International Compilation of Human Research Standards

2015 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 113 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.

Content experts from around the world, listed on pages 139-140, provided updates (or confirmations of prior listings), which are reflected in the hundreds of changes entered into this Edition. Six new countries are featured in the 2015 edition: Ghana, Guinea, Liberia, Malaysia, Saudi Arabia, and Sierra Leone.

ORGANIZATION

The Table of Contents is found on page 3. For each country, the standards are categorized by row 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 full understanding of the country's requirements.

The information is then organized into four columns:

1. Key Organizations – include those groups that issue regulations or guidelines, or serve in a national oversight role for human subjects research.
2. Legislation – 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 of 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 DOCUMENT

Documents can be accessed in four 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 many cases the documents are available in English. Sometimes the English translation is a non-official version. When the citation links to a non-English 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.

NEW STANDARDS, UPDATES, AND BROKEN LINKS

To request inclusion of a new standard in the Compilation, or to report updates or broken links, contact Edward E. Bartlett, PhD, International Human Research Liaison, Office for Human Research Protections, U.S. Department of Health and Human Services: 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.

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Country	Key Organizations	Legislation	Regulations	Guidelines
INTERNATIONAL				
General	Council for International Organizations of Medical Sciences (CIOMS): http://www.cioms.ch/			1. International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) 2. International Guidelines for Ethical Review of Epidemiological Studies (2009)
	World Medical Association: http://www.wma.net/e/			Declaration of Helsinki (2013): http://www.wma.net/en/30publications/10policies/b3/index.html
	World Health Organization: http://www.who.int/en/			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 3. Ethical Issues in Patient Safety Research: Interpreting Existing Guidance (2013): http://apps.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf
	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			Universal Declaration on Bioethics and Human Rights (2005)
	UNAIDS: http://www.unaids.org/			1. Prevention Trials (2007): http://data.unaids.org/pub/Report/2007/JC1399_ethical_considerations_en.pdf 2. Ethical Considerations in Biomedical HIV Prevention Trials Ethical Considerations in Biomedical HIV (2012): http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399_ethical_considerations_en.pdf
	Office of the United Nations High Commissioner for Human Rights (OHCHR): http://www.ohchr.org/english/	International Covenant on Civil and Political Rights, Article 7 (1976):		

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		http://www2.ohchr.org/english/law/ccpr.htm		
	International Committee of the Red Cross (ICRC): www.icrc.org	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		
Drugs and Devices	*Drugs*			
	International Conference on Harmonization (ICH): http://www.ich.org/			E6 Good Clinical Practice: Consolidated Guidance (1996): http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
	World Health Organization (WHO): http://www.who.int/en/			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			
	Global Harmonization Task Force (GHTF): http://www.ghtf.org/			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
	International Standards Organization: http://www.iso.org/iso/home.html			Clinical Investigation of Medical Devices for Human Subjects -- Good Clinical

Country	Key Organizations	Legislation	Regulations	Guidelines
				Practice. Standard Number 14155:2011: http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=45557
Research Injury	World Medical Association: http://www.wma.net/e/			Declaration of Helsinki, Paragraph 15 (2013): http://www.wma.net/en/30publications/10policies/b3/index.html
	International Conference on Harmonization (ICH): http://www.ich.org/			E6 Good Clinical Practice: Consolidated Guidance, Section 5.8 (1996): http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
	Council for International Organizations of Medical Sciences: http://www.cioms.ch/			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			1. Declaration on Ethical Considerations Regarding Health Databases (2002): http://www.wma.net/en/30publications/10policies/d1/index.html 2. Declaration of Helsinki, Paragraph 24 (2013): http://www.wma.net/en/30publications/10policies/b3/index.html
Human Biological Materials	World Health Organization: http://www.who.int/en/			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
	International Air Transport Association: http://www.iata.org/			Infectious Substances and Diagnostic Specimens Shipping Guidelines (2005)
	International Society for Biological and Environmental Repositories: http://www.isber.org			Best Practices for Repositories I: Collection, Storage and Retrieval of Human Biological Materials for Research (2005)
Genetic Research	Human Genome Organization: http://www.hugo-international.org/			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)

Country	Key Organizations	Legislation	Regulations	Guidelines
				4. Statement on Human Genomic Databases (2002)
	UNESCO Bioethics Program: http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html			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 human subject research standards.	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.forces.gc.ca/en/about-policies-standards-defence-admin-orders-directives-5000/5061-0.page Correctional Service of Canada: Commissioner's Directive - Research: DCOO9 (2004): http://www.csc-scc.gc.ca/acts-and-regulations/009-cde-eng.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) (2001): http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/reg/1024_tc-tm-eng.php	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 11: Clinical Trials (2010): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/
	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-lois.justice.gc.ca/eng/regulations/sor-98-282/FullText.html	
Research Injury	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Article 3.2(j) (2010): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-

Country	Key Organizations	Legislation	Regulations	Guidelines
				chapitre3/#toc03-1a
Privacy/Data Protection Note: Each of the Canadian provinces and territories also has 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 (September 29, 2014)	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 5: Privacy and Confidentiality (2010): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/ CIHR: CIHR Best Practices for Protecting Privacy in Health Research (2005): http://www.cihr-irsc.gc.ca/e/29072.html
Human Biological Materials	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 12: Human Biological Materials Including Materials Related to Human Reproduction (2010): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/
Genetic Research	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 2. Canadian Biotechnology Advisory Committee (CBAC): http://www.hc-sc.gc.ca/sr-sr/biotech/role/strateg-eng.php 3. Biologics and Genetic Therapies Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 13: Human Genetic Research (2010): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter13-chapitre13/
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://laws-lois.justice.gc.ca/eng/acts/A-13.4/	Assisted Human Reproduction (Section 8 Consent) Regulations (2007): http://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-137/index.html	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 12, Section F (2010) CIHR: Updated Guidelines for Human Pluripotent Stem Cell Research (2010): http://www.cihr-irsc.gc.ca/e/42071.html

Country	Key Organizations	Legislation	Regulations	Guidelines
United States 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. 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://history.nih.gov/research/downloads/PL103-43.pdf	45 CFR 46, Subparts A, B, C, D, and E: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html	Various: http://www.hhs.gov/ohrp/policy/index.html
	Department of Homeland Security: www.dhs.gov/	Public Law 108-458, Section 8306	1. 45 CFR 46, Subparts A-D 2. DHS Directive 026-04, Human Subjects Research (2007): https://www.dhs.gov/xlibrary/assets/foia/mgmt-directive-026-04-protection-of-human-subjects.pdf	
	Department of Housing and Urban Development: www.hud.gov/		24 CFR 60, Subpart A	
	1. Department of Justice Office of Justice Programs: http://ojp.gov/		1. 28 CFR 22 Privacy Regulation (1976): http://www.ecfr.gov/cgi-bin/text-	

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	2. Bureau of Prisons: www.bop.gov		idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr22_main_02.tpl 2. 42 U.S.C. § 3789g Confidentiality of Information (1984) http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap46-subchapVIII-sec3789g.htm 3. 28 CFR 46 (1991), Subpart A: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr46_main_02.tpl	
	Department of Transportation: www.dot.gov/		49 CFR 11, Subpart A	
	Department of Veterans Affairs: 1. Office of Research Oversight (ORO): http://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 (2013) 6. Subpart L: Prohibition of Third-Party Intentional Exposure	Scientific and Ethical Approaches for Observational Exposure Studies (2008): http://www.epa.gov/nerl/sots/SEAOES_doc20080707.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			Research for Pesticides in Children and Pregnant or Nursing Women (2013)	
	National Aeronautics and Space Administration: www.nasa.gov/		14 CFR 1230, Subpart A	
	National Science Foundation: www.nsf.gov/		45 CFR 690, Subpart A	
	Social Security Administration: http://www.ssa.gov/		45 CFR 46, Subpart A: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html	
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 (2012): http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm 2. Public Health Service Act, 42 USC Section 262 (1998): http://www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm	1. 21 CFR 50 (2011) 2. 21 CFR 312 (2011) 3. 21 CFR 56 (2009) 4. 21 CFR 314 (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. Other: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
	Devices			
	Food and Drug Administration, Center for Devices and Radiological Health: http://www.fda.gov/MedicalDevices/default.htm	Food, Drug, and Cosmetic Act, 21 USC Section 360 (2012): 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 (2014)	1. Good Clinical Practice and Human Subject Protections in FDA-Regulated Clinical Trials: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm 2. Other: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm
Research Injury	Same as *General*, listed above.		Sections 116(a)(6) and (7) of the Common Rule Subpart A.	
	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/	38 CFR 17.85: Treatment of Research-Related Injuries to Human Subjects	Handbook 1200.5, Appendix F, Paragraph 2a(11)	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Office of Research and Development: www.research.va.gov			
Privacy/Data Protection	1. DHHS National Institutes of Health (NIH): http://privacyruleandresearch.nih.gov/ 2. DHHS 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.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/ 3. Confidential Information Protection and Statistical Efficiency Act (CIPSEA) (2002): http://www.eia.doe.gov/oss/CIPSEA.pdf	1. HIPAA Privacy Rule: Standards for Privacy of Individually Identifiable Health Information, Final Rule, 45 CFR parts 160 and 164 (2002): http://www.hhs.gov/ocr/hipaa/privrulepd.pdf 2. HIPAA Security Rule, 45 CFR parts 160, 162, and 164: http://www.hhs.gov/ocr/privacy/hipaa/administrative/index.html	NIH: Various: http://privacyruleandresearch.nih.gov/
	Social Security Administration: http://www.ssa.gov/	Privacy Act (1974): http://www.hhs.gov/foia/privacy/index.html Health Insurance Portability and Accountability Act (1996): http://www.cms.gov/home/regsguidance.asp		
Human Biological Materials	Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/			1. Issues to Consider in the Research Use of Stored Data or Tissues (1997) 2. Guidance on Research Involving Coded Private Information or Biological Specimens (2008)
	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			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: Various: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/ucm094338.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research	1. DHHS Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/ 2. DHHS 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://www.hhs.gov/ohrp/policy/gina.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
Embryos, Stem Cells, and Cloning	Food and Drug Administration, Center for Biologics Evaluation and Research: http://www.fda.gov/BiologicsBloodVaccines/default.htm			Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products. October 14, 1993. 58 FR 53248
	National Academy of Sciences (NAS): http://www.nationalacademies.org/nrc/			1. Guidelines for Human Embryonic Stem Cell Research (2005): http://www.nap.edu/catalog.php?record_id=11278 2. 2008 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research: http://books.nap.edu/catalog.php?record_id=12260 3. 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
	National Institutes of Health: http://stemcells.nih.gov/index.asp	Research on Transplantation of Fetal Tissue. Public Law 103-43		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

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EUROPE				
European-wide				
General	European Commission: 1. European Group on Ethics in Science and New Technologies (EGE): http://ec.europa.eu/european_group_ethics/index_en.htm 2. Directorate-General for Research and Innovation: http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm			EGE: Ethical Aspects of Clinical Research in Developing Countries (2003): http://ec.europa.eu/bepa/european-group-ethics/docs/avis17_en.pdf
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics			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*			
	European Commission: Directorate-General for Health and Consumers, Pharmaceuticals Unit: http://ec.europa.eu/health/index_en.htm	1. Directive 2001/20/EC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF 2. Directive 2005/28/EC Laying Down Principles and Detailed Guidelines for Good Clinical Practice as Regards Investigational Medicinal		EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/health/documents/eudralex/vol-10/

Country	Key Organizations	Legislation	Regulations	Guidelines
		Products for Human Use, as Well as the Requirements for Authorization of the Manufacturing or Importation of Such Products: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2005_28/dir_2005_28_en.pdf 3. Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014R0536&from=EN		
	European Medicines Agency: http://www.ema.europa.eu/		Policy on Publication of Clinical Data for Medicinal Products for Human Use (2014): http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/10/news_detail_002181.jsp&mid=WC0b01ac058004d5c1#	1. Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997) 2. Reflection Paper on Ethical and GCP Aspects of Clinical Trials of Medicinal Products for Human Use Conducted Outside of the EU/EEA and Submitted in Marketing Authorization Applications to the EU Regulatory Authorities: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/04/WC500125437.pdf 3. Questions and Answers on the European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use (2014): http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/10/news_detail_002181.jsp&mid=WC0b01ac058004d5c1#
	Devices			
	European Commission: Directorate-General for Health and Consumers, Cosmetics and Medical Devices: http://ec.europa.eu/health/medical-devices/index_en.htm	1. Directive 93/42/EEC Concerning Medical Devices: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF 2. Directive 98/79/EC on in vitro Diagnostic Medical Devices (IVDD): http://eur-		Various: http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm

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		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 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	European Commission: Directorate-General for Health and Consumers, Pharmaceuticals Unit: http://ec.europa.eu/health/index_en.htm	1. Directive 2001/20/EC: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF 2. Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014R0536&from=EN		
	Council of Europe, Bioethics Division: http://www.coe.int/bioethics			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	European Commission: Directorate-General for Communications Networks, Content, and Technology:	Data Protection Directive 95/46/EC of the European Parliament and of the Council (1995):		

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	http://ec.europa.eu/dgs/connect/	http://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf		
	Council of Europe: 1. Bioethics Division: http://www.coe.int/bioethics 2. Data Protection and Cybercrime Division: http://www.coe.int/t/dghl/standardsetting/dataprotection/default_EN.asp			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): https://wcd.coe.int/ViewDoc.jsp?id=571075&Site=CM&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383 3. Article 29 Working Party Documentation: http://ec.europa.eu/justice/data-protection/article-29/documentation/index_en.htm
Human Biological Samples	European Commission: European Group on Ethics in Science and New Technologies: http://ec.europa.eu/bepa/european-group-ethics/welcome/index_en.htm	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		Ethical Aspects of Human Tissue Banking (1998)
	European Medicines Agency: http://www.ema.europa.eu/			Concept Paper on the Development of a Guideline on Biobanks Issues Relevant to Pharmacogenetics (2005)
	Council of Europe, Bioethics Division: http://www.coe.int/bioethics			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

Country	Key Organizations	Legislation	Regulations	Guidelines
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. 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 3. 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 4. Recommendation Rec (2006)4 of the Committee of Ministers to Members States on Research on Biomedical Materials of Human Origin (2006): http://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75
Embryos, Stem Cells, and Cloning	European Commission: European Group on Ethics in Science and New Technologies: http://ec.europa.eu/bepa/european-group-ethics/welcome/index_en.htm	1. Statements by the Commission Re: Article 6 (2006): http://www.uv.es/operuv/docs_7pm/FP7ECStatementsComm_Ethical.pdf 2. Statement of the Commission Related to Research Activities Involving Human Embryonic Stem Cells (2013): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF		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
	Council of Europe, Bioethics Division: http://www.coe.int/bioethics			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=9/15/2

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				008&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
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 (Armenian): http://www.pharm.am/ 2. Ethics Committee of the Ministry of Health	1. Law of the Republic of Armenia of May 4, 1996: About Medical Aid, The Maintenance of the Population, Article 21 (Armenian): http://www.arlis.am/DocumentView.aspx?DocID=71619 2. Resolution of the Government of Armenia of January 24, 2002: Procedure for Clinical Trials of New Medications in Armenia (Armenian): http://www.arlis.am/DocumentView.aspx?docID=9154		
Human Biological Materials	Ethical Committee of the National Center for AIDS Prevention	RA Law on Prevention of Disease Caused by HIV (2012) (Armenian): http://www.arlis.am/DocumentView.aspx?DocID=78616		Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2013)
Austria				
General	1. Ministry of Health (German): http://www.bmg.gv.at 2. Forum of Austrian Ethics Committees (German): http://www.ethikkommissionen.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 (2014) (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 (German): 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-	Austrian Drug Law (2013) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True		Various (German): http://www.basg.at/arzneimittel/vor-der-zulassung/klinische-pruefungen/

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	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/			
	Devices			
	Same as Drugs.	Medical Devices Act (2014) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003		Various (German): http://www.basg.at/medizinprodukte/formulare/klinische-pruefung/
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/	1. Austrian Drug Law, Article 32 (2013) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True 2. 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 Authority: https://www.dsb.gv.at/DesktopDefault.aspx?alias=dsken	Federal Act Concerning the Protection of Personal Data (2014): http://www.ris.bka.gv.at/Dokumente/Erv/ERV_1999_1_165/ERV_1999_1_165.pdf		
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 (2013) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005698&ShowPrintPreview=True	Regulation on Tissue Banks (2014) (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):

Country	Key Organizations	Legislation	Regulations	Guidelines
				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 (2012) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826&ShowPrintPreview=True		
Embryos, Stem Cells, and Cloning	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	Reproductive Medicine Act (2010) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10003046&ShowPrintPreview=True		Bioethics Commission: 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. Ordinance No. 274 on Establishing the National Bioethics Committee (2006) 2. Decree No. No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html	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 (Russian): http://rceth.by/	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. Ordinance No. 254 on Clinical Drug Trials and Good Clinical Practice (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num36/d36922/index.html 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

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			3. Decree No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.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	
	Devices			
	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. Centre for Expertise and Testing in Health Care (Russian): http://rceth.by/	Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: 1. 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 2. 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	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	

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			SSFM: Ordinance No. 38-c on Rules for Conducting Morphological Examinations (1999)	
Belgium				
General	Belgium Advisory Committee on Bioethics (BACB): http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Commitees/Bioethics/?fodnlang=en	Law Relating to Experimentation on Humans (2004): http://www.erasme.ulb.ac.be/page.asp?id=11365&langue=EN		BACB (French): http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Commitees/Bioethics/Opinions/index.htm 1. Opinion No. 13: Regarding Experimentation on Man (2001) 2. Opinion No. 31: Regarding Experimentation Involving Pregnant and Breastfeeding Women (2004)
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 (2004)		
Privacy/Data Protection	Commission for the Protection of Privacy (French and Flemish):	Law of December 8, 1992 on Privacy Protection in Relation to	Decree of February 13, 2001 Implementing the Law of	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.privacy.fgov.be/	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	December 8, 1999	
Human Biological Materials	1. Conseil Supérieur de la Santé/Hoge Gezondheidsraad (CSS) (French and Dutch): http://www.health.fgov.be/CSS_HGR 2. Federal Public Service: www.health.fgov.be	1. Royal Decree (1987) Regarding the Expression of Consent for the Removal of Organs and Tissues on Living Donors 2. Royal Decree (1997) Regarding the Removal and Allocation of Organs of Human Origin 3. Act on the Removal and Transplantation of Organs (2006) (French): 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		CSS: Common Quality Standards for All Tissues and Cells of Human Origin Intended for Human Application (2007) (French): https://portal.health.fgov.be/pls/portal/docs/PAGE/INTERNET_PG/HOMEPAGE_MENU/ABOUTUS1_MENU/INSTITUTIONSAPPARENTEES1_MENU/HOGEGEZONDHEIDSRAAD1_MENU/ADVIEZENENAANBEVELINGEN1_MENU/ADVIEZENENAANBEVELINGEN1_DOCS/7691_SQ_COMMUNS_2007_FR.PDF
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: http://health.belgium.be/eportal/Healthcare/Consultativebodies/Commissions/Embryoinvitro/19076630?ie2Term=research&ie2section=83	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		

Country	Key Organizations	Legislation	Regulations	Guidelines
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. 58/08: http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf 2. Law on Changes and Amendments of the Law on Drugs No. 29/05: http://www.almbih.gov.ba/_doc/regulative/fbih/Zakon_o_lijekovima-sluzbene_novine_FBiH_broj_29-05.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	
	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. 58/08: http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.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	Regulation about Clinical Testing of IMP and Medical Devices, 4/10: http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf	
	Republic of Srpska: Ministry of Health and Social Welfare (Bosnian):	Law on Health Insurance of the Republic of Srpska, Official Gazette Republic of Srpska No.		

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.fmoh.gov.ba/	51/01, 70/01, 51/03, 17/08, 1/09		
Privacy/Data Protection	Personal Data Protection Agency of Bosnia and Herzegovina: http://www.azlp.gov.ba/Default.aspx?langTag=en-US&template_id=147&pageIndex=1	1. 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 2. Law about Amendments of Law on the Protection of Personal Data in Bosnia and Herzegovina, Official Gazette of Bosnia and Herzegovina No. 76/11: http://www.azlp.gov.ba/index.php?type=1&a=pages&id=2		
Embryos, Stem Cells and Cloning		1. Law on Transplantation of Organs and Tissues, Official Gazette of Bosnia and Herzegovina No. 75/09: http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-transplantaciji-organa-i-tkiva-u-svrhu-lijecenja 2. Law on Blood and Blood Products, Official Gazette of Bosnia and Herzegovina No. 09/10: http://www.fbihvlada.gov.ba/bosanski/zakoni/2010/zakoni/8bos.htm		
Bulgaria				
General	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	1. Constitution of the Republic of Bulgaria, Amendment SG. 18/25, Article 29 (2007): http://www.government.bg/cgi-bin/e-cms/vis/vis.pl?p=0159&n=000007 2. Oviedo Convention on Human Rights and Biomedicine (2001) 3. Law Ratifying the Additional Protocol on Biomedical Research (2006) 4. Healthcare Act, Articles 197 and 206 (2014) 5. Law on Medicinal Products in		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Human Medicine (2014): http://en.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf		
Drugs and Devices	*Drugs*			
	1. Ministry of Healthcare (MOH) (Bulgarian): http://www.mh.government.bg/ 2. Bulgarian Drug Agency (BDA): http://en.bda.bg/	Law for Medicinal Products in Human Medicine, Chapter 4 (2014): http://en.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf	MOH: Regulation No. 31 on the Rules for GCP (2014)	
	Devices			
	Bulgarian Drug Agency (BDA) (Bulgarian): http://en.bda.bg/			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 (BDA): http://en.bda.bg/	Law on Medicinal Products in Human Medicine, Chapter 4, Articles 91 and 92 (2013): http://en.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf	Regulation 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice, Section 5.8 (2012): http://www.bda.bg/images/stories/documents/regulations/naredbi/naredba31.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 (2012): https://www.cpdp.bg/?p=element&aid=373	Regulation No. 13 of 04 April 2007 for the Terms and Conditions of Informing Bulgarian Citizens on the Activities regarding the Transplantation of Organs, Tissues and Cells	
Embryos, Stem Cells, and Cloning	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	Law Ratifying the Convention for Human Rights (2007) 2. SG No. 13/8, Article 134 (2008)		
Croatia Note: All websites and documents are in Croatian.				
General		1. Patient Protection Act, Article 20: http://www.zakon.hr/z/255/Zakon-o-za%C5%A1titi-prava-pacijenata 2. Convention on Human Rights and Biomedicine (Convention of		

Country	Key Organizations	Legislation	Regulations	Guidelines
		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 (MZ): http://www.zdravlje.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.almp.hr/#	Medicinal Product Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html	MZSS: 1. Ordinance on Clinical Trials and Good Clinical Practice (2010): http://narodne-novine.nn.hr/clanci/sluzbeni/2010_01_14_347.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			
	1. Ministry of Health and Social Welfare (MZSS): http://www.mzss.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.almp.hr/#	Medical Devices Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1521.html		
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 Mandatory Health Insurance (2013): http://www.hzzo-net.hr/dload/zakoni/2013_06_80_1666.pdf 2. Medicinal Product Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html	Rules about Clinical Trials and Good Clinical Practice, Articles 12 and 13, Act 5.3 and 8.2.5 (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2010_01_14_347.html	
Privacy/Data Protection	Croatian Personal Data Protection Agency: http://www.azop.hr/	1. Personal Data Protection Act (2012): http://www.legal500.com/c/croatia/developments/4908 http://narodne-novine.nn.hr/clanci/sluzbeni/2012_09_106_2300.html 2. Law about the Right to Access Personal Information (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_02_25_403.html		

Country	Key Organizations	Legislation	Regulations	Guidelines
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): http://zakon.poslovna.hr/public/Konvencija-o-zastiti-ljudskih-prava-i-dostojanstva-ljudskog-bica-u-pogledu-primjene-biologije-i-medicine-u-vezi-presadivanja-organa-i-tkiva-ljudskog-porijekla/243337/zakoni.aspx 2. Law about Blood and Blood Products from 2006: http://narodne-novine.nn.hr/clanci/sluzbeni/2006_07_79_1916.html 3. Rule Book on Amendments to Law about Blood and Blood Products (2011): http://narodne-novine.nn.hr/clanci/sluzbeni/2011_11_124_2476.html 4. Medical Fertilization Act: (2012): http://www.hzzo-net.hr/dload/zakoni/20_01.pdf 5. Law on the Implementation of Human Tissues and Cells (2012): http://www.hzzo-net.hr/dload/zakoni/21.pdf 6. Ordinance on the Conditions of Space, Professional Workers, Medical-Technical Equipment and Quality Assurance for Collection, Retrieval, Testing, Processing, Preservation, Storage and Allocation of Human Tissues and Cells (2013): http://www.propisi.hr/print.php?id=9354		

Country	Key Organizations	Legislation	Regulations	Guidelines
Cyprus				
General		1. Law No. 31 (III)/2001: Oviedo Convention on Human Rights and Biomedicine 2. The Safeguarding and Protection of Patients' Rights Law (2004): http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/6960B7A5AA76C4A3C22571C9002B99F0?OpenDocument		
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/$FILE/138(I)-2001_en.pdf 2. Amended in 2003: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/37(I)-2003_en.pdf		
Embryos, Stem Cells, and Cloning		Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002)		

Country	Key Organizations	Legislation	Regulations	Guidelines
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 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 22/1997 Coll., on Technical Requirements for Products and Amendments to Some Related Acts 2. Act No 123/2000 Coll., on Medical Devices and on Amendments to Some Related Acts, as Amended	Various: http://www.sukl.cz/medical-devices?highlightWords=501%2F2000	Various: http://www.sukl.cz/medical-devices-guidelines
Research Injury		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001) 2. Law No. 89/2012 Coll. Civil Code: http://www.czechlegislation.com/en/89-2012-sb		
Privacy/Data Protection	Office for Personal Data Protection: http://www.uoou.cz/uoou.aspx	Act on the Protection of Personal Data and on Amendment to Some Related Acts (No. 101 of April 4, 2000): http://www.uoou.cz/uoou.aspx?menu=4&submenu=5	Position No. 3/2004 Personal Data Processing in the Context of 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&	1. Act of 26 April 2006 on Research on Human Embryonic Stem Cells No. 227/2006 Sb.		

Country	Key Organizations	Legislation	Regulations	Guidelines
	lred=1 2. Research and Development Council, Bioethical Commission: http://www.vyzkum.cz/FrontClanek.aspx?idsekce=15908	(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 Research Ethics Review of Health Research Projects (2011): http://www.cvk.sum.dk/English/actonabiomedicalresearch.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	Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics, and Appendices (2011): http://www.cvk.sum.dk/English/guidelinesabout notification.aspx
Drugs and Devices	Danish Medicines Agency: http://www.dkma.dk	Medicinal Product Act No. 506 (2013)	1. Executive Order on Clinical Trials on Medicinal Products, Human Use (2004) 2. Executive Order No. 935 on Informed Consent from Patients in Biomedical Trials (2011) 3. Danish Guideline on Notification of Clinical Trials of Medicinal Products in Humans (2011)	Guideline on Informed Consent from Patients in Biomedical Trials (2011)
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/Behandlingsskader.aspx 2. Danish Act on the Right to Complain and Receive Compensation within the Health Service No. 904 (2013): 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/da-DK.aspx?sc_lang=en	1. Act on Processing of Personal Data (Act No. 429) (2007): http://www.datatilsynet.dk/english/t		DCE: Protection of Sensitive Personal Information

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	2. Danish Data Protection Agency (DPA): http://www.datatilsynet.dk/english/	he-act-on-processing-of-personal-data/ 2. Health Law Chapter 9 (2010)		
Human Biological Materials	Danish National Committee on Biomedical Research Ethics (CVK): http://www.cvk.sum.dk/CVK/Home/English.aspx	1. Health Law (2005) 2. Act on Processing of Personal Data (Act No. 429) (2007): http://www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/ 3. Act on Biomedical Research		
Genetic Research		Act on the DNA Profile Register, Act No. 434 of 31 May 2000		
Embryos, Stem Cells, and Cloning	Danish Council of Ethics: http://www.etiskraad.dk/da-DK.aspx?sc_lang=en	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002) 2. Act on Medically Assisted Procreation No. 602 (2012) 3. Health Law No. 913, Chapter 7 (2010)		1. Cloning (2001) 2. Research in Human Gametes, Fertilized Ova, Embryos and Fetuses (2004)
Estonia				
General	Estonian Council on Bioethics	1. Oviedo Convention on Human Rights and Biomedicine (2002) 2. Constitution of the Republic of Estonia, Paragraph 18 (2011): https://www.riigiteataja.ee/en/eli/530102013003/consolide		Code of Ethics of Estonian Scientists: http://www.akadeemia.ee/_repository/File/ALUSDOKUD/Code-ethics.pdf
Drugs and Devices	*Drugs:* 1. State Agency of Medicines: http://www.sam.ee/en/clinical-trials-medicinal-products-estonia 2. Minister of Social Affairs (MSA): http://www.sm.ee/eng.html	Medicinal Products Act, Chapter 5 (2013): https://www.riigiteataja.ee/en/compare_original?id=507112013005	MSA: 1. 1 RTL 2005, 22, 298: 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 (2005) 2. Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 (2005):	

Country	Key Organizations	Legislation	Regulations	Guidelines
			www.sam.ee/conditionsandprocedureforconductingclinicalt	
	Devices: Estonian Health Board: http://www.terviseamet.ee/en/medical-devices.html		Same as above.	
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: https://www.riigiteataja.ee/en/eli/507112013005/consolide	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 (2011): https://www.riigiteataja.ee/en/eli/512112013011/consolide		
Genetic Research		Human Genes Research Act (RT I 2000, 104, 685) (2010): https://www.riigiteataja.ee/en/eli/ee/518062014005/consolide		
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): https://www.riigiteataja.ee/akt/78569 2. Artificial Insemination and Embryo Protection Act, RT I 1997, 51, 824 (2011): https://www.riigiteataja.ee/en/eli/530102013057/consolide		
Finland				
General	1. Ministry of Social Affairs and Health (MSAH): http://www.stm.fi/en/frontpage 2. National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en 3. National Advisory Board on Research Ethics (TENK): http://www.tenk.fi/en/index.html	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 Research Ethics Council of Finland No. 1347/2002 2. Decree on Medical Research and Subsidiary Regulations Issued in Pursuance Hereof, No. 313/2004 3. Decree on Clinical Trials on	TUKIJA: 1. Checklist for Researchers and Members of Ethics Committees (2009) (Finnish): http://www.tukija.fi/fi/julkaisut/ohjeet_ja_suositukset 2. Operating Procedures of National Committee on Medical Research Ethics (2010): http://www.tukija.fi/en/publications

Country	Key Organizations	Legislation	Regulations	Guidelines
			Medicinal Products No. 841/2010 4. Decree on the National Committee on Medical Research Ethics No. 820/2010 5. Decree on Fees, No. 650/2013	
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 (Finnish): 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. 2/2012 (Finnish): http://www.fimea.fi/download/22302_Maarays_2-2012_kliiniset_laaketutkimukset.pdf	
	Devices			
	National Supervisory Authority for Welfare and Health (VALVIRA): http://www.valvira.fi/en/licensing/medical_devices	Medical Devices Act No. 629/2010 (Finnish): http://www.finlex.fi/fi/laki/kokoelma/2010/20100085.pdf	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. Pharmaceutical Injuries Insurance http://www.laakevahinko.fi/in-english/	Patient Injuries Act No. 585/1986 (Finnish): http://www.finlex.fi/fi/laki/ajantasa/1986/19860585		Pharmaceutical Injuries Insurance: General Terms and Conditions (2013): http://www.laakevahinko.fi/in-english/terms-and-conditions/
Privacy/Data Protection	Office of the Data Protection Ombudsman: http://www.tietosuoja.fi/1560.htm	Personal Data Act No. 523/1999 (Finnish): 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	1. Act on the Medical Use of Human Organs ,Tissues and Cells No. 101/2001 (Finnish and Swedish): http://www.finlex.fi/fi/laki/ajantasa/2001/20010101 2. Law on Biobanks, No 688/2012 (Finnish and Swedish): http://www.finlex.fi/fi/laki/ajantasa/2012/20120688	1. Decree on Consent for Biobank No. 643/2013 2. Decree on information on Biobank No. 649/2013	National Supervisory Authority for Welfare and Health (Finnish): http://www.valvira.fi/luvat/kudosluvat/lupa_elimien_kudoksien_ja_solujen_laaketieteelliseen_kayttoon
Genetic Research	1. National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en	1. Medical Research Act No. 488/1999 (Amended 295/2004		

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Board for Gene Technology http://www.geenitekniikanlautakunta.fi/en	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 Social affairs and Health (French): http://www.sante.gouv.fr/ 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr/en 3. National Commission for Informatics and Freedoms (CNIL): http://www.cnil.fr/english/the-cnil/	Law No. 2004-806 of 9 August 2004 on Biomedical Research: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000441469&dateTexte=&categorieLien=id	Public Health Code Articles R1121-1 and subsequent sections: http://legifrance.gouv.fr/	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. National Health Products Safety Agency (ANSM): http://ansm.sante.fr/	Medications for Human Use, Articles L5121-11, L5124-1, and L5126-1) (2004): http://www.legifrance.gouv.fr/		CCNE: 1. Phase I Trials in Cancer (2002) 2. Transposition into French Law of the European Directive Relating to Clinical Trials on Medicinal Products: A New Ethical Framework for Human Research (2003)
Privacy/Data Protection	1. National Commission of Information and Liberty (CNIL): http://www.cnil.fr/index.php?id=4 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	Law 2004-801 of August 6, 2004 Modifying Law 78-17 of January 6, 1978 Relating to the Protection of Data Subjects as Regards the Processing of Personal Data	CNIL: Decree No. 2005-1309 of 20 October 2005 Enacted for the Application of Act No. 78-17 of 6 January 1978 on Data Processing, Files and Individual Liberties	CCNE: 1. Ethical Questions Arising from the Transmission of Scientific Information Concerning Research in Biology and Medicine (1995) 2. Biometrics, Identifying Data and Human Rights (2007)

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			(Amended by Decree 2007-451 of 25 March 2007): http://www.cnil.fr/fileadmin/documents/en/Decree%202005-1309.pdf	
Human Biological Materials	National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	1. 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/ 2. Public Health Code Articles L1241-1 and following sections: (2010) (French): http://www.legifrance.gouv.fr/initRechCodeArticle.do		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	Civil Code Articles 16-10 to 16-13: http://www.legifrance.gouv.fr/affichCode.do;jsessionid=D2DE023194483D3384DE19DE8959BDDA.tpdjo17v_3?idSectionTA=LEGISCTA000006136513&cidTexte=LEGITEXT000006070721&dateTexte=20131006		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	Law No. 2013-715 of 6th August 2013: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000027811435&dateTexte=&categorieLien=id		CCNE: 1. Commercialization of Human Stem Cells and Other Cell Line (2006) 2. Opinion on the Ethical Reflection Concerning Research on Human Embryonic Cells and on Human Embryos in Vitro (2010)

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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. Law on Health Care, Chapter XIX (1997) 2. Oviedo Convention on Human Rights and Biomedicine ETS No.164 (2001) 3. Additional Protocol to the Convention's on Human Rights and Biomedicine, concerning Biomedical Research, ETS No. 195 (2010)		
Drugs and Devices	Drug Agency of the Ministry of Labor, Health, and Social Affairs: http://www.moh.gov.ge/	1. Drug and Pharmacy Law No. 659 (1997) 2. Licenses and Approvals Law (2005) 3. 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 2. Central Ethics Committee 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:			BÄK: (Model) Professional Code for Physicians in Germany, Article 15 (2011) (German): http://www.bundesaerztekammer.de/downloads/MBOen2012.pdf

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	http://www.ethikrat.org/?set_language=en 5. Federal Ministry of Health: http://www.bmg.bund.de/ministerium/english-version.html			
Drugs and Devices	*Drugs*			
	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html 2. Federal Ministry of Education and Research (BMBF): http://www.bmbf.de/en/index.php 3. Paul Ehrlich Institute (PEI): http://www.pei.de/EN/home/node.html;jsessionid=8A56CBB11CA133D70C010434A47D96B7.1_cid329 4. Federal Ministry of Health (BMG): http://www.bmg.bund.de/ministerium/english-version.html	Medicinal Products Act, Sections 40-42 (2014): http://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p0917	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 (2012) (German): http://www.gesetze-im-internet.de/bundesrecht/gcp-v/gesamt.pdf BMBF: Principles and Responsibilities When Carrying Out Clinical Studies (2013) (German): http://www.gesundheitsforschung-bmbf.de/_media/Grundsaetze_und_Verantwortlichkeiten_20130424.pdf	BfArM and PEI: Third Notification on Clinical Trials of Medicinal Products for Humans (2006): http://www.pei.de/SharedDocs/Downloads/EN/pu/clinical-trials/3rd-notification-clinical-trials-2006-08-10.pdf?__blob=publicationFile&v=1
	Devices			
	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html 2. Paul Ehrlich Institute (PEI) http://www.pei.de/EN/home/node.html	Act on Medical Devices (2014) (German): http://bundesrecht.juris.de/mpg/index.html Also see (German): 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 (2014): http://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p0917		
Privacy/Data Protection	Federal Commissioner for Data Protection and Freedom of Information:	Federal Data Protection Act, as Amended (2009): http://www.bfdi.bund.de/EN/DataPr		

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Note: The 16 German states also have data protection laws (German): http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html	http://www.bfdi.bund.de/EN/Home/homepage_node.html	otectionActs/DataProtectionActs_node.html		
Human Biological Materials	German Ethics Council (DER): http://www.ethikrat.org/welcome?set_language=en	1. Act of Quality and Security of Human Tissue and Cells (2007) (German): http://www.gesetze-im-internet.de/gewebeg/BJNR157400007.html 2. Transfusion Law (2009) (German): http://www.gesetze-im-internet.de/bundesrecht/tfg/gesamt.pdf 3. Transplantation Law (2013) (German): http://www.gesetze-im-internet.de/tpg/		Opinion on Human Biobanks for Research (2010): http://www.ethikrat.org/files/der_opinion_human-biobanks.pdf
	Central Ethics Committee of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/			Opinion of the Central Ethics Commission (2003) (German): http://www.zentrale-ethikkommission.de/downloads/Koerpermat.pdf
	German Society of Surgery (DGCH) (German): http://www.dgch.de/index.php?id=118		DGCH Guidelines on Good Professional Practice (GPP) for the Procurement of Human Tissue and Cells for Drug Production (German): http://www.dgch.de/fileadmin/media/pdf/servicemeldungen/069_Gewebegesetz_GFP-Leitfaden_der_DGCH_fuer_die_Gewinnung_menschlicher_Gewebe.pdf	
	German Institute for Cell and Tissue Replacement (DIZG) (German): http://www.dizg.de/en.html			1. Ethical Code (2000) 2. Common Standards: Tissues and Cell Banking (2004)
Genetic Research	Paul-Ehrlich-Institut (PEI): http://www.pei.de/EN/home/node.html	Law of 20 June 1990/16.12.1993 to Regulate Matters Related to Gene Technology (2013): http://www.gesetze-im-internet.de/bundesrecht/gentg/gesa		Various: http://www.pei.de/DE/service/linklisten/links-gentherapie/links-thema-gentherapie-node.html

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		mt.pdf		
	German Society of Human Genetics: http://www.gfhev.de/en/gfh/			1. Position Paper of the German Society of Human Genetics (2007) (German) http://www.medgenetik.de/sonderdruck/2007_gfh_positionspapier.pdf 2. DNA Banking and Personal Data in Biomedical Research: Technical, Social, and Ethical Questions (2004) http://www.medgenetik.de/sonderdruck/en/DNA%20Banking_engl_060605.pdf
Embryos, Stem Cells, and Cloning	Federal Ministry of Education and Research (BMBF): http://www.bmbf.de/en/index.php	1. Embryo Protection Act (2011): http://www.gesetze-im-internet.de/bundesrecht/eschg/gesamt.pdf 2. Law on the Protection of Embryos in connection with the Import and Use of Human Embryonic Stem Cells (Stem Cell Act) (2013) (German): http://www.gesetze-im-internet.de/bundesrecht/stzg/gesamt.pdf Information in English: http://www.drze.de/in-focus/stem-cell-research/modules/german-stem-cell-act?set_language=en	Implementation Regulation for the Stem Cell Act (German): http://bundesrecht.juris.de/zesv/index.html	
	German Ethics Council: http://www.ethikrat.org/welcome?set_language=en			1. Cloning for Reproductive Purposes and Cloning for the Purposes of Biomedical Research (2004): http://www.ethikrat.org/dateien/pdf/klonen-zu-fortpflanzungszwecken.pdf 2. Position Paper on Changes to the Stem Cell Act (2007): http://www.ethikrat.org/dateien/pdf/Stn_Stammzellgesetz.pdf
	Central Ethics Committee of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/			Statement on Stem Cell Research (2002) (German): http://www.zentrale-ethikkommission.de/downloads/Stammzell.pdf
	German Research Foundation (DFG): http://www.dfg.de/en/			Opinion on Stem Cell Research (2006) (German): http://www.dfg.de/download/pdf/dfg_magazin/forschungspolitik/stammzellforschung/stammzellforschung_deutschland_lang_0610.pdf
	Central Ethics Committee for Stem-Cell Research (ZES):			

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	http://www.rki.de/EN/Content/Institute/DepartmentsUnits/StemCell/StemCell_node.html			
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): 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		

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		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 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 4. Opinion on Direct-To-Consumer Genetic Testing (2012): http://www.bioethics.gr/index.php/en/gnomes/91-direct-to-consumer-dtc-genetic-testing
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,		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

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		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		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
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 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 2. 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	
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	*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	*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:	Rules Governing Medicinal Products in the European Union, Volume 10: http://ec.europa.eu/health/documents/eudralex/vol-10/

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		Care, Chapter VIII: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV	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	
	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:	1. Act XLVII of 1997 on the Handling of Medical and Other Related Data:		

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.naih.hu/general-information.html	http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700047.TV&celpara=#xcelparam 2. 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		
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

Country	Key Organizations	Legislation	Regulations	Guidelines
Iceland				
General	1. Ministry of Welfare (MOW): http://ministryofhealth.is 2. National Bioethics Committee (NBC): www.visindasidanefnd.is (Select "English" in the upper-right hand corner.)	1. Act on the Rights of Patients No. 74/1997, Article 10 (2009): http://eng.velferdarraduneyti.is/acts-of-Parliament/nr/20100 2. Oviedo Convention on Human Rights and Biomedicine (2004)	MOW: 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 Agency (MCA): http://www.imca.is/ 2. National Bioethics Committee (NBC): www.visindasidanefnd.is	Medicinal Products Act No. 93/1994 (2013): http://eng.heilbrigdisraduneyti.is/laws-and-regulations/laws//nr/3128	MCA: Regulation on Clinical Trials of Medicinal Products in Humans No. 443/2004 (2010): http://eng.heilbrigdisraduneyti.is/media/Reglugerdir-enska/Regulation_on_clinical_trials_of_medicinal_products_in_humans_No443-2004.pdf	
	Devices			
	Ministry of Welfare: http://eng.heilbrigdisraduneyti.is/	Act on Medical Devices No 16/2001 (2011): http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/687	1. Regulation on Medical Devices No. 934/2010 (2010): http://eng.velferdarraduneyti.is/media/Reglugerdir-enska/Regulation-on-Medical-Devices-No-934-2010.pdf 2. Regulation on Active Implantable Medical Devices No. 320/2011 (Icelandic): http://www.stjornartidindi.is/Advert.aspx?ID=c50d676c-4651-46c2-83b5-ad946f3deeaa 3. Regulation on In Vitro Diagnostic Medical Devices No. 936/2011 (Icelandic): http://stjornartidindi.is/Advert.aspx?ID=f20b3e4e-ab25-44d3-8e32-e5f42a7b02f0	
Research Injury	Icelandic Medicines Control Agency (MCA): http://www.imca.is/	1. Act on Patient Insurance No. 111/2000 (2011): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act_on_Patient_Insurance_as_amended.pdf 2. Act on Health Insurance No. 112/2008 (2012): http://eng.velferdarraduneyti.is/media/acrobat-	Regulation on Clinical Trials of Medicinal Products in Humans No 443/2004 (2010): http://eng.heilbrigdisraduneyti.is/media/Reglugerdir-enska/Regulation_on_clinical_trials_of_medicinal_products_in_humans_No443-2004.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
		enskar_sidur/Act_on_Health_Insurance_No_112_2008.pdf		
Privacy/Data Protection	Data Protection Authority: http://www.personuvernd.is/information-in-english/	Act on the Protection of Privacy as Regards the Processing of Personal Data, No. 77/2000 (2011): 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 Welfare: http://ministryofhealth.is 2. National Bioethics Committee (NBC): www.visindasidanefnd.is	Biobanks Act No. 110/2000 (2009): 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. Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No. 55/1996 (2010): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act_No_55_1996_on_Artificial_Fertilisation_etc_as_amended.pdf	Regulation on Artificial Fertilization No 144/2009 (Icelandic): http://stjornartidindi.is/Advert.aspx?ID=9442c80d-2b63-4a43-9526-41d03d9b2495	
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)	IMB: Guide to Clinical Trials (2004)

Country	Key Organizations	Legislation	Regulations	Guidelines
			(Amendment No. 2) Regulations 2006 (S.I. 374 of 2006): http://www.dohc.ie/legislation/statutory_instruments/?year=2006&number=374	
	Devices			
	Irish Medicines Board: http://www.imb.ie/EN/Medical-Devices.aspx			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/4.htm	Data Protection Act (1988), as amended (2003): http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html		
Human Biological Materials	1. Irish Medicines Board: http://www.imb.ie/EN/Blood-Tissues--Cells~.aspx 2. 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)

Country	Key Organizations	Legislation	Regulations	Guidelines
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) 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-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	Numerous: 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 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	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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)	
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.zva.gov.lv/doc_upl/MK_not_	1. Pharmaceutical Law, Section 26 (2009)	Cabinet Regulation No. 289: Regulations on Conducting	

Country	Key Organizations	Legislation	Regulations	Guidelines
	289_English_02062010.pdf 2. Central Medical Ethics Committee	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	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/default/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_-	

Country	Key Organizations	Legislation	Regulations	Guidelines
			_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_Protection_of_the_Body_of_Deceased_Human_Beings_and_the_Use_of_Human_Tissues_and_Organs_in_Medicine.doc	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/Cab._Reg._No._208_-_Bankingx_Storage_and_Utilisation_of_Human_Tissues_and_Organs.doc	
Genetic Research	1. Ministry of Health: http://www.vm.gov.lv/index.php?setlang=en 2. Data State Inspectorate: http://www.dvi.gov.lv/eng/ 3. Central Medical Ethics Committee	1. Human Genome Research Law (2005): http://www.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	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Oviedo Convention on Human Rights and Biomedicine (2002): http://conventions.coe.int/treaty/en/t	Government of the Republic of Lithuania: Decree Nr. 1458 on State Fees (2013)	

Country	Key Organizations	Legislation	Regulations	Guidelines
		reaties/html/164.htm 2. Law on Ethics of Biomedical Research (2014): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=477235	MOH: 1. Decree No. V-405 on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage, and Providing Information on Biomedical Research (2010) 2. Decree No. 677 on the Procedure for the Estimation and Covering of Expenses Incurred by Research Subjects (2011)	
	Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1073108465		1. Decree No. V-14 on the 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)	Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical Research of the LBEC (2010)
Drugs and Devices	*Drugs*			
	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Law on Ethics of Biomedical Research (2014): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=477235 2. Law on Pharmacy (2013): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=460720	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)	
	State Medicines Control Agency (SMCA): http://www.vvkt.lt/lit/English		Decree No. 1A-396 on 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)	
	Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1073108465		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	Guidelines to Advertise clinical trials, adopted by the Group of Experts on Biomedical Research of the LBEC (2007)

Country	Key Organizations	Legislation	Regulations	Guidelines
			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)	
	Devices			
	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG		Decree No. V-2 on the Procedure to Issue Approvals to Conduct Biomedical Research (2011)	
	State Health Care Accreditation Agency Under the Ministry of Health (SHCA): http://www.vaspvt.gov.lt/en	Law on Ethics of Biomedical Research (2014): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=477235	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 (2014): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=477235	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: https://www.ada.lt/go.php/lit/English	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?-1073108465	Law on Ethics of Biomedical Research (2014): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=477235	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 (2014): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=477235 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	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	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Medicine, on the Prohibition of Cloning Human Beings (2002): http://conventions.coe.int/Treaty/EN/Treaties/Html/168.htm	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)	
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 Note: All websites and documents are in Macedonian.				
Drugs and Devices	*Drugs*			
	1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Drug Register: https://lekovi.zdravstvo.gov.mk/	1. Law on Medicinal Products and Medical Devices (2007): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/838483160?t:ac=2 2. Laws on Amendments and Modifications to the Law on Medicines and Medical Devices:	1. Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2009): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/817325622?t:ac=1/1 2. Rulebook for Changes in the	Guideline for the Clinical Trial Applicant (Annex 3) (2012): Open sub-folder 23.2: https://lekovi.zdravstvo.gov.mk/documents/1/1

Country	Key Organizations	Legislation	Regulations	Guidelines
		Click on file folder 1., then open sub-folders 1.1 to 1.10: https://lekovi.zdravstvo.gov.mk/documents/2	Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2010) (Macedonian): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:download file/879452170?t:ac=1/1 3. Rulebook for Changes in the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2012) (Macedonian): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:download file/880033320?t:ac=1/1 4. Regulation on the Manner of Reporting, Contents of the Reporting Form for Adverse Reactions to Medicinal Products and the Manner of Organisation of Pharmacovigilance System (2012): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:download file/880287913?t:ac=1/1	
	Devices			
	1. Macedonian Drug Agency http://moh.gov.mk/index.php?category=39 2. Macedonian Drug Agency: http://www.reglek.com.mk/	Same as above.	Rulebook for the Required Documentation and the Method of Application for Clinical Trials on Medical Devices and the Amendments, and Reporting of Drug Adverse Reactions and Events: https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:download file/844338380?t:ac=1/2	Same as above.
Research Injury	1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Drug Register: https://lekovi.zdravstvo.gov.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 Contents (2009): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:download file/817325622?t:ac=1/1	

Country	Key Organizations	Legislation	Regulations	Guidelines
Privacy/Data Protection	Directorate for Personal Data Protection (Macedonian): www.dzlp.mk	1. Law on Personal Data Protection (2005): http://dzlp.mk/sites/default/files/Dokumenti/DOMASNI%20PROPISI/ZZLP_precisten_2012.pdf 2. Law On Amendments And Modifications to the Law on Personal Data Protection (2008): http://www.dzlp.mk/sites/default/files/ZZLP%20izmeni%202008_0.pdf 3. Law on Ratification on Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2005): http://www.dzlp.mk/sites/default/files/pdf/Zakon_za_ratifikacija_na_Konvencijata_108.pdf 4. Law on Ratification on Additional Protocol to the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2008): http://www.dzlp.mk/sites/default/files/pdf/Dopolnitelen_protokol_Konvencija_108.pdf 5. Law on Amendments and Modifications To The Law on Personal Data Protection (2010): http://www.dzlp.mk/sites/default/files/Izmeni%20na%20ZZLP%202010_0.pdf 6. Law on Amendments to the Law on Personal Data Protection (2011): http://dzlp.mk/sites/default/files/ZZLP_DOPOLNUVANJE_2011.pdf	Regulations on Protection of Personal Data: http://www.dzlp.mk/mk/podzakonski_akti	
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:	Regulations for Transplantation of Tissues and Organs: http://www.fzo.org.mk/default.asp?ItemID=6541AC10FFC3C5498F0887C57131D996	Regulation on Criteria Relating to Space, Personnel and Equipment for Collection, Transplantation and Exchange of Organs and Tissues, the Necessary Space, Equipment and Staff Required to be Provided by the Health Institution for the Collection, Transfer, Exchange and Storage of Organs and Tissues from

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zemanje-i-presaduvanje-na-delovi-od-coveckoto-telo-precisten.pdf Sub-Law Acts : http://www.fzo.org.mk/default.asp?ItemID=6541AC10FFC3C5498F0887C57131D996 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/documentDetail.php?id=5543		Human Body for Treatment Purposes (2012): http://zdravstvo.gov.mk/wp-content/uploads/2012/12/za_pobliskite_kriteriumi_vo_odnos_na_prostorot_kadarot_i_opremata_za_zemawe_presaduvawe_i_razmenuvawe_na_organite_i_tkivata_za_potrebniot_pr.pdf
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://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-za-zastita-na-pravata-na-pacientite-precisten.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/documentDetail.php?id=5543		

Country	Key Organizations	Legislation	Regulations	Guidelines
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: 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		Guidance Notes on Good Clinical Practice (2010): http://medicinesauthority.gov.mt/clinicaltrials.htm
	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, 427.16, *In Vitro* Diagnostic Medical Devices Regulations, 2003 http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10756&l=1 3. Subsidiary Legislation, 427.44, Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10781&l=1 4. Subsidiary Legislation,		

Country	Key Organizations	Legislation	Regulations	Guidelines
		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		
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 Note: All websites and documents are in Moldovian.				
General	National Committee of Bioethics of the Ministry of Health: http://www.ms.gov.md/	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/ 2. Medicines Agency: http://www.amed.md/	1. Moldova Republic Law on Medicines of December 17, 1997, Articles 11 and 12: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311586 2. Law No. 263 of 27.10.2005 on Rights and Responsibilities of Patient. Articles 9, 10, 11, 12, 13, and 14: 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/	1. Law No. 411-XIII of 28.03.1995 "Regarding Health Protection" 2. 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		
Privacy/Data Protection	National Center for Personal Data Protection of the Republic of Moldova: http://www.datepersonale.md/en/start/	1. 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 2. Law No.133 of 08.07.2011	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	

Country	Key Organizations	Legislation	Regulations	Guidelines
		on the Protection of Personal Data: http://lex.justice.md/md/340495/	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/ 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=327709	MOH: Ordnance No. 10: On Performance of Clinical Trials in the Republic of Moldova (2002)	
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 (Montenegrin): http://www.mzd.gov.me/ministarstvo	Law on Medicinal Products, Articles 36-49 (2004): www.gov.me/files/1241604402.doc		
Research Injury	Agency for Medicines and Medical Devices (Montenegrin): http://www.gov.me/naslovna	Law on Medicinal Products, Article 48 (2004): www.gov.me/files/1241604402.doc		
Netherlands				
General	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/en/	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 been translated into English): http://www.ccmo.nl/attachments/files/wmo-engelse-vertaling-29-7-2013-afkomstig-van-vws.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	Medicines Act (2007) (Dutch): http://wetten.overheid.nl/BWBR002	VWS:	CCMO:

Country	Key Organizations	Legislation	Regulations	Guidelines
	Sport (VWS): http://www.government.nl/ministries/vws#ref-minvws 2. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/en/ 3. Medicines Evaluation Board (MEB): http://www.cbg-meb.nl/cbg/en/default.htm	1505	1. Medicines Act Decree (2007): http://www.ccmo.nl/attachments/files/eng-decree-on-scientific-research-with-medicinal-products.pdf 2. Medicines Act Regulation (2007) (Dutch): http://wetten.overheid.nl/BWBR0022160	Clinical Research with Medicinal Products in the Netherlands: Instructional Manual (2005): http://www.vumc.nl/afdelingen-themas/1646433/7876770/7876776/7955410/Clinical_research_with_medi1.pdf
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.nl/attachments/files/wmo-engelse-vertaling-29-7-2013-afkomstig-van-vws.pdf	Regulation on Mandatory Insurance Regarding Medical Research Involving Human Subjects (2003): http://www.ccmo.nl/attachments/files/verzekeringsbesluit-2003-eng.pdf	
Privacy/Data Protection	1. Federation of Biomedical Scientific Societies (FMWV): http://www.federa.org/english 2. Dutch Data Protection Authority: http://www.dutchdpa.nl/Pages/home.aspx	Personal Data Protection Act (2004) (Dutch): http://wetten.overheid.nl/BWBR0011468		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: http://www.federa.org/english	Civil Code, Article 467 (1994) (Dutch): http://www.ccmo.nl/attachments/files/wgbo-pdf.pdf		Code for Proper Secondary Use of Human Tissue in the Netherlands (2002): http://www.federa.org/sites/default/files/bijlagen/coreon/codepropersecondaryuseofhumantissue1_0.pdf
Genetic Research	1. Ministry of Infrastructure and the Environment (IenM): http://www.government.nl/ministries/ienm 2. Dutch Health Care Inspectorate (IGZ): http://www.igz.nl/english/ 3. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/en/	Medical Research Involving Human Subjects Act (2006): http://www.ccmo.nl/attachments/files/wmo-engelse-vertaling-29-7-2013-afkomstig-van-vws.pdf		IenM, VWS, and CCMO: Guidelines for Researchers and Sponsors with Regard to the Assessment by Official Bodies of Clinical Research Involving Gene Therapeutics in the Netherlands (2012): http://www.ggo-vergunningverlening.nl/dsresource?type=pdf&objectid=rivmp:193539&versionid=&subobjectname=
Embryos, Stem Cells, and Cloning	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/en/	1. Foetal Tissue Act (2001) (Dutch): http://wetten.overheid.nl/BWBR0012983/ 2. Embryos Act (2002): http://www.ccmo.nl/attachments/files/embryos-act.pdf		

Country	Key Organizations	Legislation	Regulations	Guidelines
Norway				
General	National Committee for Medical and Health Research Ethics: 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 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*&&		1. Research Ethical Review in Norway (1998) 2. Standard Operating Procedures for the Regional Committees for Medical Research Ethics (2002)
	National Committee for Research Ethics in the Social Sciences and the Humanities: http://www.etikkom.no/en/In-English/			Guidelines for Research Ethics in the Social Sciences, Law, and the Humanities (2001)
	National Committee for Research Ethics in Science and Technology: https://www.etikkom.no/en/In-English/Committee-for-Research-Ethics-in-Science-and-Technology/			Research Ethics Guidelines for Science and Technology (2007) (Norwegian): https://www.etikkom.no/Forskningsetikk/Etiske-retningslinjer/Naturvitenskap-og-teknologi/
Drugs and Devices	*Drugs*			
	Norwegian Medicines Agency: http://www.legemiddelverket.no/English/Sider/default.aspx		Regulation Relating to Clinical Trials on Medicinal Products for Human Use (2009) (Norwegian): http://lovdata.no/dokument/SF/forskrift/2009-10-30-1321?q=forskrift+om+kliniske+utpr%C3%B8vning	Guidelines for the Regulations Concerning Clinical Trials of Human Drugs (1999) (Norwegian): http://www.legemiddelverket.no/Godkjenning_og_regelverk/Klinisk-utproving/Regelverk%20og%20veiledninger/Documents/Veiledning%20-%20revidert%20versjon%202.2%2006.11.2012.pdf
	Devices			
	1. Norwegian Directorate of Health: http://www.helsedirektoratet.no/kvalitet-planlegging/medisinsk-utstyr/klinisk-utprovning/Sider/default.aspx 2. Regional Committees for Medical and Health Research Ethics: https://helseforskning.etikkom.no/ikbViewer/page/forside	Act of 12 January 1995 No. 6 Relating to Medical Devices (1995) (Norwegian): http://lovdata.no/dokument/NL/lov/1995-01-12-6?q=lov+om+medisinsk+utstyr	Regulation of December 15th 2005 No. 1690 Relating to Medical Devices (2005) (Norwegian): http://lovdata.no/dokument/SF/forskrift/2005-12-15-1690?q=forskrift+medisinsk+utstyr	Guidelines on Notification for Clinical Investigation of Medical Devices in Norway (2010): http://www.helsedirektoratet.no/kvalitet-planlegging/medisinsk-utstyr/klinisk-utprovning/Documents/veiledning-ved-meldinger-om-klinisk-utprøving-av-medisinsk-utstyr.pdf
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No.		

Country	Key Organizations	Legislation	Regulations	Guidelines
		164 (2007)		
Privacy/Data Protection	Data Inspectorate: http://www.datatilsynet.no/English	Personal Data Act No. 31 (2000): http://lovdata.no/dokument/NL/lov/2000-04-14-31	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.regjeringen.no/en/dep/kd.html?id=586	1. Act on Biobanks (February 21, 2003, No. 12): http://lovdata.no/dokument/NL/lov/2003-02-21-12?q=biobank 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*&&	MHCS: Guidelines for the Norwegian Act on Biobanks (2003): http://www.datatilsynet.no/English/Regulations/Personal-Data-Act1/	
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/english/ 3. Regional Committees for Medical Research Ethics (REK): https://www.etikkom.no/en/In-English/Committee-for-Medical-and-Health-Research/	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/kvalitet-planlegging/bio-genteknologi/Sider/default.aspx	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		

Country	Key Organizations	Legislation	Regulations	Guidelines
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)
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/filema		

Country	Key Organizations	Legislation	Regulations	Guidelines
		nager_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		

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

Country	Key Organizations	Legislation	Regulations	Guidelines
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		
Genetic Research	Ministry of Health: http://www.portugal.gov.pt/en/the-ministries/ministry-of-health.aspx	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/	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	MOH: Guideline for Clinical Trials in Pediatric Populations (CPMP/ICH/2711/99) (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
			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	
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		

Country	Key Organizations	Legislation	Regulations	Guidelines
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 Federation" (2011) (Russian): http://base.garant.ru/12191967/		
Drugs and Devices	Council of Ethics of the Ministry of Healthcare of the Russian Federation (MOH) (Russian): http://www.grls.rosminzdrav.ru/	Federal Law #61FZ "On Circulation of Medicines" (2011): http://acto-russia.org/files/en_circulation_medicines_02072013.doc	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.garant.ru/12178437/ 2. Ministry of Health Order No. 774n (August 31, 2010) "On Council of Ethics" (Russian): http://www.rg.ru/2013/02/22/etika-dok.html GOST: Good Clinical Practice. GOST-R 52379-2005 (September 27, 2005) (Russian): http://acto-russia.org/index.php?option=com_content&task=view&id=17	
Research Injury		Federal Law #61FZ "On Circulation of Medicines" (2011), Art. 38-44: http://acto-russia.org/files/en_circulation_medicines_02072013.doc		
Privacy/Data Protection		1. Federal Law of the Russian Federation on Information, Information Technologies, and Protection of Information (2006) (Russian): http://www.consultant.ru/document/cons_doc_LAW_165971/ 2. Federal Law of the Russian Federation No. 152-FZ on		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Personal Data (2006): http://base.garant.ru/12148567/		
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" (Russian): http://base.garant.ru/10135402/	Order of the Ministry of Education and Science of the Russian Federation #154 (2005): "Statute of the Inter-Departmental Commission on Genetic-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.garant.ru/184467/		
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/eng/	Law on Medicines and Medical Devices, Official Gazette of RS No. 30/2010 and 107/2012: http://www.alims.gov.rs/ciril/files/2012/11/zakon-30-2010-107-2012.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 and 91/2013: http://www.alims.gov.rs/ciril/files/2014/01/pravilnik-ki-91-2013.pdf	
Research Injury	1. Ministry of Health (MOH): http://www.alims.gov.rs/eng/ 2. Serbian Drug Agency http://www.alims.gov.rs	Law on Medicines and Medical Devices, Article 72 (Serbian): http://www.alims.gov.rs/ciril/files/2012/11/zakon-30-2010-107-2012.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 August 2011 2. Law on Patients' Rights, Article 25 Official Gazette of RS, 45/13: http://www.parlament.gov.rs/upload/archive/files/lat/pdf/zakoni/2013/1283-	

Country	Key Organizations	Legislation	Regulations	Guidelines
			13Lat.pdf	
Privacy/Data Protection	Commissioner for Information of Public Importance and Personal Data Protection: http://www.poverenik.rs/en/the-commissioners-authority-di.html	Law on the Protection of Personal Data, Official Gazette 97/08, 104/09, 68/20 and 107/12: http://www.poverenik.rs/images/stories/dokumentacija-nova/zakon-o-zastiti-podataka-o-licnosti_en.pdf		
Embryos, Stem Cells, and Cloning	National Health Insurance Fund: http://www.rfzo.rs/	Law on Organ Transplantation, Official Gazette No. 72/2009 (Serbian): http://www.rfzo.rs/download/zakoni/Zakon_transplantacija.pdf		
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. 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.		
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. Additional Protocol to the Convention for the Protection of		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998) 2. Act No. 576/2004 Coll. on Health Care, Section 26.10.a.		
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		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Data Protection Act No. 57/2001		
Human Biological Materials	1. National Medical Ethics Committee (NMEC) 2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/index.php?id=56		On Interventions into the Human Corpse Which are not Part of the Routine Autopsy and on Handling with Biologic Material of Human Origin (2004)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999)
Embryos, Stem Cells, and Cloning		1. Law on Biomedically Assisted Fertilization No. 70 (2000) 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)		
Spain For an overview of human subject protections in Spain, see "National Information – Spain": http://www.eurecnet.org/information/spain.html. Note: Many of the 17 Spanish autonomous regions have their own laws and regulations on human subject protections.				
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	*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: http://www.aemps.gob.es/en/legislacion/espana/investigacionClinica/docs/rcl_2004_325.pdf 2. Law 29/2006, of Guarantees and Rational Use of Medicines and Sanitary Products (Spanish): http://www.aemps.gob.es/en/legislacion/espana/laAEMPS/docs/general/rcl_2006_1483.pdf 3. Royal Decree 1015/2009:	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	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Drug Availability for Special Purposes (Spanish): http://www.boe.es/boe/dias/2009/07/20/pdfs/BOE-A-2009-12002.pdf 4. Royal Decree 577/2013, Regulating Pharmacovigilance in Human Use Medicines: http://www.boe.es/diario_boe/txt.php?id=BOE-A-2013-8191 5. Law 10/2013, Incorporating into Spanish Laws Certain EU Directives About Monitoring and Preventing Commercialization of Counterfeit Medicines (Spanish): http://www.boe.es/diario_boe/txt.php?id=BOE-A-2013-8083	(Spanish): http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rcl_2008_410.pdf 3. Order SAS/3470/2009 on Drugs Post Authorization Research (Spanish): http://www.aemps.gob.es/legislacion/espana/medicamentosUsoHumano/docs/farmacovigilancia/rcl_2009_2577.pdf	
	Devices			
	Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/investigacionClinica/productosSanitarios/home.htm	Royal Decree 1591/2009, Regulating Sanitary Devices: http://www.ont.es/infesp/Legislacin/RD_1591_2009.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	1. Royal Decree 223/2004: Regulation of Medication Clinical Trials, Article 8: http://www.aemps.gob.es/en/legislacion/espana/investigacionClinica/docs/rcl_2004_325.pdf 2. 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	

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	Ministry of Health and Consumption: http://www.msc.es/en/home.htm	1. Royal Decree 2070/1999 of December 30, Regarding Activities of Collection and Clinical Use of Human Organs for Organ Transplants and Tissues 2. Royal Decree 1301/2006 of November 10 Regarding the Use of Cells and Human Tissue: http://www.ont.es/legislacion/ficherosPDF/RD1301.pdf 3. Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf 4. Royal Decree 1716/2011 on Biobanks: http://www.comitedebioetica.es/normativa/docs/RD%201716_2011_de%20autorizacion%20y%20funcionamiento%20de%20los%20biobancos.pdf	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	
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	1. Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US 2. National Commission for the Donation and Use of Embryos, Cells, and Human Tissues for Biomedical Research: http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/organizacion.shtml 3. National Biobank Register: http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/organizacion.shtml	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-		

Country	Key Organizations	Legislation	Regulations	Guidelines
		documentation/Spain/page.aspx/1703. 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	Central Ethical Review Board: http://www.epn.se/start/startpage.aspx	Law No. 460 on the Ethical Review of Research Involving Humans (2003): http://www.epn.se/media/75686/the_ethical_review_act.pdf	1. Ordinance No. 615 Concerning the Ethical Vetting of Research Involving Humans (2003): http://www.epn.se/media/75683/2003_615.pdf 2. Statute No. 2007:1069 Containing Instructions for Regional Ethical Review Boards (2007): http://www.epn.se/media/45228/1069.pdf 3. Statute No. 2007:1068 Containing Instructions for the Central Ethical Review Boards (2007): http://www.epn.se/media/45225/1068.pdf	Information for Research Participants
	Swedish Research Council: http://www.vr.se/english		Regulations and General Counsel VRFS 2012:1 on Ethical Vetting of Human Subjects Research: http://www.epn.se/media/48216/vrfs_2012_1.pdf	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
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-	1. Swedish Medical Devices Act (SFS 1993:584) 2. Medical Devices Ordinance	1. Swedish Implementation of Directive 90/385/EEC -- LVFS 2001:5	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Investigations/	(SFS1993:876)	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	1. Patient Data Act: SFS 2008:355 (Swedish): http://www.notisum.se/rnp/sls/lag/20080355.htm 2. SFS 2009:400 - Public Access to Information and Secrecy Act: http://www.notisum.se/rnp/sls/lag/20090400.htm 3. Act on Certain Health Research Registers, SFS 2013:794 (Swedish): http://www.notisum.se/Pub/Doc.aspx?url=/rnp/sls/lag/20130794.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: http://www.datainspektionen.se/Documents/rapport-biobanker.pdf 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/	1. Biobanks in Medical Care Act No. 297 (2002): http://vavnad.se/files/live/sites/Biobanken/files/biobanksverige/9.%20Documetns%20in%20English/Biobanks%20in%20medical%20care%20act%20(2002-297).pdf 2. Regulation No. 746 (2002): http://www.notisum.se/rnp/sls/lag/20020746.htm	SOS: Consolidated regulations (Swedish): http://www.socialstyrelsen.se/sosfs/2002-11	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	Drug Administration Regulations and Guidelines (LVFS 2004:10) on the Intentional Release of Clinical Trials of Medicinal Products Containing or Consisting of Genetically Modified Organisms: http://www.lakemedelsverket.se/upload/lvfs/LVFS_2004-10.pdf	Genetics and Gene Technology in the Health Care: State of the Art and Guidelines for Ethical Considerations (1999)
Embryos, Stem Cells, and Cloning		Act on Genetic Integrity (2006:351) (Swedish): http://www.notisum.se/rnp/sls/lag/20060351.htm	1. Legal Regulation of Stem Cell Research 2002:119: http://www.regeringen.se/sb/d/108/a/2717 2. Regulations and Guidelines for the Use of Tissues and Cells in Healthcare and Clinical Research - SOSFS 2009:32: http://www.socialstyrelsen.se/sosfs/2009-32	SRC: Guidelines for Ethical Vetting of Human Stem Cell Research (Swedish): http://www.vr.se/download/18.6b2f98a910b3e260ae28000362/human_stamcellsforskning_16.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Switzerland				
General	1. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en 2. National Advisory Commission on Biomedical Ethics (NEK-CNE): http://www.nek-cne.ch/en/index.html 3. Swiss Association of Research Ethics Committees: http://www.swissethics.ch/index_e.html	1. Council of Europe Convention on Human Rights and Biomedicine of 4 April 1997, ETS No. 164, Articles 15-18: http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Constitution of the Swiss Confederation of 18 April, 1999, RS 101, Article 118b: http://www.admin.ch/opc/en/classified-compilation/19995395/index.html 3. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	1. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance ClinO), RS 810.305 (2014) (French): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.305 (2014) (French): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 3. Ordinance of 20 September 2013 on Organizational Aspects of the Human Research Act (HRA Organizational Ordinance, OrgO-HRA), RS 810.305 (2014) (French): http://www.admin.ch/opc/fr/official-compilation/2013/3455.pdf	Swiss Clinical Trial Organization, Guidelines for Good Operational Practice (GGOP) (2014): http://www.scto.ch/dms/SCTO/de/Publikationen/Richtlinien/Guidelines-for-Good-Operational-Practice_V2-0/Guidelines%20for%20Good%20Operational%20Practice_V2.0.pdf *Access*: http://www.scto.ch/en/News.html
Drugs and Devices	*Drugs*			
	1. Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en 2. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en	Swissmedic: 1. Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), RS 812.21 (art. 53-54): http://www.admin.ch/opc/en/classified-compilation/20002716/index.html 2. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	1. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance ClinO), RS 810.305 (2014) (French): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.305 (2014) (French): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 3. Ordinance of 20 September 2013 on Organizational Aspects of the Human Research Act (HRA Organizational Ordinance, OrgO-HRA), RS 810.305 (2014)	

Country	Key Organizations	Legislation	Regulations	Guidelines
			(French): http://www.admin.ch/opc/fr/official-compilation/2013/3455.pdf	
	Devices			
	Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en	Swissmedic: 1. Federal Law on Medicinal Products and Medical Devices, RS 812.21 (2002) (French): http://www.admin.ch/ch/f/rs/c812_21.html Unofficial English version: http://www.swissmedic.ch/leitfaden/00016/index.html?lang=en&download=NHzLpZeg7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCDdIR,gmym162epYbg2c_JjKbNoKSn6A-- 2. Federal Act on Research Involving Human Beings (2014) (French): http://www.admin.ch/opc/fr/federal-gazette/2011/6823.pdf	1. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance ClinO), RS 810.305 (2014) (French): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.305 (2014) (French): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 3. Ordinance of 20 September 2013 on Organizational Aspects of the Human Research Act (HRA Organizational Ordinance, OrgO-HRA), RS 810.305 (2014) (French):http://www.admin.ch/opc/fr/official-compilation/2013/3455.pdf	Guide to the Regulation of Medical Devices: http://www.swissmedic.ch/php/modules/leitfaden/leitfaden.html?lang=en
Research Injury	1. Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en 2. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en	Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 19, 20, and 65: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	1. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance ClinO), RS 810.305, Articles 7, 10, 11, 12, 25, and 71, Annexes 2-3 (2014) (French): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.305 . Articles 8, 12, 13, 15, and 48, Annexes 1 and 2(2014) (French): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html	
Privacy/Data Protection	Federal Data Protection and Information Commissioner:	1. Federal Act of 19 June 1992 on Data Protection (FADP), RS	1. Ordinance of 20 September 2013 on Clinical Trials in Human	

Country	Key Organizations	Legislation	Regulations	Guidelines
Note: Most Swiss cantons have enacted laws regarding data collection in the public sector that are similar to the FADP.	http://www.edoeb.admin.ch/index.html?lang=en	235.1: http://www.admin.ch/opc/en/classified-compilation/19920153/index.html 2. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 2, 3, 16, 17, 32 - 43, 45, 47, 49, 58, 59, and 63): http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	Research (Clinical Trials Ordinance, CLinO), RS 810.305 Articles 5, 7, 9, 16-18, and 25, Annexes 2 and 3: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html 2. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 5 - 8, 10, 15, 21, 24 to 34, 37-39, 41, 44, and 45, and Annex 2: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html	
Human Biological Materials	1. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en 2. Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/en/News/News.html	Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30 Articles 2, 3, 17, 18, 31, 32 - 35, 41 to 43, 45, 47, 49, and 63: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	1. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 7, 9, 12, 16 - 18 and Annex 2: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html 2. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301 Articles 5 - 8, 10, 15, 21, 24 to 30, 33-34, 37 - 39, 41, 44, and 45 and Annex 2): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 3. Ordinance of 14 February 2007 on Human Genetic Testing, RS 810.122.1 (French): http://www.admin.ch/opc/fr/classified-compilation/20051790/index.html	SAMS: Biobanks: Obtainment, Preservation and Utilization of Human Biological Material (2006): http://www.samw.ch/en/Ethics/Guidelines/Archive.html
Genetic Research	Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en	1. Constitution of the Swiss Confederation of 18 April, 1999, RS 101, Article 119: http://www.admin.ch/opc/en/classified-compilation/19995395/index.html 2. Federal Act of 8 October 2004 on Human Genetic	1. Ordinance of 14 February 2007 on Human Genetic Testing, RS 810.122.1 (French): http://www.admin.ch/opc/fr/classified-compilation/20051790/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Testing (HGTA), RS 810.12: http://www.admin.ch/opc/en/classified-compilation/20011087/index.html 3. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30 Articles 3, 32 - 35, 42, and 49: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	Ordinance, CLinO), RS 810.305 Articles 22 and 35, and Annexes 3 and 4: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html 3. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301 Articles 28 - 32: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html	
Embryos, Stem Cells, and Cloning	Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE): http://www.nek-cne.ch/en/index.html	*Embryos in Vivo:* Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30 Articles 2, 25 - 27, 39, 40, 44, and 62: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html *Others:* Federal Act of 19 December 2003 on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), RS 810.13: http://www.admin.ch/opc/en/classified-compilation/20022165/index.html	*Embryos in Vivo:* 1. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 49, 53, 55, and 56, and Annexes 3 and 4: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html 2. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 44 – 46, and Annex 2: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html *Others:* Ordinance of 2 February 2005 on Research involving Embryonic Stem Cells (Stem Cell Research Ordinance, SCRO), RS 810.311: http://www.admin.ch/opc/en/classified-compilation/20042542/index.html	NEK-CNE: 1. Pre-Implantation Genetic Diagnosis, Opinion No. 10/2005: http://www.nek-cne.ch/fileadmin/nek-cne-dateien/Themen/Stellungnahmen/en/pid_en.pdf 2. Research Involving Human Embryos and Fetuses. Opinion No. 11/2006: http://www.nek-cne.ch/fileadmin/nek-cne-dateien/Themen/Stellungnahmen/en/embryonen_en.pdf 3. Pre-Implantation Genetic Diagnosis II, Opinion No. 14/2007: http://www.nek-cne.ch/fileadmin/nek-cne-dateien/Themen/Stellungnahmen/PID_II_d.pdf *Access:* http://www.nek-cne.ch/en/topics/opinions/index.html
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	1. Regulation on Medical Deontology, Article 11 (1960) 2. Bylaw on Patient Rights No. 23420 (1998)	

Country	Key Organizations	Legislation	Regulations	Guidelines
		(2004)		
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): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=1&thelawId=347 2. Regulation on Clinical Trials (2014): http://www.klinikarastirmalar.org.tr/en/document.php?id=314	1. Guideline for Good Clinical Practice (2014) (Turkish): http://www.klinikarastirmalar.org.tr/doc/file_311.pdf 2. Guidance on the Ethics of Pediatric Clinical Research (2013) (Turkish): http://www.iegm.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=6&thelawId=319 3. Drug Observational Studies Guide (2014) (Turkish): http://www.klinikarastirmalar.org.tr/dokuman.php?id=312 4. Guideline for Independent Data Review Committees (2013) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=6&thelawId=316 5. Guidance on Education Programs Related to GCP and Clinical Trials (2014) (Turkish): http://www.klinikarastirmalar.org.tr/dokuman.php?id=313 6. Guidance on Archiving in Clinical Research (2014) (Turkish): http://www.klinikarastirmalar.org.tr/dokuman.php?id=316 7. Guidance on Ethical Committee Submission (2013) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=6&thelawId=456?qqepojzfbzargwzp 8. Guidance on Submission to the Turkey Pharmaceuticals and Medical Devices Agency in Clinical Trials (2013) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-TR&thelawtype=6 9. Guidance on Adverse Event Reaction Reporting in Clinical Trials (2013) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klinik_mevzuat&lang=tr-

Country	Key Organizations	Legislation	Regulations	Guidelines
				TR&thelawtype=6&thelawId=461
	Devices			
	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr		Regulation on Research on Medical Devices (2014) (Turkish): http://www.klinikarastirmalar.org.tr/doc/file_318.pdf	
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 Tissue Transplantation Services (2005) 3. Regulation on Cordon Blood Banks (2005)	1. Circular on Research of Embryonic Stem Cells (2005) 2. Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)
Ukraine				
General	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	1. Constitution of Ukraine Art. 28 (1996) 2. Health Care Law, Article 45 (1992) 3. Criminal Code of Ukraine 2001, Article 141 and 142	Order of Higher Attestation Commission of Ukraine from 29.05.2007 No. 342	
Drugs and Devices	1. Ministry of Health of Ukraine State Expert Center: http://www.dec.gov.ua	1. Ministry of Health Act 23.09/2009 No. 690, with 2012 changes:	1. Ukrainian Ministry of Health Order No. 95 About Approval of Documents Related to the Quality	Bioethics Committee: 1. Information Letters on Ethics Questions of Clinical Trials and Implementation of

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. National Academy of Sciences Bioethics Committee: http://biomed.nas.gov.ua/index-en/bioethics-committee	http://zakon4.rada.gov.ua/laws/show/z1235- 2. On Medicines, Articles 7 and 8 No. 123/96BP (2014): http://zakon4.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80	Assurance of Medicines (2009): http://www.moz.gov.ua/ua/portal/dn_20090216_95.html 2014 changes: http://www.moz.gov.ua/ua/portal/dn_20140716_0497.html 2. Ministry of Health Act 14.12.2009 N 944 on Approval of the Clinical Trial and Expertise of Clinical Trials: http://zakon4.rada.gov.ua/laws/show/z0053-10	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) Guidelines for Pre-Clinical and Clinical Trials (Ukrainian): http://www.dec.gov.ua/index.php/ekspertiza-materialiv-doklinichnikh-ta-klinichnikh-viprobuvan/metodichni-rekomendatsiji-shchodo-provedennya-doklinichnikh-ta-klinichnikh-viprobuvan
Research Injury	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	On Medicines, Article 8 No. 123/96BP (2014): http://zakon4.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80		
Privacy/Data Protection	1. State Service of Ukraine on Personal Data Protection: http://zpd.gov.ua/dszpd/en/index 2. Ukrainian Parliament Commissioner for Human Rights: www.ombudsman.gov.ua	1. Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2010) 2. On Protection Personal Data Act, 01.06.2010 with changes from 13.05.2014: http://zakon3.rada.gov.ua/laws/show/2297-17	Cabinet of Ministry of Ukraine 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/		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 with changes from 2009: http://zakon1.rada.gov.ua/laws/show/z1206-07	
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 Academy of Sciences Bioethics Committee:	1. About the Ban of Human Reproductive Cloning	1. Ukrainian Ministry of Health Order No. 630 Regarding	NBC: Ethical Regulations and Problems of

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://biomed.nas.gov.ua/index-en/bioethics-committee 2. Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	(2004) 2. About Organs and Other Human Materials Transplantology No. 1007-XIV (2007)	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 2. Ukrainian Ministry of Health Order No. 787 on Approval of the Use of Reproductive Technologies in Ukraine 09.09.2013: http://zakon4.rada.gov.ua/laws/show/z1697-13	Embryo-Tissue Storage (Recommendations)
United Kingdom Unless otherwise noted, all laws, regulations, and guidelines listed for England apply to the entire United Kingdom. For a more detailed discussion about clinical research regulations in the United Kingdom, see: http://clinregs.niaid.nih.gov/single_country.php?c_id=226				
General	*England:*			
	Department of Health (DH): http://www.dh.gov.uk/Home/fs/en	http://www.dh.gov.uk/health/category/publications/legislation/		1. Research Governance Framework for Health and Social Care (2005) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962 2. Governance Arrangements for NHS Research Ethics Committees (2011): http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474
	Health Research Authority (HRA)/ National Research Ethics Service (NRES): http://www.hra.nhs.uk/			1. Directory of NRES Guidance: http://www.hra.nhs.uk/resources/ 2. Integrated Research Application System: https://www.myresearchproject.org.uk/
	Medical Research Council (MRC): http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm			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

Country	Key Organizations	Legislation	Regulations	Guidelines
				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/PublicationsPolicyAndGuidance/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*			
	Medicines and Healthcare Products Regulatory Agency (MHRA): http://www.mhra.gov.uk	Medicines Act (1968): http://www.legislation.gov.uk/ukpga/1968/67/contents	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	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
	Medical Research Council (MRC): http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm			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)

Country	Key Organizations	Legislation	Regulations	Guidelines
	Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk/Pages/default.aspx			Guidelines for Phase I Clinical Trials (2012): http://www.abpi.org.uk/our-work/library/guidelines/Pages/phase-1-trials-2012.aspx
	Health Research Authority (HRA)/ National Research Ethics Service (NRES): http://www.hra.nhs.uk/			
	Devices			
	Medicines and Healthcare Products Regulatory Agency (MHRA): http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/index.htm		Medical Devices Regulations (2002): http://www.opsi.gov.uk/si/si2002/20020618.htm	Clinical Trials for Medical Devices: http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/index.htm
	Health Research Authority (HRA)/ National Research Ethics Service (NRES): http://www.hra.nhs.uk/			Medical Devices Guidance: http://www.nres.nhs.uk/applications/guidance/guidance-and-good-practice/#medical
Research Injury	Medicines and Healthcare Products Regulatory Agency (MHRA): http://www.mhra.gov.uk		Medicines for Human Use (Clinical Trials) Regulations, 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	
	Department of Health (DH): http://www.dh.gov.uk/Home/fs/en			Research in the NHS: Indemnity and Arrangements (2005): http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4125284.pdf
	Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk			Clinical Trial Compensation Guidelines (1994): http://www.abpi.org.uk/our-work/library/guidelines/Pages/ct-compensation.aspx
	Association of the British Healthcare Industry (ABHI): http://www.abhi.org.uk/			Clinical Investigations Compensation Guidelines (1995): http://www.abhi.org.uk/multimedia/groups/clinical-investigations/ci_compensationguidelines.doc
Privacy/Data Collection	*England:*			
	Information Commissioner's Office: http://www.informationcommissioner.gov.uk/	Data Protection Act (1998): http://www.legislation.gov.uk/ukpga/1998/29/contents		
	Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm			Personal Information in Medical Research (2000)

Country	Key Organizations	Legislation	Regulations	Guidelines
	Health Research Authority (HRA)/ National Research Ethics Service (NRES): http://www.hra.nhs.uk/			Ethical Review of Research Databases: http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-databases/
	Confidentiality Advisory Group (CAG): http://www.hra.nhs.uk/about-the-hra/our-committees/section-251			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	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/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		Codes of Practice: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice.cfm
	Medical Research Council (MRC): http://www.mrc.ac.uk/index.htm			Human Tissue and Biological Samples for Use in Research (2001) and Annex (2004)
	Royal College of Physicians (RCP): http://www.rcplondon.ac.uk/			Research Based on Archived Information and Samples (1999)
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	National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/	National Health and Medical Research Council Act 1992 (2014): http://www.comlaw.gov.au/Details/C2014C00364	National Health and Medical Research Regulations 2006: http://www.comlaw.gov.au/Details/F2006L03519	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/guidelines/publications/e65 *Guidelines developed jointly by the Australian Research Council (ARC) and Universities Australia (UA):* 1. Australian Code for the Responsible Conduct of Research (2007): http://www.nhmrc.gov.au/guidelines/publications/r39 2. National Statement on Ethical Conduct in Human Research, 2007 (2014): http://www.nhmrc.gov.au/guidelines/publications/e72
	Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS): http://www.aiatsis.gov.au/index.html			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 (2014): http://www.comlaw.gov.au/Details/C2014C00410	Therapeutic Goods Regulations 1990 (2014): http://www.comlaw.gov.au/Details/F2014C00898	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/industry/clinical-trials-handbook.htm#.VCiQP0um1Cg NHMRC, ARC, and UA: 1. National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2014): http://www.nhmrc.gov.au/guidelines/publicatio

Country	Key Organizations	Legislation	Regulations	Guidelines
				ns/e72 2. Mutual Acceptance of Ethical Review of Clinical Trials: http://www.health.vic.gov.au/clinicaltrials/mutual-acceptance.htm
	Devices			
	Therapeutic Goods Administration: http://www.tga.gov.au/industry/devices.htm	Therapeutic Goods Act 1989 (2014): http://www.comlaw.gov.au/Details/C2014C00410	Therapeutic Goods (Medical Devices) Regulations 2002 (2014): http://www.comlaw.gov.au/Details/F2014C00912	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/industry/clinical-trials-note-ich13595.htm#.VCiR1Eum1Cg 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 (2014): 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.oaic.gov.au/	Privacy Act 1988 (2014): http://www.comlaw.gov.au/Details/C2014C00076	1. Guidelines under Section 95 of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr1 2. Guidelines Approved under Section 95A of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr2 3. Guidelines Approved under Section 95AA of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr3	1. Australian Privacy Principles Guidelines (2014): http://www.nhmrc.gov.au/guidelines/publications/pr1 2. Guidelines Approved under Section 95A of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr2 3. Guidelines Approved under Section 95AA of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr3

Country	Key Organizations	Legislation	Regulations	Guidelines
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 (2014): Chapters 3.2 and 3.4: http://www.nhmrc.gov.au/guidelines/publications/e72 TGA: Australian Regulatory Guidelines for Biologicals (2014): 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 (2014): http://www.comlaw.gov.au/Details/C2014C00587		NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research, Chapter 3.5 (2014): http://www.nhmrc.gov.au/guidelines/publications/e72
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 for Reproduction Act 2002 (2008): http://www.comlaw.gov.au/Details/C2008C00694 2. Research Involving Human Embryos Act 2002 (2014): http://www.comlaw.gov.au/Details/C2014C00605	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 3.4 (2014): 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)

Country	Key Organizations	Legislation	Regulations	Guidelines
Burma (Myanmar)				
General	1. Ministry of Health National Ethics Committee on Clinical Research: www.moh.gov.mm 2. Department of Medical Research (DMR): http://www.moh.gov.mm/file/Department%20of%20Medical%20Research%20(Lower%20Myanmar).pdf 3. Myanmar Academy of Medical Sciences Ethics Awareness Program			DMR: Operational Guidelines for Institutional Ethical Review Committee (2005)
Drugs and Devices	Ministry of Health, Food and Drug Administration	National Drug Law (1992)		
Human Biological Materials		1. Blood and Blood Products Law (2003) (Burmese): http://www.moh.gov.mm/file/Law/Blood%20and%20Blood%20Product%20Law%20(2003).pdf 2. Body Organ Donation Law (2004)		
China, People's Republic of For a more detailed discussion about clinical research regulations in China, see: http://clinregs.niaid.nih.gov/single_country.php?c_id=44				
General	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Ministry of Science and Technology of the People's Republic of China: http://www.most.cn/eng/	Law on Practicing Doctors (June 26, 1998), Articles 26 and 37 (Mandarin): http://www.gov.cn/banshi/2005-08/01/content_18970.htm		NHFPC: Interim Measures for Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2007) (Mandarin): http://www.moh.gov.cn/qjjys/s3581/200804/b9f1bfee4ab344ec892e68097296e2a8.shtml
Drugs and Devices	*Drugs*			
	China Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/	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): 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. 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/CL0058/55613.html

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://eng.sfda.gov.cn/WS03/CL0768/61646.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. Rules on the Administration of Report and Supervision of Adverse Drug Reactions (2010) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/62621.html 7. Good Manufacturing Practice for Drugs (2010 Revision): http://eng.sfda.gov.cn/WS03/CL0768/65113.html	
	Devices			
	Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/		Provisions for Clinical Trials of Medical Devices (2004): 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. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Food and Drug Administration (SFDA): http://eng.sfda.gov.cn/WS03/CL0755/	Chinese Good Clinical Practice, Article 43 (2003) (Mandarin): http://www.sda.gov.cn/WS01/CL0053/24473.html	NHFPC: 1. Interim Measures for Guidelines on Ethical Review of Biomedical Research Involving Human Subjects, Article 20 (2007) (Mandarin): http://www.moh.gov.cn/qjjys/s3581/200804/b9f1bfee4ab344ec892e68097296e2a8.shtml 2. Regulations on Recall of Medical Devices (Interim), Article 37 (2011) (Mandarin): http://www.gov.cn/flfg/2011-06/13/content_1882686.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

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Ministry of Science and Technology of the People's Republic of China (MOST): http://www.most.cn/eng/		NHFPC and MOST: 1. Interim Measures for the Administration of Human Genetic Resources (1998) (Mandarin): http://www.most.gov.cn/bszn/new/rlyc/wjxz/200512/t20051226_55327.htm 2. Regulations for the Administration of Human Genetic Resources (2012) (Mandarin): http://www.gov.cn/gzdt/2012-10/31/content_2254379.htm	
Embryos, Stem Cells, and Cloning	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Ministry of Science and Technology of the People's Republic of China (MOST): http://www.most.cn/eng/		NHFPC: 1. Ethical Principles and Conduct Norms for Human Assisted Reproductive Technologies. (2003) (Mandarin): http://www.moh.gov.cn/qjjys/s3581/200805/f69a925d55b44be2a9b4ada7fcdec835.shtml 2. Regulation on the Clinical Application of Medical Technique (2009) http://www.moh.gov.cn/yzygj/s3589/201308/0c579ba3babf47dc8f0e811810d438a2.shtml	NHFPC 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
	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 For a more detailed discussion about clinical research regulations in India, see: http://clinregs.niaid.nih.gov/single_country.php?c_id=100				
General	Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			1. Ethical Guidelines for Biomedical Research on Human Participants (2006): http://icmr.nic.in/ethical_guidelines.pdf 2. Guidelines for Preparing Standard Operating Procedures (SOP) for IECs for Human Research: http://www.icmr.nic.in/ethics_SOP.pdf 3. Ethical Guidelines for Social Science Research in Health: http://www.cehat.org/publications/ethical.html

Country	Key Organizations	Legislation	Regulations	Guidelines
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: 1. Good Clinical Practices for Clinical Research in India (2001): http://cdsco.nic.in/html/GCP.htm 2. Compensation: GSR 53 (E) 3. Permission for Clinical Trials: GSR 63(E) 4. Ethics Committee Registration: GSR 72(E) 5. A/V Consent – GSR 364 (E) (2013)	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	Compensation in Case of Injury or Death During Clinical Trial, Schedule Y, Appendix XII (2013) (Scroll half way down to see English): http://www.pharmamedtechbi.com/~/media/Supporting%20Documents/Pharmasia%20News/2013/February/Clinical%20Trials%20Compensation%20Guidelines.pdf	Compensation Formula (Clinical Trial): http://www.cdsco.nic.in/writereaddata/formula2013SAE.pdf	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 and Family Welfare: http://mohfw.nic.in/		Govt. of India Office Memorandum (O.M. No.19015/53/1997 - IH Pt.) 19th November, 1997 on Exchange of Human Biological Material for Biomedical Research Purposes	Guidance on Transfer of Human Biological Material for Commercial Purposes and /or Research for Development of Commercial Products http://icmr.nic.in/ihd/ihd.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): http://dbtindia.nic.in/uniquepage.asp?id_pk=41 ICMR:

Country	Key Organizations	Legislation	Regulations	Guidelines
				Ethical Guidelines for Biomedical Research on Human Subjects: Statement of Specific Principles for Human Genetics and Genomics Research (2006): http://www.icmr.nic.in/ethical_guidelines.pdf
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

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			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			MHLW: Ethical Guidelines for Clinical Research (2004): http://www.ncgm.go.jp/rinri/main/03english.htm MEXT and MHLW: Ethics Guidelines for Epidemiological Research (2013) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1146_01.pdf English (2002 version): http://www.niph.go.jp/wadai/ekigakurinri/guidelines.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	Law Ensuring Quality, Efficacy and Safety of Medical Products and Devices (Revised Pharmaceutical Affairs Law, (2014) (Japanese):	MHLW: Ministerial Ordinance on Good Clinical Practice for Drugs (2014): http://www.pmda.go.jp/english/servic	MHLW: Guidance for the Ministerial Ordinance on Good Clinical Practice for Drugs (2013) (Japanese): http://www.jmacct.med.or.jp/plan/files/gcp130

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://law.e-gov.go.jp/htmldata/S35/S35HO145.html	e/pdf/ministerial/20130329No_28.pdf	404.pdf
	Devices			
	1. Ministry of Health, Labor, and Welfare (MHLW) 2. Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html	Law Ensuring Quality, Efficacy and Safety of Medical Products and Devices (Revised Pharmaceutical Affairs Law, (2014) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html	MHLW: Ministerial Ordinance on Good Clinical Practice for Medical Devices (2014) (Japanese): http://law.e-gov.go.jp/htmldata/H17/H17F19001000036.html English (2009 version): http://www.pmda.go.jp/english/service/pdf/ministerial/20110307No_36.pdf	MHLW: Guidance for the Ministerial Ordinance on Good Clinical Practice for Medical Devices (2013) (Japanese): http://www.jmacct.med.or.jp/plan/files/gcp_130404_1.pdf
Privacy/Data Protection	Consumer Affairs Agency: http://www.caa.go.jp/en/index.html	Act on the Protection of Personal Information (2009) (Japanese): http://law.e-gov.go.jp/htmldata/H15/H15HO057.html English (2003 version): http://www.japaneselawtranslation.go.jp/law/detail/?id=130&vm=04&re=01		
Research Injury	Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html	Pharmaceutical Affairs Law, (2013) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html	1. Ministerial Ordinance on Good Clinical Practice for Drugs, Chapter II, Article 14 and 15 (2014): http://www.pmda.go.jp/english/service/pdf/ministerial/20130329No_28.pdf 2. Ministerial Ordinance on Good Clinical Practice for Medical Devices, Chapter II, Article 14 and 23 (2014) (Japanese): http://law.e-gov.go.jp/htmldata/H17/H17F19001000036.html English (2009 version) http://www.pmda.go.jp/english/service/pdf/ministerial/20110307No_36.pdf	Ethical Guidelines for Clinical Research , Part 2, Article 1(4) and Part 4, Article 1(3) (2008) (Japanese): http://www.mhlw.go.jp/general/seido/kousei/i-kenkyu/rinsyo/dl/shishin.pdf English (2004 version): http://www.ncgm.go.jp/rinri/index.html
Human Biological Materials	Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html			1. On Research and Development Utilizing Human Tissues Removed by Surgery and Other Procedures (1998) (Japanese)

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www1.mhlw.go.jp/shingi/s9812/s1216-2_10.html 2. Guidelines for Assurance of Quality and Safety of Medical Products and Medical Devices Manufactured from Human (Allogenic) Cells and Tissues (2008) (Japanese): http://www.nihs.go.jp/cgtp/cgtp/guidline/0912006-2002I200912006.pdf 3. Guidelines for Assurance of Quality Assurance and Safety of Medical Products and Medical Devices Manufactured from Human (Autologous) Cells and Tissues (2008): (Japanese): http://www.kuhp.kyoto-u.ac.jp/~ccmt/files/20080208.pdf 4. On Assurance of Quality and Safety of Medical Products and Medical Devices Manufactured from Cells and Tissues (2010) (Japanese): http://www.tri-kobe.org/references/pdf_index/r_4_1_1_2.pdf
Genetic Research	1. Council for Science and Technology Policy (CSTP): http://www8.cao.go.jp/cstp/english/index.html 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)			CSTP: Fundamental Principles of Research on the Human Genome (2000): http://www.lifescience.mext.go.jp/files/pdf/43_137.pdf MEXT and MHLW: Guidelines for Clinical Research in Gene Therapy (2008) (Japanese): http://www.mhlw.go.jp/general/seido/kousei/i-kenkyu/idenshi/0504sisin.html MEXT, MHLW, and METI: Ethics Guidelines for Human Genome/Gene Analysis Research (2013) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1115_01.pdf English (2008 version): http://www.lifescience.mext.go.jp/files/pdf/n796_00.pdf
Embryos, Stem Cells, and Cloning	1. Council for Science and Technology Policy (CSTP): http://www8.cao.go.jp/cstp/english/index.html	Act on Regulation of Human Cloning Techniques (2000) (Japanese): http://law.e-	Rules for Enforcement of Act on Regulation of Human Cloning Techniques (2009) (Japanese): http://www.lifescience.mext.go.jp/file	CSTP: Fundamental Philosophy on Handling of Human Embryo (2004) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/6_2

Country	Key Organizations	Legislation	Regulations	Guidelines
	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/	gov.go.jp/htmldata/H12/H12HO146.html English: http://www.cas.go.jp/jp/seisaku/hourei/data/htc.pdf Act on Safety of Regenerative Medicine (2013) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000030847.pdf	s/pdf/29_224.pdf Rules for Enforcement of Act on Safety of Regenerative Medicine (2014) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000059295.pdf	8.pdf MHLW: Guidelines for Clinical Research Using Human Stem Cells (2013) (Japanese): http://www.mhlw.go.jp/bunya/kenkou/iryousaisei06/pdf/131001_1.pdf English (2010 version): http://www.mhlw.go.jp/english/policy/health-medical/medical-care/dl/guidelines.pdf MEXT: 1. Guidelines for Handling of a Specified Embryo (2009) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/30_226.pdf English (2001 version): http://www.lifescience.mext.go.jp/files/pdf/30_82.pdf 2. Guidelines for Derivation and Distribution of Human Embryonic Stem Cells (2010): http://www.lifescience.mext.go.jp/files/pdf/n743_00.pdf 3. Guidelines for Utilization of Human Embryonic Stem Cells (2010): http://www.lifescience.mext.go.jp/files/pdf/n743_01.pdf 4. Guidelines on Research on Producing Germ Cells from Human Induced Pluripotent Stem Cells or Human Tissue Stem Cells (2013) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1146_03.pdf English (2010 version): http://www.lifescience.mext.go.jp/files/pdf/n743_02.pdf MEXT and MHLW: Ethical Guidelines for Research on Assisted Reproductive Technology to Develop Human Fertilized Embryos (2013) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1146_05.pdf English (2010 version):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.lifescience.mext.go.jp/files/pdf/n796_02.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)		
Embryos, Stem Cells, and Cloning		Stem Cell By-law No. 10 (2014)		
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				
Drugs and Devices	*Drugs*			
	Ministry of Food and Drug Safety (MFDS) (2013): http://www.mfds.go.kr/eng	Pharmaceutical Affairs Act No. 12450 (2014)	Enforcement Rule of Medicinal Product Safety No. 1089 (2014)	
	Devices			
	Ministry of Food and Drug Safety (MFDS) (2013): http://www.mfds.go.kr/eng	Medical Device Act No. 11998 (2013) : http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyC	1. Enforcement Regulations of the Medical Device Act [Ministerial Decree Number18 of the Ministry of Health and Welfare, Effective	

Country	Key Organizations	Legislation	Regulations	Guidelines
		ode=125&page=1&mode=view&boardSeq=67030	as of September 2, 2014, and Amendment of Other Laws] http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyCode=125&page=1&mode=view&boardSeq=66026 2. Enforcement Decree of the Medical Device Act (2014): http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyCode=125&page=1&mode=view&boardSeq=66026	
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. Medical Affairs Act No. 10609 (2011) 2. Personal Information Protection Act (2013)	Enforcement Rules to Personal Information Protection Act (2013)	Enforcement Decrees to Personal Information Protection Act (2014)
Genetic Research	Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/	Bioethics and Safety Act No. 11690 (2008): http://www.moleg.go.kr/english/korLawEng?pstSeq=47518	Presidential Order of Regulation for Bioethics and Safety No. 24454 (2013)	Guidelines for Bioethics and Safety Act No. 18 (2013)
Embryos, Stem Cells, and Cloning	Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/	Bioethics and Safety Act No. 12447 (2014)	Enforcement Rule of Bioethics and Safety Act (2013)	Enforcement Decree of Bioethics and Safety Act (2013)
Kuwait				
General	Ministry of Health, Kuwait Institute for Medical Specialization: http://www.kims.org.kw/			Ethical Guidelines for Biomedical Research: http://www.kims.org.kw/Ethical%202.doc
Kyrgyzstan Note: All websites and documents are in Russian.				
General	1. Government of the Kyrgyz Republic: 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: http://www.pharm.kg/ru/legislation	The Code of Professional Ethics of Medical Worker of Kyrgyz Republic: http://www.med.kg/index/documenty-2/kodex-prof-etiki-2.html	
Drugs and Devices	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): 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): http://www.pharm.kg/ru/legislation	DDMDP: 1. Technical Regulations on the Safety of Medical Products for Medical Application, Approved by the Governmental Order # 74 from February 1, 2012: http://www.pharm.kg/ru/legislation/ 2. National Standard KMC	

Country	Key Organizations	Legislation	Regulations	Guidelines
			1195:2010: Medical Devices: Rules of Preparing Clinical Testing (2010) 3. The Ethical Code of Pharmacists: http://www.pharm.kg/ru/legislation	
Research Injury	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): 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): http://www.pharm.kg/ru/legislation	DDMDP: 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: 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	Technical Regulations on the Safety of Medical Products for Medical Application, Approved by the Governmental Order #74 from February 1, 2012: http://www.pharm.kg/ru/legislation/	
Privacy/Data Protection	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): 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	1. Technical Regulations on the Safety of Medical Products for Medical Application, approved by the Governmental Order #74 from February 1, 2012: 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)	
Malaysia				
Drugs and Devices	Ministry of Health: http://www.moh.gov.my/			Malaysian Guidelines of Good Clinical Practice (2011): http://www.nih.gov.my/mrec/documents/Malaysian%20GCP.pdf
Privacy/Data Protection	Malaysian Government	Act 709: Personal Data Protection Act 2010: http://www.pdp.gov.my/images/LAWS_OF_MALAYSIA_PDPA.pdf		
Human Biological Materials	1. National Committee for Clinical Research 2. Malaysian Government	1. Act 130: Human Tissues Act (1974): http://www.agc.gov.my/Akta/Vol.%203/Act%20130.pdf 2. Act 699: DNA Identification Act 2009. Malaysian Government Gazette of 3	DNA Identification Regulations 2012. Malaysian Government Gazette of 30 Aug 2012.	Guideline on the Use of Human Biological Tissues for Research (2006): http://www.nccr.gov.my/index.cfm?menuid=25&parentid=17

Country	Key Organizations	Legislation	Regulations	Guidelines
		September 2009		
Genetic Research	Malaysian Medical Council: http://www.mmc.gov.my/v1/			Medical Genetics and Genetic Services. MMC Guidelines 010/2006: http://www.mmc.gov.my/v1/docs/Medical%20Genetics%20&%20Genetic%20Services.pdf
Embryos, Stem Cells and Cloning	Ministry of Health, Medical Research and Ethics Committee			Checklist for Research on Stem Cell and Cell-Based Therapies: http://www.nih.gov.my/mrec/documents/Research_On_Stem_cell_and_Cell_based_Therapies.pdf
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.mbie-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/	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

Country	Key Organizations	Legislation	Regulations	Guidelines
				and Disability Ethics Committees (2012): http://www.ethics.health.govt.nz/operating-procedures
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(2012) 2. Accident Compensation Act 2001, Section 32 (2010)	Medsafe: Medicines Regulations 1984 http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM95668.html	Medsafe: 1. Good Clinical Research Practice and Obtaining Approval for Clinical Trials (2013): http://www.medsafe.govt.nz/medicines/clinical-trials.asp 2. Researched Medicines Industry 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. Standard Operating Procedures for Health and Disability Ethics Committees (2012): http://www.ethics.health.govt.nz/operating-procedures 2. Various: http://medsafe.govt.nz/regulatory/DevicesNew/13ConductingClinicalTrials.asp
Privacy/Data Protection	Privacy Commissioner: http://www.privacy.org.nz/	1. Official Information Act 1982 (2012) 2. Public Records Act (2005) 3. Privacy Act 1993 (2012)	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. Ministry of Health (MOH): http://www.moh.govt.nz/ 2. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval 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 Business, Innovation and Employment: http://www.mbie-govt.nz/	1. Health Act 1956 (2012) 2. Human Tissue Act 2008		MOH: Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (2007): http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research	1. Environmental Protection Authority: http://www.epa.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 (2012)		
Embryos, Stem Cells, and Cloning	1. Ministry of Health: http://www.moh.govt.nz/ 2. Advisory Committee on Assisted Reproductive Technology (ACART): http://acart.health.govt.nz/ 3. Ethics Committee on Assisted Reproductive Technology (ECART): http://ecart.health.govt.nz/	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 Embryo Donation for Reproductive Purposes (2008) 4. Guidelines on Donation of Eggs or Sperm between Certain Family Members (2010) *Access:* http://acart.health.govt.nz/publications-and-resources
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
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): www.ethics.healthresearch.ph 2. Department of Science and Technology (DOST): http://www.dost.gov.ph/ 3. Department of Health (DOH) 4. Commission of Higher Education (CHED): www.ched.gov.ph/	Republic Act No. 10532: An Act Institutionalizing the Philippine National Health Research System (2013): http://www.gov.ph/2013/05/07/republic-act-no-10532/	DOST: 1. Administrative Order 001 Series 2007: Requirement for Review of All Research Involving Human Subjects/Participants (2007): http://ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/112-ao-001-2007	PHREB: National Ethical Guidelines for Health Research (2011): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
			2. Administrative Order 001 Series 2008: Registration of All Ethics Review Committee at the PHREB (2008): http://ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/111-ao-001 CHED: Memo 34 Series 2007: Endorsement of DOST Administrative Order 001, Series 2007: http://www.ched.gov.ph/chedwww/index.php/eng/content/download/623/3597/file/cmo_34_s2007.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): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011
	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 Board (PHREB): http://www.pchrd.dost.gov.ph/index.php?option=com_frontpage&Itemid=1			DOST: National Guidelines for Biomedical/Behavioral Research, page 14 (2000): www.nus.edu.sg/irb/Articles/PCHRD_DOST_NEC%20Guidelines.pdf PHREB: National Ethical Guidelines for Health Research, pages 19-20 (2011): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011
Genetic Research	Philippine Health Research Ethics Board (PHREB)			Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research (2011): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-

Country	Key Organizations	Legislation	Regulations	Guidelines
				ethics-guidelines-2011
Embryos, Stem Cells, and Cloning	Philippine Health Research Ethics Board (PHREB)			Ethical Guidelines for Genetic Research, with a Section on Stem Cell Research (2006): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011
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
Saudi Arabia				
General	National Committee of BioEthics: http://bioethics.kacst.edu.sa/?lang=en-US	Law of Ethics of Research on Living Creatures (Arabic): http://bioethics.kacst.edu.sa/getattachment/4bd0d4e2-1b93-4c32-b483-57902227fae2/Bioethic-Rgl-fin-bks.aspx	Implementing Regulations of the Law of Ethics of Research on Living Creatures, Royal Decree No. M/59: http://www.kacst.edu.sa/ar/depts/bioethics/Documents/The%20final%20draft%20of%20the%20translation%20Law%20and%20Regulations2.pdf	
Singapore				
General	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Ministry of Health National Medical Ethics Committee (NMEC) 3. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org 4. Singapore Medical Council (SMC): http://www.smc.gov.sg	Medical Registration Act (Cap. 174) (1985): http://statutes.agc.gov.sg/	MOH: Directive of June 25, 1998: Hospital Ethics Committees	NMEC: Ethical Guidelines on Research Involving Human Subjects (1997) BAC: Research Involving Human Subjects: Guidelines for IRBs (2004) MOH: 1. Governance Framework for Human Biomedical Research (2007) 2. Operational Guidelines for IRBs (2007) 3. Code of Ethical Practice in Human Biomedical Research (2009)
Drugs and Devices	*Drugs*			
	1. Health Sciences Authority of Singapore (HSA): http://www.hsa.gov.sg 2. Ministry of Health National Medical Ethics Committee (NMEC)	Medicines Act (1975): http://statutes.agc.gov.sg/	Medicines (Clinical Trials) Regulations (1998): http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/legislation.html#Medicine	HSA: 1. Singapore Guideline for Good Clinical Practice (1998) 2. Various Guidelines on Clinical Trials: http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials/guidelin

Country	Key Organizations	Legislation	Regulations	Guidelines
				es.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/corporate-functions/about-nea/legislation	
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/corporate-functions/about-nea/legislation	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 Communications and Information (MCI) 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 Act (2012) http://statutes.agc.gov.sg/		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) BAC: Genetic Testing and Genetic Research (2005): http://www.bioethics-singapore.org/uploadfile/55211%20PMGT%20Research.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
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/content/dam/moh_web/Publications/Guidelines/Private%20healthcare%20institutions/2011/AR_LTCs_260411.pdf	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	Ministry of Health and Welfare: http://www.mohw.gov.tw/EN/Ministry/Index.aspx	1. Human Subjects Research Act (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020176 2. Medical Care Act (2012): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020021	1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162 2. Enforcement Rules of the Medical Care Act (2010) (Chinese): http://law.moj.gov.tw/Law/LawSearchResult.aspx?p=A&t=A1A2E1F1&k1=%E9%86%AB%E7%99%82%E6%B3%95 Partial Amended Articles of Enforcement Rules of Medical Care Act (2010) http://mohwlaw.mohw.gov.tw/Chi/EngDownLoad.asp?msgid=249&file=efile1 3. Regulations Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020179 4. Exempt Review Categories for Human Research (2012) (Chinese): http://gazette.nat.gov.tw/EG_FileManager/eguploadpub/eg018127/ch08/type1/gov70/num35/Eg.htm 5. Informed Consent Exemptions for Human Research (2012) (Chinese): http://gazette.nat.gov.tw/EG_FileManager/eguploadpub/eg018127/ch08/type1/gov70/num36/Eg.htm 6. Expedited Review Categories for Human Research (2012)	Healthcare Institution Institutional Review Board Organization and Operations (2003) (Chinese): http://mohwlaw.mohw.gov.tw/Chi/FLAW/FLAWDAT01.asp?lsid=FL027593

Country	Key Organizations	Legislation	Regulations	Guidelines
			(Chinese): http://gazette.nat.gov.tw/EG_FileManager/eguploadpub/eg018127/ch08/type1/gov70/num37/Eg.htm	
Drugs and Devices	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Taiwan Food and Drug Administration (FDA): http://www.fda.gov.tw/	MOHW: Medical Care Act (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020021 FDA: Pharmaceutical Affairs Act (2013): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0030001	MOHW: 1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162 2. Guideline for Good Clinical Practice (2010) (Chinese): http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0030056 3. Pharmaceutical Affairs Act Enforcement Rules (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0030002 4. Regulations for Drug Safety Monitoring (2013) http://mohwlaw.mohw.gov.tw/Chi/EngContent.asp?msgid=516&KeyWord= 5. Regulations for Bioavailability and Bioequivalence Studies (2013): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0030065 6. Regulations for Governing the Management of Medical Devices (2014): http://mohwlaw.mohw.gov.tw/Chi/EngContent.asp?msgid=528&KeyWord=	
Research Injury	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Food and Drug Administration (FDA), MOHW: http://www.fda.gov.tw/EN/index.aspx	Medical Care Act, Article 79 (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020021	FDA: Guideline for Good Clinical Practice, Article 22 (2010) (Chinese): http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0030056	
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		

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	Ministry of Health and Welfare: http://www.mohw.gov.tw/EN/Ministry/Index.aspx	1. Medical Care Act (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020021 2. Human Subjects Research Act (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020176 3. Human Biobank Management Act (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020164	Regulations on Human Trials (2009): http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0020170	1. Good Tissue Practice (2002) (Chinese): http://mohwlaw.mohw.gov.tw/Chi/FLAW/FLAWDAT01.asp?lsid=FL022759 2. Guidelines for Collection and Use of Human Specimens for Research (2006) (Chinese)
Genetic Research	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Food and Drug Administration (FDA): http://www.fda.gov.tw/EN/index.aspx 3. National Science Council: http://www.most.gov.tw/mp.aspx?mp=7	MOHW: Human Biobank Management Act (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020164	MOHW: 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 the Establishment of Human Biobanks (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020173	MOHW: Guidance for Information Safety of Human Biobank (2010) (Chinese): http://mohwlaw.mohw.gov.tw/Chi/FLAW/FLAWDAT01.asp?lsid=FL022759 FDA: Guidance for Informed Consent Forms for Pharmacogenetic Research (2005) (Chinese): http://mohwlaw.mohw.gov.tw/Chi/FLAW/FLAWDAT01.asp?lsid=FL013662
Embryos, Stem Cells, and Cloning	Health Promotion Administration, MOHW: http://www.hpa.gov.tw/BHPNet/English/Index.aspx	Artificial Reproduction Act (2007): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0070024		MOHW: Policy Instructions on the Ethics of Human Embryo and Embryonic Stem Cell Research (2007)
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	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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)
	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	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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. Regulation on Clinical Trials (2007) 2. Decision No. 799/QD-BYT of the Minister of Health on the Promulgation of the "Guidelines on Good Clinical Practice of Clinical Trials" (2008) 3. Decision No. 23 /2008/QD-BYT of the Minister of Health on the Promulgation of the "Regulations on Utilization of Vaccine and Medical Immuno-Biological Products in Prevention and Treatment" (2008) 4. Circular No. 08/2010/TT-BYT on the Guidance to Report Data from the Research of Bioequivalence of Drug Registration (2010)	Guidelines on Good Clinical Practice of Clinical Trials (2008)

Country	Key Organizations	Legislation	Regulations	Guidelines
LATIN AMERICA and the CARIBBEAN				
Pan American Health Organization				
Drugs and Devices	*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 102/09: National Register for Clinical Trials 2. 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	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 For a more detailed discussion about clinical research regulations in Brazil, see: http://clinregs.niaid.nih.gov/single_country.php?c_id=30				
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.planalto.gov.br/ccivil_03/decreto/1990-1994/D98830.htm Decree No. 8.065/2013 (Portuguese): http://www.planalto.gov.br/ccivil_0	CNS/CONEP: 1. Regulation of Resolution CNS No. 292/99 on Research with Foreign Cooperation: http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/regulation_res_292_english.doc 2. Resolution No. 304/2000: http://conselho.saude.gov.br/resolucoes/2000/Res304_en.pdf 3. Internal CONEP Regulation	CNS/CONEP: 1. Operating Manual for Research Ethics Committees (2007) (Portuguese): http://conselho.saude.gov.br/biblioteca/livros/Manual_Operacional_miolo.pdf 2. Guide Review of Research Ethics Committees (2009) (Portuguese): http://www.conselho.saude.gov.br/Web_comissoes/conep/aquivos/documentos/norma_procedimentos_006.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
		3/_Ato2011-2014/2013/Decreto/D8065.htm	(2001) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/aquivos/conep/regimento.doc 4. Resolution No. 301, 16th March 2002: http://conselho.saude.gov.br/resolucoes/2000/Res301_en.pdf 5. Resolution No. 346/2005 on Multicenter Research: http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf 6. Resolution CNS No. 370/07on Registration and Accreditation or Renewal of Registration and Accreditation of CEP (Portuguese): http://conselho.saude.gov.br/resolucoes/2007/Reso370.doc 7. Resolution CNS No. 421/09 (Portuguese): http://conselho.saude.gov.br/resolucoes/2009/Reso421.doc 8. Resolution No. 446/2011on Composition of the National Commission on Research Ethics (Portuguese): http://conselho.saude.gov.br/resolucoes/2011/Reso446.DOC 9. Resolution MS/CNS No. 466/2012 (Portuguese): http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf	Standard Operating Nº 001/2013 (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/aquivos/CNS%20%20Norma%20Operacional%20001%20-%20conep%20finalizada%2030-09.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 3. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html		CNS: 1. Resolution 251/1997: On Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests (1997): http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf 2. Resolution 404/2008: On Helsinki Declaration (2000) (Portuguese): http://conselho.saude.gov.br/resoluco	

Country	Key Organizations	Legislation	Regulations	Guidelines
			es/2008/Reso_404.doc 3. Resolution MS/CNS No. 466/2012: http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf	
Research Injury	1. National Healthcare Surveillance Agency (ANVISA) (Portuguese): http://www.anvisa.gov.br 2. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 3. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html	ANVISA: Law Nº 6360/76 (Portuguese): http://www.planalto.gov.br/ccivil_03/leis/l6360.htm	CNS/CONEP: 1. Standards Survey of New Drugs, Medicines, Vaccines, and Diagnostic Tests Involving Human Beings - Resolution CNS 251/97 (Portuguese): http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf 2. Resolution No. 346/2005 on Multicenter Research (Portuguese): http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf	CNS/CONEP: Orientation of Adverse Event Reporting in Clinical Trials (2011) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/carta_circular/Informacoes_sobre_o_formulario_para_submissao_de_Eventos_Adversos_Serios_a_CONEP.pdf
Human Biological Materials	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	Ordinance No. 2.201/11: Establishing the National Guidelines for Biobanks of Human Biological Material for Research Purposes (2011) (Portuguese): http://www2.inca.gov.br/wps/wcm/connect/8b19d5804eb688ee9cb39ef11fae00ee/portaria_2201_de_14_de_set_2011.pdf?MOD=AJPERES&CACHEID=8b19d5804eb688ee9cb39ef11fae00ee	CONEP: Resolution CNS No. 441 of 12 May 2011: http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/Resolution441_English_contribuicao_pesquisadora.doc	
Genetic Research	1. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 2. National Biosafety Technical Commission (CTNBio) (Portuguese): http://www.ctnbio.gov.br 3. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/	1. Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/12847.html 2. Decree No. 5,591, of November 22, 2005 (Portuguese): http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/Decreto/D5591.htm	CONEP: Resolution 340/2004 : On Research on Human Genetics (2004): http://conselho.saude.gov.br/resolucoes/2004/Res340_en.pdf CTNBio: 1. Instruction CTNBio No. 8 of 9 July 1997 (Portuguese): http://www.ctnbio.gov.br/index.php/content/view/11971.html 2. Instruction CTNBio No. 9 of 10 October 1997 (Portuguese): http://www.ctnbio.gov.br/index.php/content/view/11972.html	

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	1. National Biosafety Technical Commission (Portuguese): http://www.ctnbio.gov.br 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 3. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/	1. Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/12847.html 2. Decree No. 5,591, of November 22, 2005 (Portuguese): http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/Decreto/D5591.htm	CNS/CONEP: Resolution MS/CNS No. 466/2012: http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf	
Chile				
General	1. Ministry of Health (Spanish): http://www.minsal.cl 2. Institute of Public Health (Spanish): http://www.ispch.cl	1. Law No. 20.120 Regarding Scientific Research in Human Beings, their Genome, and the Prohibition of Human Cloning (2006) (Spanish): http://www.leychile.cl/Navegar?idNorma=253478 2. 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 3. Law No. 20.724 Modifying the Health Code in the Area of the Regulation of Pharmacies and Medications (2014) (Spanish): http://www.leychile.cl/Navegar?idNorma=1058373	Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011 (Spanish): http://www.leychile.cl/Navegar?idNorma=1032919	
Drugs and Devices	1. Ministry of Health (Spanish): http://www.minsal.cl 2. Institute of Public Health (Spanish): http://www.ispch.cl	Law No. 20.724 Modifying the Health Code in the Area of the Regulation of Pharmacies and Medications (2014) (Spanish): http://www.leychile.cl/Navegar?idNorma=1058373	1. Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011 (Spanish): http://www.leychile.cl/Navegar?idNorma=1032919 2. Supreme Decree No. 3 of 2010. Regulation of the National Control System of Pharmaceutical Products for Human Use. Official	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Diary of June 25, 2011 (Spanish): http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/ds_minsal_3_2010.pdf	
Research Injury	Ministry of Health: http://www.minsal.cl	Law No. 20.120 Regarding Scientific Research in Human Beings, their Genome, and the Prohibition of Human Cloning (2006) (Spanish): http://www.leychile.cl/Navegar?idNorma=253478	1. Supreme Decree No. 3 of 2010. Regulation of the National Control System of Pharmaceutical Products for Human Use. Official Diary of Jun 25, 2011 (Spanish): http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/ds_minsal_3_2010.pdf 2. General Technical Rule No. 140 Regarding the National System of Pharmacovigilance of Pharmaceutical Products for Human Use. June 20, 2012 (Spanish): http://web.minsal.cl/portal/url/item/c4a31ad6db50e085e040010165017a39.pdf	
Privacy/Data Protection		Law for the Protection of Private Life No. 19.628 (1999) (Spanish): http://www.bcn.cl/leyes/141599	Supreme Decree No. 41 of 2012: Regulation Regarding Clinical Records of December 15, 2012 (Spanish): http://www.leychile.cl/Navegar?idNorma=1046753	
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	Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011 (Spanish): http://www.leychile.cl/Navegar?idNorma=1032919	
Embryos, Stem Cells, and Cloning		Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2006) (Spanish): http://www.leychile.cl./Navegar?idNorma=253478	Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011 (Spanish): http://www.leychile.cl/Navegar?idNorma=1032919	

Country	Key Organizations	Legislation	Regulations	Guidelines
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 (Spanish): http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=31169 2. Resolution No. 2011020764 June 10th, 2011: Regulation Related to the Content and Frequency of Adverse Event Reports in Clinical Investigation in Humans: http://www.google.com/url?url=http://www.andi.com.co/downloadfile.aspx%3FId%3Dc76263e4-f924-4324-87c9-fc4b4d0483e9&rct=j&frm=1&q=&esrc=s&sa=U&ei=ka0pVO6gBYSFyQSP4oHoDw&ved=0CBQQFjAA&usg=AFQjCNGL3IYmmQOqBgOPQ2p8QV08HGBXdw	
	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: http://web.invima.gov.co/portal/faces/index.jsp?id=2285
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.	

Country	Key Organizations	Legislation	Regulations	Guidelines
			008430, Title II, Chapter I, Article 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				
Drugs and Devices	Ministry of Health (Spanish): www.ministeriodesalud.go.cr	Regulatory Law of Biomedical Research No. 17.777 (2014) (Spanish): www.conare.ac.cr/proyectos/17777%202M137.pdf		
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 (Spanish): http://www.salud.gob.ec/	Organic Health Law of 22 December 2006, Articles 207-208 (2011): http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf		National Policy on Scientific Research. Ministerial Agreement 209, Public Registry No. 87 of August 23, 2005
Drugs and Devices	Ministry of Public Health: http://www.salud.gob.ec/		1. Regulation on Research, Ministerial Agreement No. 0066, Public Registry No. 292, March 11, 2008. 2. Regulation for the Approval of Ethics Committees (2014): http://www.bioetica.org.ec/registro_comites.pdf	
Biological Materials	National Institute on Donation and Transplantation of Organs, Tissues, and Cells (Spanish): http://www.donaciontrasplante.gob.ec/indot/	1. Organic Health Law of December 22, 2006, Articles 81-86 (2006) (Spanish): 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. Executive Order 1205, July 13, 2012 (Spanish):	

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells (2011) (Spanish): http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_de_donacion_y_trasplantes.pdf	http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_de_donacion_y_trasplantes.pdf	
Genetic Research	Ministry of Public Health: http://www.salud.gob.ec/	Organic Health Law, December 22, 2006, Articles 209-210 (2011): 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.salud.gob.ec/	Organic Health Law of 22 December 2006, Article 214 (2011): 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/school-of-medicine/institutional-review-board.html			45 CFR 46: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
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	
México Note: All websites and documents are in Spanish.				
General	1. Secretariat of Health: http://www.salud.gob.mx/ 2. General Health Council: www.csg.salud.gob.mx/ 3. National Bioethics Commission (CNB): http://www.conbioetica-mexico.salud.gob.mx/ 4. Federal Commission for Protection Against Health Risks: http://www.cofepris.gob.mx/Paginas/Inicio.aspx	General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2014): http://www.diputados.gob.mx/LeyesBiblio/pdf/142_040614.pdf	1. Rule NOM-012-SSA3-2012 Establishing Criteria for the Conduct of Health Research Projects (2013): http://dof.gob.mx/nota_detalle.php?codigo=5284148&fecha=04/01/2013 2. Regulation on the General Health Law in the Matter of Health Research (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf	CNB: 1. Agreement by Which General Provisions are Issued for the Integration and Operation of Research Ethics Committees and Their Hospital Units, In Accordance with Criteria Established by the National Bioethics Commission (2012): http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatinacional/AcuerdoCHB.pdf 2. National Guidelines for the Integration and Operation of Research Ethics Committees (2013): http://www.conbioetica-mexico.salud.gob.mx/interior/registrocomites/Guias.html
Drugs and Devices	Federal Commission for Protection Against Health Risks (COFEPRIS): http://www.cofepris.gob.mx/Paginas/Inicio.aspx	General Health Law, Title V, Chapter I, Articles 96-103: Health Research (2014): http://www.diputados.gob.mx/LeyesBiblio/pdf/142_040614.pdf	Regulation on the General Health Law in the Matter of Health Research (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf	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/Moléculas%20Nuevas/Formatos/CONFIDENCIALIDAD%20CMN%20CAS-CAS-P-02-F-02.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Privacy/Data Protection	Federal Institute on Access to Public Information (Spanish): www.ifai.org.mx/	1. Federal Law for the Protection of Personal Data in the Possession of Private Individuals (2010): http://www.diputados.gob.mx/LeyesBiblio/pdf/LFPDPPP.pdf 2. Federal Law on Transparency and Access to Public Governmental Information (2014): http://www.diputados.gob.mx/LeyesBiblio/pdf/244_140714.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	Regulation of the General Law of Health in Matter of Transplants (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MT.pdf	
Genetic Research	National Institute of Genomic Medicine: http://www.inmegen.gob.mx/es/	1. Biosafety Law on Genetically Modified Organisms (2008) 2. Modifications to the General Health Law to Protect Genomic Sovereignty (2008) 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): www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmis.html	
Panamá				
General	1. Ministry of Health (MINSA) (Spanish): http://www.minsa.gob.pa/ 2. ICGES Bioethics Research Committee (CBI): http://www.gorgas.gob.pa/index.php?option=com_content&view=article&id=54&Itemid=103&lang=es		MINSA: 1. Resolution No. 390 Adopting the Operational Guide for Research Bioethics, Official Gazette 24,938 (2003) (Spanish): http://www.gorgas.gob.pa/images/Gaceta%20N%2024%20938%20%20Resolucion390.doc 2. Executive Decree No. 1 on the National Research Ethics Committee of Panama (2013) (Spanish): http://www.gacetaoficial.gob.pa/pdfTemp/27207/40366.pdf	CBI : Various (Spanish): http://www.gorgas.gob.pa/index.php?option=com_content&view=article&id=54&Itemid=103&lang=es
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		

Country	Key Organizations	Legislation	Regulations	Guidelines
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		
Embryos, Stem Cells, and Cloning			Executive Decree No. 2 on Stem Cells (2013) (Spanish): http://www.gacetaoficial.gob.pa/pdfTemp/27207/40367.pdf	
Perú For a more detailed discussion about clinical research regulations in Peru, see: http://clinregs.niaid.nih.gov/single_country.php?c_id=170				
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	1. Law 29733 for the Protection of Personal Information: http://www.minjus.gob.pe/legislacion/ 2. Law for Electronic Medical Charts (2013): http://elperuanolegal.blogspot.com/2013/05/ley-30024-ley-que-crea-el-registro.html		

Country	Key Organizations	Legislation	Regulations	Guidelines
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	Decree No. 370/2008: Regulation Concerning Research with Humans	
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%20BPPesquisaClinica.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/	Constitution, Article 46 (Spanish)	Resolution No. 48 (1998)	FONACIT: Code on Bioethics and Biosecurity (2002) IVIC: 1. Annex 1: General Ethical Issues in

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Venezuelan Institute of Scientific Research, Bioethics Commission (IVIC)			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)
Cameroon For an overview of human subject protections in Cameroon, see: http://elearning.trree.org/mod/resource/view.php?id=31&lang=en				
General	Cameroon Bioethics Initiative: www.cambin.org		Ministerial Order No. 079/A/MSP/DS of MINSANTE of October 22, 1987	Operational Guidelines for Ethics Committees in Charge of the Evaluation of Biomedical Research
Egypt				
General	Medical Profession Union	Constitution of the Arab Republic of Egypt, Article 43: http://www.sis.gov.eg/En/Politics/Constitution/Text/040703000000000001.htm	Professional Ethics Regulations: Conducting Medical Research on Human Beings, Articles 52-61 (2003)	
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)	
Ethiopia				
General	Ethiopian Science and Technology Commission, Health Department: http://www.most.gov.et/	Proclamation 60/1999, Section 21		National Health Research Ethics Review Guideline, Fourth Edition (2005): www.most.gov.et/Ethics%20Guideline.pdf
Drugs and Devices	Food, Medicine, and Health Administration and Control Authority: www.fmhaca.gov.et		Drug Administration and Control Proclamation No. 176/1999, Article 21	
Human Biological Materials	Ethiopian Science and Technology Commission, Health Department: http://www.most.gov.et/			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)
Ghana				
Drugs and Devices	Food and Drugs Authority: http://www.fdaghana.gov.gh	Public Health Act, 2012: ACT 851	Act 851 Section 150-166	1. Conduct of Clinical Trials Document No. FDA/SMC/CTD/GL-CCT/2013/0, Version No. 02

Country	Key Organizations	Legislation	Regulations	Guidelines
				2. Good Clinical Practice Document No. FDA/SMC/CTD/GL-GCP/2013/02, Version No. 01
Guinea				
General	National Ethics Committee on Health Research: http://cners-guinee.org/	Public Health Code, Articles 237-316 (1997) (French): http://www.vertic.org/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf		
Research Injury	National Ethics Committee on Health Research: http://cners-guinee.org/	Public Health Code, Articles 301-302 (1997) (French): http://www.vertic.org/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf		
Kenya For a more detailed discussion about clinical research regulations in Kenya, see: http://clinregs.niaid.nih.gov/single_country.php?c_id=111				
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)	
Liberia				
Drugs and Devices	Ministry of Health and Social Welfare: http://www.mohsw.gov.lr/		National Drug Policy (2001): https://www.healthresearchweb.org/?action=download&file=NationalDrugPolicy2001scan21Jul20101.doc	
Malawi For a more detailed discussion about clinical research regulations in Malawi, see: http://clinregs.niaid.nih.gov/single_country.php?c_id=129				
General	1. National Commission for Science and Technology (NCST) 2. National Health Sciences Research Committee (NHSRC) 3. College of Medicine Research and	1. Presidential Decree on 30th March 1974 2. Malawi Government Gazette, June 11, 1976, General Notice No. 398		NCST: 1. The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011) 2. Policy Requirements, Procedures and

Country	Key Organizations	Legislation	Regulations	Guidelines
	Ethics Committee (COMREC): http://www.medcol.mw/ 4. Ministry of Health	3. Constitution of Malawi, Article 19(5) (1994)		Guidelines for the Conduct and Review of Research (2012) 3. National Policy Measures and Requirements for the Improvement of Health Research Co-ordination in Malawi (2012) 4. National Policy Requirements and Guidance for the Provision of Insurance Cover for Research Participants in Clinical Trials in Malawi (2012) 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)	
Mozambique For an overview of human subject protections in Mozambique, see: http://elearning.trree.org/mod/resource/view.php?id=61&lang=en				
General				Science and Technology Ethics Code (2007)
Nigeria For an overview of human subject protections in Nigeria, see: http://elearning.trree.org/mod/resource/view.php?id=57&lang=en				
General	National Health Research Ethics Committee: http://nhrec.net/	National Health Bill 2009		National Code of Health Research Ethics (2007): http://www.nhrec.net/nhrec/NCHRE_10.pdf
Drugs and Devices	National Agency for Food, Drug Administration and Control (NAFDAC): http://www.nafdac.gov.ng/	Decree No. 15 of 1993	Good Clinical Practice Regulations (2009): http://apps.who.int/medicinedocs/documents/s17103e/s17103e.pdf	
Rwanda				
General	Ministry of Health, National Ethics Committee			Standard Operating Procedures (2009): http://www.moh.gov.rw/index.php?option=com_docman&task=doc_download&gid=126&It

Country	Key Organizations	Legislation	Regulations	Guidelines
				emid=81
Sierra Leone				
General	Sierra Leone Ethics and Scientific Review Committee	Committee Application Form: https://www.healthresearchweb.org/?action=download&file=SierraLeoneEthicsandScientificReviewCommittee.docx		
South Africa For an overview of human subject protections in South Africa, see: http://elearning.trree.org/course/view.php?id=9&lang=en For a more detailed discussion about clinical research regulations in South Africa, see: http://clinregs.niaid.nih.gov/single_country.php?c_id=199				
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): www.info.gov.za/view/DownloadFileAction?id=68039 3. MRC Act: http://www.mrc.ac.za/about/MRCAct.pdf 4. HSRC Act: www.hsrc.ac.za/en/about/hsrc-act	Regulations Relating to Research with Human Participants No. R719 (2014): http://www.google.co.za/url?url=http://www.lawsofsouthafrica.up.ac.za/index.php/browse/medical-and-health/national-health-act-61-of-2003/regulations-and-notices/61-of-2003-national-health-act-regs-gnr-719-19-sept-2014-to-date-pdf/download&rct=j&frm=1&q=&esrc=s&sa=U&ei=W6UtVOOvLa6S7Aa34YDwAg&ved=0CBUQFjAA&usg=AFQjCNFpKA9W0jNyeWhk0n0l0Q-WxazBtg	DH: Ethics in Health Research: Principles, Structures, and Processes (2004): www.health.uct.ac.za/usr/health/research/hrec/links/Department_of_Health-Ethics_in_Health_Research_Principles_Structures_and_Processes_2004.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:	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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/regulations/2012/regr175.pdf	
Genetic Research	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za			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	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 For an overview of human subject protections in Tanzania, see: http://elearning.trree.org/mod/resource/view.php?id=41&lang=en For a more detailed discussion about clinical research regulations in Tanzania, see: http://clinregs.niaid.nih.gov/single_country.php?c_id=212				
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)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	*Drugs*			
	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003): http://www.tfda.or.tz/tfdaact.pdf		
	Devices			
	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Medical Device Act (1988)		
Tunisia				
Drugs and Devices	Ministry of Public Health, Institut Pasteur: www.pasteur.tn		Conditions of Contract and Specifications Related to Medical or Scientific Experimentation of Medicines Intended for Humans	Disposals and Director's Principles Related to Good Practices in Clinical Trials
Uganda				
For a more detailed discussion about clinical research regulations in Uganda, see: http://clinregs.niaid.nih.gov/single_country.php?c_id=223				
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 (2014): http://www.uncst.go.ug/dmdocuments/Human%20Subjects%20Protection%20Guidelines%20July%202014.pdf
Drugs and Devices	National Drug Authority: http://www.nda.or.ug/	National Drug Policy and Authority Act (CAP 206) (1993)		
Zambia				
General	Ministry of Health: http://www.moh.gov.zm/	National Health Research Act (2013)		
Zimbabwe				
General	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw	1. Medical Research 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	

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	Research Council of Zimbabwe: www.rcz.ac.zw			1. Foreign Researcher Application 2. Specimen Shipment Guidelines 3. Material Transfer Agreements
Genetic Research	National Biotechnology Authority of Zimbabwe: http://www.nba.ac.zw/	National Biotechnology Authority Act, Chapter 14:31 (2006): http://www.nba.ac.zw/index.php/our-resources/finish/1-national-biotechnology-association/2-national-biotechnolgy-authority-act		

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Spain: Iñigo de Miguel Beriain and Nuria Terribas
Sweden: Stefan Eriksson
Switzerland: Dominique Sprumont, Géraldine Marks, Songül Yavavli, Brigitte Meier
Turkey: Hamdi Akan
Ukraine: Zoryana Chernenko
United Kingdom: Clive Collett

Asia/Pacific/Middle East:
Australia: Colin Thomson
Burma: Yin Thet Nu Oo
China, People's Republic of: Yali Cong
India: Nandini Kumar
Japan: Ryuichi Ida, Shimon Tashiro, and Takashi Tsuchiya
Jordan: Henry Silverman
Korea: Seil Jang
Kyrgyzstan: Tamara Kudaibergenova
Malaysia: Teguh Haryo Sasongko
New Zealand: Lana Lon and Stewart Jessamine
Pakistan: Muhammad Arif Munir
Philippines: Ruben C. Alcaraz
Saudi Arabia: Henry Silverman
Taiwan: Hazel Chang

Latin America and the Caribbean:
Pan American Health Organization: Carla Saenz
Brazil: Janaina Sallas and Sergio Litewka
Chile: Isabel Pacheco
Colombia: Maria Consuelo
Costa Rica: Lisa M. López and Carmen Di Mare
Dominica: Liris Benjamin

Ecuador: Karina Castro and Giannella Sánchez
Grenada: Cheryl Macpherson
México: Manuel H. Ruiz de Chávez and Nadine Mascareñas
Panama: Claude Vergès
Perú: Roxana Lescano

Africa:
Egypt: Henry Silverman
Ethiopia: Hagos Biluts
Ghana: Mimi Darko and Okyere Boateng
Malawi: Lucinda Manda-Taylor
Sierra Leone: Patricia E. Powers
South Africa: Douglas Wassenaar
Uganda: Karen Hansen
Zimbabwe: Paul Ndebele