic Health Law, Articles 209-210, of 22 December 2006: http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf		
Embryos, Stem Cells, and Cloning	Ministry of Public Health: http://www.msp.gov.ec/	Organic Health Law, Article 214, of 22 December 2006: http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf		
Grenada				
General	St. George's University/Windward Islands Research and Education Foundation (WINDREF): http://www.sgu.edu/research/research.html			Guidelines for the Conduct of Research of WINDREF
Guatemala				
Drugs and Devices	Ministry of Public Health and Social Assistance: http://www.mspas.gob.gt/		Rules for the Regulation of Human Clinical Trials. Ministerial Accord SP-M-466-2007: http://medicamentos.com.gt/index.php/legislacion-vigente/acuerdos	
Haiti				
General	Ministry of Public Health and Population (French): http://www.mspp.gouv.ht/site/index.php			Internal Regulations (2010) (French)
Honduras				
General			Health Code, Decree No. 65-91, Articles 175 and 176	

Country	Key Organizations	Legislation	Regulations	Guidelines
Jamaica				
General	Ministry of Health: http://www.moh.gov.jm/legislation/gcrhs-link			Ministry of Health Guidelines for the Conduct of Research on Human Subjects (2012)
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	1. Secretariat of Health: http://www.salud.gob.mx/ 2. General Health Council: www.csg.salud.gob.mx/ 3. National Commission of Bioethics: http://cnb-mexico.salud.gob.mx/interior/ingles/ingles.html	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 As amended (2011): http://www.diputados.gob.mx/LeyesBiblio/ref/lgs/LGS_ref49_10jun11.pdf. As amended (2012): http://www.cnb-mexico.salud.gob.mx/opencms/opencms/descargas/pdf/normatividad/normatinacional/7._NAL._Reforma_al_ART_41_Bis_LGS.pdf	Regulation on the General Health Law in the Matter of Health Research (1984) (Spanish): http://www.cofepris.gob.mx/MJ/Documents/Reglamentos/investigsalud060187.pdf	
Drugs and Devices	*Drugs*			
	Federal Commission for Protection Against Health Risks: http://www.cofepris.gob.mx/AS/Paginas/Moléculas%20nuevas/Descripción-de-Protocolos.aspx	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	1. Guidelines to Fulfill Good Clinical Practice in Health Research (Spanish): http://www.cofepris.gob.mx/AS/Documents/Moléculas%20Nuevas/Lineamientos/Lineamientos%20BPC%2031052012.pdf 2. Technical Rule No. 314 for Registration and Follow-up in the Area of Health Research (Spanish) 3. Technical Rule 315 for the Operation of Research Commissions in Healthcare Institutions (Spanish): http://www.cofepris.gob.mx/AS/Documents/M

Country	Key Organizations	Legislation	Regulations	Guidelines
				oléculas%20Nuevas/Formatos/CONFIDENCIALIDAD%20CMN%20CAS-CAS-P-02-F-02.pdf
	Devices			
	Federal Commission for Protection Against Health Risks: http://www.cofepris.gob.mx/AS/Paginas/Moléculas%20nuevas/Descripción-de-Protocolos.aspx		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): http://www.salud.gob.mx/unidades/cdi/legis/lgs/index-indice.htm		
Genetic Research	National Institute of Genomic Medicine: http://www.inmegen.gob.mx/es/	1. Biosafety Law on Genetically Modified Organisms (2008 (Spanish) 2. Modifications to the General Health Law to Protect Genomic Sovereignty (2008)	Regulation on the General Health Law in the Matter of Health 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
Privacy/Data Protection		Law 68 of 2003, Official Gazette 24,935 (Spanish): http://www.asamblea.gob.pa/APPS/LEGISPAN/PDF_GACETAS/2000/2003/24935_2003.PDF		
Human Biological Materials		Law 3 of 2003, Official Gazette 26,468-B (Spanish): http://www.asamblea.gob.pa/APPS/LEGISPAN/PDF_GACETAS/2010/2010/26468-B_2010.PDF		

Country	Key Organizations	Legislation	Regulations	Guidelines
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): http://www.digemid.minsa.gob.pe/normatividad/LEY2684202.HTM		
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) (Spanish): 2. Supreme Decree No. 006-2007-SA: Modification of the Regulation on Clinical Trials in Peru (2007) (Spanish): *Access:* http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990	
Research Injury	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		Regulation on Clinical Trials in Peru: Articles 26, 27 and 28 (Spanish): http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990	
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	
Uruguay				
General	Ministry of Public Health (Spanish): http://www.msp.gub.uy/index_1.html	1. Decree 379/008: http://www.habeasdata.org.uy/wp-content/uploads/2008/08/decreto-379008.pdf 2. Decree 189/998 http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF		
Drugs and Devices	Ministry of Public Health (Spanish): http://www.msp.gub.uy/index_1.html	Decree 189/998: http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPes		

Country	Key Organizations	Legislation	Regulations	Guidelines
		quisaClinica.PDF		
Research Injury	Ministry of Public Health (Spanish): http://www.msp.gub.uy/index_1.html	1. Decree 379/008: http://www.habeasdata.org.uy/wp-content/uploads/2008/08/decreto-379008.pdf 2. Decree 189/998: http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF		
Privacy/Data Protection	Ministry of Public Health (Spanish): http://www.msp.gub.uy/index_1.html	1. Law 18.331: http://www0.parlamento.gub.uy/leyes/AccesoTextoLey.asp?Ley=18331 2. Decree 379/008: http://www.habeasdata.org.uy/wp-content/uploads/2008/08/decreto-379008.pdf		
Human Biological Materials	1. Ministry of Public Health (Spanish): http://www.msp.gub.uy/index_1.html 2. Instituto Nacional de Donación y Trasplante (Spanish): www.indt.edu.uy	Decree 160/006: http://www.indt.edu.uy/documentos/documentacion_legal/decreto_160-006.pdf		
Venezuela				
General	1. National Fund on Science and Technology, Commission on Bioethics and Biosecurity (FONACIT) (Spanish): www.fonacit.gov.ve/ 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, then 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)

Country	Key Organizations	Legislation	Regulations	Guidelines
Kenya				
General	1. National Council for Science and Technology (NCST) 2. Ministry of Health (MOH)	1. Science and Technology Act (2001) 2. HIV and AIDS Prevention and Control Act, Chapter 14 (2006)	NCST: Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (2004): https://webapps.sph.harvard.edu/live/gremap/files/ke_NCST_guidelines.pdf	
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 Commission for Science and Technology (NCST) 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)	NCST: 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/researchguidelines.htm
Drugs and Devices	Pharmacy, Medicines, and Poisons Board of Malawi	1. Pharmacy, Medicines, and Poisons Act, Act 15 of 1988) 2. Section 42(1) of PMPB Act, 2003 Supplement		
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	

Country	Key Organizations	Legislation	Regulations	Guidelines
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
South Africa				
General	1. Department of Health (DH): http://www.doh.gov.za 2. National Health Research Ethics Council: http://www.nhrec.org.za/ 3. Medical Research Council of South Africa (MRC): http://www.mrc.ac.za 4. Human Sciences Research Council (HSRC): http://www.hsrc.ac.za/index.phtml	1. Constitution of South Africa, Section 12 (2) (1996) 2. National Health Act No. 61, Chapter 9 (2003): http://www.doh.gov.za/docs/legislation-f.html 3. MRC Act: http://www.mrc.ac.za/about/MRCAct.pdf 4. HSRC Act: http://www.hsrc.ac.za/Document-2931.phtml		DH: Ethics in Health Research: Principles, Structures, and Processes (2004): http://www.doh.gov.za/nhrec/norms/ethics.pdf MRC: 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) *Access:* http://www.sahealthinfo.org/ethics/index.htm
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	General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (2003): 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	1. Regulations Relating to the Use of Human Biological Material, 2 March 2012: http://www.doh.gov.za/docs/regulations/2012/regr177.pdf 2. Regulations Regarding General Control of Human Bodies, Tissues, Blood Products and Gametes, 2 March 2012 3. Regulations Relating to Blood and Blood Products, 2 March 2012: http://www.doh.gov.za/docs/regulations/2012/regr179.pdf 4. Regulations Relating to Artificial Insemination of Persons, 2 March 2012: http://www.doh.gov.za/docs/regulatio	

Country	Key Organizations	Legislation	Regulations	Guidelines
			ns/2012/regr175.pdf	
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	Regulations relating to Stem Cell Banks, 2 March 2012: http://www.doh.gov.za/docs/regulations/2012/regr183.pdf	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)		
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): https://webapps.sph.harvard.edu/live/gremap/files/Guildelines-2001-TZ-full.pdf 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)		

Country	Key Organizations	Legislation	Regulations	Guidelines
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 for Science and Technology (UNCST): http://www.uncst.go.ug/	Uganda National Council for Science and Technology Act (CAP 209)		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 Policy and Authority Act (CAP 206) (1993)		
Zimbabwe				
General	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw	1. Government Notice Act (1974) 2. Research Act (1986)		Ethics Guidelines for Health Research Involving Human Participants in Zimbabwe
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	Research Council of Zimbabwe: www.rcz.ac.zw			1. Foreign Researcher Application 2. Specimen Shipment Guidelines 3. Material Transfer Agreements

Representatives from the following countries or organizations provided an update (or verification of accuracy of the existing entry) for the 2013 Edition of the International Compilation of Human Research Standards:

International:
World Health Organization

North America:
Canada
United States

Europe:
European Union
European Medicines Agency
Council of Europe
Austria
Bosnia and Herzegovina
Bulgaria
Croatia
Czech Republic
Estonia
France
Greece
Hungary
Latvia
Lithuania
Luxemburg
Macedonia
Malta
Moldova
Netherlands
Romania
Russia
Serbia
Sweden
Switzerland
Turkey
Ukraine
United Kingdom

Asia/Pacific/Middle East:
Australia
Burma
China
India
Israel
Japan
Kyrgystan
New Zealand
Pakistan
Singapore
Taiwan
Vietnam

Latin America and the Caribbean:
Argentina
Chile
Colombia
Dominica
Ecuador
Jamaica
Mexico
Peru

Africa:
Egypt
Kenya
Malawi
Nigeria
South Africa
Uganda
Zimbabwe