

International Compilation of Human Research Standards

2017 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 126 countries, as well as 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 at the back of the Compilation, provided updates (or confirmations of prior listings), which are reflected in the hundreds of changes entered in this Edition. Six new countries are featured in the 2017 Edition: Benin, Bermuda, Democratic Republic of the Congo, Dominican Republic, Guyana, and Senegal. The countries of the Middle East are now found in a separate section beginning on page 136.

ORGANIZATION

The Table of Contents is on pages 3-4. 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. Clinical Trial Registries
4. Research Injury
5. Privacy/Data Protection (also see Privacy International reports: <https://www.privacyinternational.org/reports>)
6. Human Biological Materials
7. Genetic (also see the HumGen International database: <http://www.humgen.umontreal.ca/int/>)
8. Embryos, Stem Cells, and Cloning

These eight categories often overlap, so it may be necessary to review the other standards to obtain an accurate 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 a 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, provincial, or local levels. Nor does the Compilation cover:

1. Enabling legislation, i.e., laws that authorize an agency to promulgate human subjects standards, but do not direct the content of those regulations.
2. Laws, regulations, or guidelines specific to research integrity, clinical bioethics, product liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, or informed consent in clinical practice.
3. Ethics codes of academic, medical, or other professional organizations – see the Ethics Codes Collection: <http://ethics.iit.edu/ecodes/about>
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				
<i>General</i>	Council for International Organizations of Medical Sciences (CIOMS): http://www.cioms.ch/			1. International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002): http://www.cioms.ch/publications/layout_guid_e2002.pdf 2. International Guidelines for Ethical Review of Epidemiological Studies (2009): http://www.ufrgs.br/bioetica/cioms2008.pdf
	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 (2011): 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): http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html
	UNAIDS: http://www.unaids.org/			1. Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials (2011): http://www.unaids.org/sites/default/files/media_asset/JC1853_GPP_Guidelines_2011_en_0.pdf 2. Ethical Considerations in Biomedical HIV Prevention Trials (2012): http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399_ethical_considerations_en.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
	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): http://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx		
	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): https://www.icrc.org/applic/ihl/ihl.nsf/7c4d08d9b287a42141256739003e636b/6fef854a3517b75ac125641e004a9e68 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		
<i>Drugs and Devices</i>	<i>Drugs</i>			
	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 (2005): http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf 2. Operational Guidance: Information Needed to Support Clinical Trials of Herbal Products (2005)
	<i>Devices</i>			
International Medical Device Regulators Forum (IMDRF): http://www.imdrf.org/			IMDRF: Statement Regarding Use of ISO 14155:2011 “Clinical Investigation of Medical Devices for Human Subjects- Good Clinical Practice” (2015): http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-150326-statement-iso141552011.pdf Archived Documents from the Global Harmonization Task Force (GHTF),	

Country	Key Organizations	Legislation	Regulations	Guidelines
				replaced by the IMDRF in 2012: 1. Reportable Events During Pre-Market Clinical Investigations (2012) 2. Clinical Evaluation (2007) 3. Clinical Evidence – Key Definitions and Concepts (2007) 4. Post-Market Clinical Follow-Up Studies (2010) 5. Clinical Investigations (2010) 6. Clinical Evidence for IVD Medical Devices (2012) 7. Scientific Validity Determination and Performance Evaluation (2012) 8. Clinical Performance Studies for IVD Medical Devices (2012) Access: http://www.imdrf.org/ghf/ghf-archived-docs.asp
	International Standards Organization: http://www.iso.org/iso/home.html			Clinical Investigation of Medical Devices for Human Subjects -- Good Clinical Practice. Standard Number 14155:2011: http://www.iso.org/iso/catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=45557
<i>Clinical Trials Registry</i>	World Health Organization – International Clinical Trials Registry Platform: http://www.who.int/ictrp/en/			Resolution WHA 58.34 (2005): http://www.wpro.who.int/health_research/policy_documents/ministerial_summit_on_health_research_may2005.pdf?ua=1
	World Medical Association: http://www.wma.net/e/			Declaration of Helsinki, Article 35 (2013): http://www.wma.net/en/30publications/10policies/b3/index.html
	International Committee of Medical Journal Editors: http://www.icmje.org/			Clinical Trial Registration: http://icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html
<i>Research Injury</i>	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

Country	Key Organizations	Legislation	Regulations	Guidelines
	Council for International Organizations of Medical Sciences: http://www.cioms.ch/			International Ethical Guidelines for Biomedical Research Involving Human Subjects, Guideline 19 (2002): http://www.cioms.ch/publications/layout_guide2002.pdf
<i>Privacy/Data Protection</i>	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
<i>Human Biological Materials</i>	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/reproductivehealth/topics/ethics/human_tissue_use.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 (2012): http://c.ymcdn.com/sites/www.isber.org/resource/resmgr/Files/ISBER_Best_Practices_3rd_Edi.pdf
<i>Genetic Research</i>	Human Genome Organization: http://www.hugo-international.org/			1. Statement on the Principled Conduct of Genetic Research (1996): http://www.eubios.info/HUGO.htm 2. Statement on DNA Sampling: Control and Access (1998): http://www.hugo-international.org/img/dna_1998.pdf 3. Statement on Gene Therapy Research (2001): http://www.hugo-international.org/img/gene_2001.pdf 4. Statement on Human Genomic Databases (2002): http://www.hugo-international.org/img/genomic_2002.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
	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 Section 16 of III Programme for 1998-1999 (1997): http://unesdoc.unesco.org/images/0011/001102/110220e.pdf#page=47 2. International Declaration on Human Genetic Data: Section 22 of Major Programme III – Social and Human Sciences (2003): http://unesdoc.unesco.org/images/0013/001331/133171e.pdf#page=45
<i>Embryos, Stem Cells, and Cloning</i>	International Society for Stem Cell Research: http://www.isscr.org/			Guidelines for the Conduct of Human Embryonic Stem Cell Research (2006): http://www.isscr.org/docs/default-source/hesc-guidelines/issrhescguidelines2006.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
NORTH AMERICA				
Canada				
Note: Several Canadian provinces and territories also have human subject research standards.				
<i>General</i>	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 2. National Defence and the Canadian Armed Forces: http://www.forces.gc.ca/en/index.page 3. Correctional Service of Canada: http://www.csc-scc.gc.ca/index-eng.shtml			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2 nd Edition (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/ National Defence and the Canadian Armed Forces: 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/politiques-et-lois/009-cd-eng.shtml
<i>Drugs and Devices</i>	<i>Drugs</i>	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 (2004): http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/e6-eng.pdf 2. Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials) (2001): http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/1024-eng.pdf	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2 nd Edition, Chapter 11: Clinical Trials (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/
	<i>Devices</i>	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	
<i>Clinical Trials Registry</i>	Health Canada Clinical Trial Database: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdonclin/index-eng.php			Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 11.3 (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-

Country	Key Organizations	Legislation	Regulations	Guidelines
				chapitre11/
<i>Research Injury</i>	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, 2 nd Edition, Article 3.2(j) (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/
<i>Privacy/Data Protection</i> Note: Each of the Canadian provinces and territories also has enacted privacy legislation.	1. Office of the Privacy Commissioner of Canada (OPC): https://www.priv.gc.ca/en 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://laws-lois.justice.gc.ca/PDF/P-21.pdf 2. Personal Information Protection and Electronic Documents Act, Articles 5 and 7 (2001): http://laws-lois.justice.gc.ca/PDF/P-8.6.pdf	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, 2 nd Edition, Chapter 5: Privacy and Confidentiality (2014): 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/documents/et_pbp_nov05_sept2005_e.pdf
<i>Human Biological Materials</i>	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, 2 nd Edition, Chapter 12: Human Biological Materials Including Materials Related to Human Reproduction (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/
<i>Genetic Research</i>	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/bgt-dpbtg/index-eng.php			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2 nd Edition, Chapter 13: Human Genetic Research (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter13-chapitre13/
<i>Embryos, Stem Cells, and Cloning</i>	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index	Assisted Human Reproduction Act (2004): http://laws-lois.justice.gc.ca/eng/acts/A-13.4/	Assisted Human Reproduction (Section 8 Consent) Regulations	PRE: Tri-Council Policy Statement: Ethical

Country	Key Organizations	Legislation	Regulations	Guidelines
			(2007): http://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-137/index.html	Conduct for Research Involving Humans, 2 nd Edition, Chapter 12, Sections E and F (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/
<p>United States</p> <p>All of the following departments and agencies subscribe to subpart A, often referred to as the Common Rule (last updated in 2009), codified in the relevant section of the Code of Federal Regulations: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html Some departments and agencies subscribe to additional subparts:</p> <ul style="list-style-type: none"> • Subpart B: Additional Protections for Pregnant Women, Human Fetuses, and Neonates (2001) • Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (1978) • Subpart D: Additional Protections for Children Involved as Subjects in Research (1991) • Subpart E: Institutional Review Board Registration Requirements (2009) 				
<i>General</i>	Agency for International Development: www.usaid.gov/		22 CFR 225, Subpart A	Protection of Human Subjects in Research Supported by USAID: A Mandatory Reference for ADS Chapter 200 (2015): https://www.usaid.gov/sites/default/files/documents/1870/200.pdf
	Central Intelligence Agency: https://www.cia.gov/index.html		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/		1. 7 CFR 1c, Subpart A 2. 45 CFR 46, Subparts B, C, and D	Protection of Human Subjects (2011): http://www.afm.ars.usda.gov/ppweb/PDF/605-1.pdf
	Department of Commerce: www.commerce.gov/		15 CFR 27	
	Department of Defense, Human and Animal RDT&E Protection Programs: http://www.acq.osd.mil/rd/hptb/programs/regulatory/	United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects	1. 32 CFR 219, Subpart A 2. DoDI 3216.02 (2011): http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf	
	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: http://science.energy.gov/ber/human-subjects/		1. 10 CFR 745 (1991), Subpart A 2. DOE Order 443.1B 3. DOE Order 481.1	

Country	Key Organizations	Legislation	Regulations	Guidelines
	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/regulations-and-policy/
	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/f oia/mgmt-directive-026-04-protection-of-human-subjects.pdf	
	Department of Housing and Urban Development: www.hud.gov/		24 CFR 60.101	
	1. Department of Justice Office of Justice Programs: http://ojp.gov/ 2. Bureau of Prisons: www.bop.gov		1. 28 CFR 22 Privacy Regulation (1976): http://www.ecfr.gov/cgi-bin/text-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/USC ODE-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: https://www.epa.gov/osa/basic-information-about-human-subjects-research-0		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	Scientific and Ethical Approaches for Observational Exposure Studies (2008): http://www.epa.gov/nerl/sots/SEAOES_doc20080707.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			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 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	
<i>Drugs and Devices</i>	<i>Drugs</i>			
	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/FederalFoodDrugandCosmeticActFDCA/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 Other: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
	<i>Devices</i>			
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/FederalFoodDrugandCosmeticActFDCA/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 Other: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm	

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Clinical Trials Registry</i>	Food and Drug Administration: http://www.fda.gov/Drugs/default.htm	1. Food and Drug Administration Modernization Act, Section 113 (1997): http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendments/totheFDCAct/FDAMA/FullTextofFDAMAlaw/default.htm 2. Food and Drug Administration Amendments Act, Section 801 (2007): https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf		ault.htm Food and Drug Administration: Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions: 2002: http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126838.pdf
	National Institutes of Health ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/home		1. Clinical Trials Regulation and Results Information Submission, 42 CFR 11 (2016): https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission 2. NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (2016): https://www.federalregister.gov/documents/2016/09/21/2016-22379/dissemination-of-nih-funded-clinical-trial-information	FAQs on ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/manage-recs/faq
	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			FAQ: http://www.research.va.gov/resources/ORD_Admin/clinical_trials/registration-faq.pdf
<i>Research Injury</i>	Same as <i>General</i> , listed above.		Sections 116(a)(6) and (7) of the Common Rule.	
	Department of Defense, Regulatory Affairs: http://www.acq.osd.mil/rd/hptb/programs/regulatory/		DoDI 3216.02 (2011): http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf	
	Department of Veterans Affairs: 1. Office of Research Oversight (ORO): www1.va.gov/oro/ 2. Office of Research and Development: www.research.va.gov	38 CFR 17.85: Treatment of Research-Related Injuries to Human Subjects: https://www.gpo.gov/fdsys/pkg/CFR-2013-title38-vol1/pdf/CFR-2013-title38-vol1-sec17-85.pdf	Handbook 1200.5, Appendix F, Paragraph 2a(11)	

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Privacy/Data Protection</i>	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): https://www.gpo.gov/fdsys/pkg/PLAW-104publ191/content-detail.html 3. Confidential Information Protection and Statistical Efficiency Act (CIPSEA) (2002): http://www.eia.gov/cipsea/cipsea.pdf 4. Health Information Technology for Economic and Clinical Health (HITECH) Act (2009): http://www.hhs.gov/hipaa/for-professionals/special-topics/HITECH-act/enforcement-interim-final-rule/index.html	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/privacy/hipaa/administrative/privacyrule/index.html 2. HIPAA Security Rule, 45 CFR parts 160, 162, and 164: http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html 3. HIPAA Breach Notification Rule, 45 CFR §§ 164.400-414: http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html	NIH: Various: http://privacyruleandresearch.nih.gov/
	Department of Homeland Security: www.dhs.gov/	Public Law 107-347: https://www.gpo.gov/fdsys/pkg/PLAW-107publ347/pdf/PLAW-107publ347.pdf		
	Social Security Administration: http://www.ssa.gov/	Privacy Act (1974): http://www.hhs.gov/foia/privacy/index.html		
<i>Human Biological Materials</i>	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 (CBER): - Office of Cellular, Tissue and Gene Therapies - Office of Blood Research and Review:			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/GuidanceDoc

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	http://www.fda.gov/BiologicsBloodVaccines/default.htm			uments/UCM071230.pdf 3. CBER-Specific: Various: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/ucm094338.htm
<i>Genetic Research</i>	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 (1993): http://www.hhs.gov/ohrp/regulations-and-policy/guidance/public-law-103-43/index.html 2. Genetic Information Nondiscrimination Act (2008): https://www.gpo.gov/fdsys/pkg/PLAW-110publ233/content-detail.html		OHRP: Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (2009): http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html NIH: NIH Guidelines for Research Involving Recombinant DNA Molecules, Appendix M (2009): http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc446948489
<i>Embryos, Stem Cells, and Cloning</i>	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: http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/UCM148113.pdf
	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

Country	Key Organizations	Legislation	Regulations	Guidelines
	National Institutes of Health: http://stemcells.nih.gov/	Research on Transplantation of Fetal Tissue. Public Law 103-43 (1993): https://history.nih.gov/research/downloads/PL103-43.pdf		<p>1. Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Executive Order 13505 (2009): https://www.whitehouse.gov/the-press-office/removing-barriers-responsible-scientific-research-involving-human-stem-cells</p> <p>2. NIH Guidelines on Human Stem Cell Research (2009): http://stemcells.nih.gov/policy/2009-guidelines.htm</p> <p>3. NIH Human Embryonic Stem Cell Registry (2016): https://grants.nih.gov/stem_cells/registry/current.htm</p> <p>Access: http://stemcells.nih.gov/</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
EUROPE				
Regionwide				
<i>General</i>	<p>European Commission: 1. European Group on Ethics in Science and New Technologies (EGE): https://ec.europa.eu/research/ege/index.cfm 2. Directorate-General for Research and Innovation: http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm</p>			<p>EGE: 1. Ethical Aspects of Clinical Research in Developing Countries (2003): http://ec.europa.eu/bepa/european-group-ethics/docs/avis17_en.pdf 2. Horizon 2020: How to Complete your Ethics Self –Assessment (2015): http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-msca-if-2015/1645175-h2020_guidance_ethics_self_assess_en.pdf</p>
	<p>Council of Europe, Bioethics Unit: http://www.coe.int/bioethics</p>			<p>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</p>
<i>Drugs and Devices</i>	<p><i>Drugs</i> European Commission: DG SANTE: Directorate-General for Health and Food Safety: http://ec.europa.eu/health/index_en.htm</p>	<p>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://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf 2. Directive 2005/28/EC Laying Down Principles and Detailed Guidelines for Good Clinical Practice as Regards Investigational Medicinal</p>		<p>EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/health/documents/eudralex/vol-10/</p>

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/eudra_lex/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://ec.europa.eu/health/files/eudra_lex/vol-1/reg_2014_536/reg_2014_536_en.pdf		
	European Medicines Agency: http://www.ema.europa.eu/		Policy on Publication of Clinical Data for Medicinal Products for Human Use (2015): 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 (2012): 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#
	<i>Devices</i>			
	DG GROWTH: Internal Market, Industry, Entrepreneurship, SMEs: https://ec.europa.eu/growth/sectors/medical-devices_en	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		Various: http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
		Devices (IVD): https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en 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://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007L0047&from=EN		
<i>Clinical Trials Registry</i>	EU Clinical Trials Register: https://www.clinicaltrialsregister.eu/			FAQs: https://www.clinicaltrialsregister.eu/doc/EU_CTR_FAQ.pdf
<i>Research Injury</i>	European Commission: DG SANTE: Directorate-General for Health and Food Safety: http://ec.europa.eu/health/index_en.htm	1. Clinical Trials Directive 2001/20/EC: http://ec.europa.eu/health/human-use/clinical-trials/directive/index_en.htm 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://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf		
	Council of Europe, Bioethics Unit: 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/

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Privacy/Data Protection</i>	European Commission: Directorate-General for Justice and Consumers: http://ec.europa.eu/justice/mission/index_en.htm	1. Data Protection Directive 95/46/EC of the European Parliament and of the Council (1995): http://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf 2. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation): http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN		2007&CL=ENG
	Council of Europe: 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/index_en.htm
<i>Human Biological Samples</i>	European Commission: European Group on Ethics in Science and New Technologies: http://ec.europa.eu/research/ege/index.cfm	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)

Country	Key Organizations	Legislation	Regulations	Guidelines
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics			<p>1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG</p> <p>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=FFA C75</p>
<i>Genetic Research</i>	European Medicines Agency: http://www.ema.europa.eu/	Regulation (EC) No. 1394/2007 on Advanced Therapy Medicinal Products and Amending Directive 2001/83/EC and Regulation (EC) No. 726/2004: http://ec.europa.eu/health/files/eudralex/vol-1/reg_2007_1394/reg_2007_1394_en.pdf		Various: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000294.jsp
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics			<p>1. Recommendation No. R (92) on Genetic Testing and Screening for Health Care Purposes (1992): http://wcd.coe.int/ViewDoc.jsp?id=612007&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFA C75</p> <p>2. 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</p> <p>3. 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</p> <p>4. Recommendation Rec (2006)4 of the Committee of Ministers to Members States on Research on Biological</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
				Materials of Human Origin (2006): http://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75
<i>Embryos, Stem Cells, and Cloning</i>	European Commission: European Group on Ethics in Science and New Technologies: http://ec.europa.eu/research/ege/index.cfm	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. Commission Staff Working Paper Report on Human Embryonic Stem Cell Research (2003): https://ec.europa.eu/research/press/2003/pdf/se_c2003-441report_en.pdf 2. Opinion No. 22 - The Ethics Review of hESC FP7 Research Projects (2007): http://bookshop.europa.eu/ga/recommendations-on-the-ethical-review-of-hesc-fp7-research-projects-pbKAAJ07022/downloads/KA-AJ-07-022-EN-C/KAJ07022ENC_002.pdf;pgid=y8dIS7GUWMdSR0EAIMEUUsWb0000dz-kvfzb;sid=lexx3tq0IOFxyokBvtfvebiRJj93DZfXP54=?FileName=KAAJ07022ENC_002.pdf&SKU=KAAJ07022ENC_PDF&CatalogueNumber=KA-AJ-07-022-EN-C
	Council of Europe, Bioethics Unit: 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=9/15/2008&CL=ENG 2. Additional Protocol on Prohibition of Human Cloning, ETS No. 168 (1998): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=168&CM=7&DF=9/15/2008&CL=ENG
<p>Armenia</p> <p>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</p> <p>Note: All websites and documents are in Armenian.</p>				
<i>Drugs and Devices</i>	1. Drug and Medical Technology Agency: 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: http://www.arlis.am/DocumentView.aspx?DocID=71619 2. Resolution of the Government of Armenia of January 24, 2002: Procedure for Clinical Trials of		

Country	Key Organizations	Legislation	Regulations	Guidelines
		New Medications in Armenia: http://www.arlis.am/DocumentView.aspx?docID=9154		
<i>Human Biological Materials</i>	Ethical Committee of the National Center for AIDS Prevention: http://www.arm aids.am/main/index.php?lng=1	RA Law on Prevention of Disease Caused by HIV (2012): http://www.arlis.am/DocumentView.aspx?DocID=78616		Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2013)
Austria				
For an overview of human subject protections in Austria, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPR eportFiles/Austria%20definitive.pdf				
<i>General</i>	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/Er v/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	Bioethics Commission: 1. Codification of Legislation on Medical Research (2011) 2. Research on Persons without the Capacity to Consent (2013) Access: http://www.bundeskanzleramt.at/site/4070/default.aspx
<i>Drugs and Devices</i>	<i>Drugs</i>	1. Ministry of Health (German): http://www.bmg.gv.at 2. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/en/ages-austrian-agency-for-health-and-food-safety/ 3. Austrian Federal Office for Safety in Health Care: http://www.basg.gv.at/en/basg-austrian-federal-office-for-safety-in-health-care/	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/
	<i>Devices</i>	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/
<i>Research Injury</i>	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		

Country	Key Organizations	Legislation	Regulations	Guidelines
		&Gesetzesnummer=10011003&ShowPrintPreview=True		
<i>Privacy/Data Protection</i> Note: The Austrian states also have privacy/data protection laws	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		
<i>Human Biological Materials</i>	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) 2. Biobanks for Medical Research - Amendments to the Bioethics Commission Report of May 2007 (2011) Access: http://www.bundeskanzleramt.at/site/4070/default.aspx
<i>Genetic Research</i>	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		
<i>Embryos, Stem Cells, and Cloning</i>	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: 1. Stem Cell Research in the Context of the EU's Sixth Framework Programme Research (2002) 2. 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				
<i>General</i>	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,	MOH: 1. Ordinance No. 274 on Establishing the National Bioethics Committee (2006) 2. Decree No. No. 55 on Ethics Committees (2008) (Russian):	MOH: 1. Code of Medical Ethics (1999) (Russian): http://www.levonevski.net/pravo/norm2009/nm37/d37726.html 2. Guidelines for Ethics Committees on

Country	Key Organizations	Legislation	Regulations	Guidelines
		Articles 40, 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	http://www.levonevski.net/pravo/norm2009/num05/d05639.html	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)
<i>Drugs and Devices</i>	<i>Drugs</i>	<p>1. Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435</p> <p>2. Law on Drugs, Articles 15,16 (2009) (Russian): http://pravo.by/webnpa/text.asp?RN=h10600161</p>	<p>MOH:</p> <p>1. Ordinance No. 254 on Clinical Drug Trials and Good Clinical Practice (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num36/d36922/index.html</p> <p>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</p> <p>3. Decree No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html</p> <p>4. Decree No. 50 on Certain Aspects of Clinical Drug Trials (2009)</p>	<p>MOH:</p> <p>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</p>
	<i>Devices</i>	<p>Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435</p>	<p>MOH:</p> <p>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</p> <p>2. Decree No. 216 on Certain Aspects of Clinical Trials of Medical Devices (2008) (Russian): http://86.57.250.247/data/pravo/ipb_p</p>	<p>MOH:</p> <p>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</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
			rikazmz/N216_2008.htm	
<i>Privacy/Data Protection</i>	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		
<i>Human Biological Materials</i>	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. National Bioethics Committee 3. 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_p_rikaznew/N111_1993(1994).doc SSFM: Ordinance No. 38-c on Rules for Conducting Morphological Examinations (1999)	
Belgium				
For an overview of human subject protections in Belgium, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Belgium%20definitive.pdf				
<i>General</i>	Belgium Advisory Committee on Bioethics (BACB): http://www.health.belgium.be/en	Law Relating to Experimentation on Humans (2004): http://www.erasme.ulb.ac.be/page.asp?id=11365&langue=EN		BACB: 1. Opinion No. 13: Regarding Experimentation on Man (2001) 2. Opinion No. 31: Regarding Experimentation Involving Pregnant and Breastfeeding Women (2004) 3. Opinion 36: Ethical Evaluation of Research in Certain Areas of the Humanities (French and Dutch) (2006) 4. Opinion No. 40: Scope of the Law Relating to Experimentation on Humans (French and Dutch) (2007) 5. Opinion No. 51: Publication of the Results of Human Experimentation (2012) Access: http://www.health.belgium.be/en/belgian-advisory-committee-bioethics

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Drugs and Devices</i>	Medicines Directorate-General: http://www.health.belgium.be/eportal		<ol style="list-style-type: none"> 1. Royal Decree of September 27, 1994 2. Royal Decree of June 30, 2004 Determining the Implementation Measures of the Law 3. Royal Decree of June 30, 2004 Modifying the Royal Decree of June 6, 1960 4. Royal Decree of July 15, 2004 Determining Payments for Ethical Opinions or Authorization for the Conduct of a Clinical Trial or Experiment 5. Application of the Law of May 7, 2004 Relating to Experiments on Human Volunteers who Participate in Phase I Trials (2004) 6. Explanations Concerning the Submission of a Request for an Ethical Opinion or Authorization for the Conduct of a Clinical Trial (2004) 	
<i>Research Injury</i>		Law Relating to Experimentation on Humans, Chapter XVII (Responsibility and Insurance) Article 29 (2004)		
<i>Privacy/Data Protection</i>	Commission for the Protection of Privacy: http://www.privacycommission.be/	Privacy Act: http://www.privacycommission.be/en/privacy-act	Decree of February 13, 2001 Implementing the Law of December 8, 1999: http://www.privacycommission.be/sites/privacycommission/files/documents/Royal_Decree_2001.pdf	
<i>Human Biological Materials</i>	<ol style="list-style-type: none"> 1. Belgian Advisory Committee on Bioethics: http://www.health.belgium.be/en 2. Superior Health Council (CSS): http://www.health.belgium.be/eportal/Aboutus/relatedinstitutions/SuperiorHealthCouncil/index.htm 3. Federal Public Service: www.health.fgov.be 	<ol style="list-style-type: none"> 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 		<p>Belgian Advisory Committee on Bioethics: Opinion No. 54: Post Mortem Removal of Human Body Material for Human Medical Applications or for Scientific Research Purposes (2012): http://www.health.belgium.be/en/opinion-no-54-post-mortem-removal-human-body-material-human-medical-applications-or-scientific</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
		Transplantation of Organs (2006) 4. 2007 Amendment		CSS: Various: http://www.health.belgium.be/eportal/Aboutus/relatedinstitutions/SuperiorHealthCouncil/domains/cellstissuesorgans/index.htm#_Viobr88XQ0U
<i>Embryos, Stem Cells, and Cloning</i>	1. Federal Public Service: www.health.fgov.be 2. Federal Commission for Medical and Scientific Research on Embryos in Vitro: 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		Belgian Advisory Committee on Bioethics: Opinion No. 52: Use of Human Tissues and Cells in Reproductive Medicine (2012): http://www.health.belgium.be/en/opinion-no-52-use-human-tissues-and-cells-reproductive-medicine
Bosnia and Herzegovina Note: All websites and documents are in Bosnian.				
<i>General</i>		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) 3. Law on Health Protection, MoH Republic of Srpska (2015): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20zdravstvenoj%20zastiti%20sa%20izmjename%20106-99%20%2044-15.pdf 4. Law on Health Protection, MoH Federation of Bosnia and Herzegovina, No 46/10: http://www.fmoh.gov.ba/index.php/		

Country	Key Organizations	Legislation	Regulations	Guidelines
		zakoni-i-strategije/zakoni/zakon-o-zdravstvenoj-zastiti		
Drugs and Devices	<i>Federation of Bosnia and Herzegovina</i>			
	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 3. Law on Drugs Federation of Bosnia and Herzegovina, No 109/2012: http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-lijekovima-fbih	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	
Drugs and Devices	<i>Republic of Srpska</i>			
	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	<i>Federation of Bosnia and Herzegovina</i>			
	Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Medicinal Products and Medicinal Devices Act, Articles 52 and 116 2. Law on Health Insurance of the Federation of Bosnia and Herzegovina, Official Gazette No. 46/10	Regulation about Clinical Testing of IMP and Medical Devices, 4/10: http://www.almbih.gov.ba/doc/regulative/pravilnik_klinicka_bos.pdf	
	<i>Republic of Srpska</i>			
	Ministry of Health and Social Welfare (Bosnian):	1. Medicinal Products and Medicinal Devices Act, Article	Regulation about Clinical Testing of IMP and Medical Devices,	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx	52 and 116 2. Law on Health Insurance of the Republic of Srpska, Official Gazette Republic of Srpska No. 106/09: http://www.farmaceutska-komora.org/images/stories/5Zakon_o_zdravstvenoj_zastiti.pdf	4/10: http://www.almbih.gov.ba/doc/regulative/pravilnik_klinicka_bos.pdf	
<i>Privacy/Data Protection</i>	Personal Data Protection Agency of Bosnia and Herzegovina: http://www.azlp.gov.ba/Default.aspx?lang=Tag=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	Regulation about Personal Data Collection and Form of Records (2009): http://www.azlp.gov.ba/images/PropisiBOS/Pravilnik_vodjenje_i_obrazac_BOS.pdf	
<i>Embryos, Stem Cells and Cloning</i>	<i>Federation of Bosnia and Herzegovina</i>			
	Ministry of Health: http://www.fmoh.gov.ba/	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		
	<i>Republic of Srpska</i>			
	Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx	1. Law on Transplantation of Organs (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20transplantaciji%20judskih%20organa.pdf 2. Law on Transplantation of human tissues and cells (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Doc		Rulebook about Testing Procedure for Donor of Transplant Organs in Terms of Diseases Which can be Transmitted by Transplantation (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/%d0%9f%d1%80%d0%b0%d0%b2%d0%b8%d0%bb%d0%bd%d0%b8%d0%ba_%d0%be_%d0%ba%d1%80%d0%b8%d1%82%d0%b5%d1%80%d0%b8%d1%98%d1%83%d0%bc%d0%

Country	Key Organizations	Legislation	Regulations	Guidelines
		uments/Zakon%20o%20transplanta ciji%20Ijudskih%20tkiva%20i%20c elija.pdf		b8%d0%bc%d0%b0_%d0%b7%d0%b0_%d1 %82%d0%b5%d1%81%d1%82%d0%b8%d1 %80%d0%b0%d1%9a%d0%b5_%d0%b4%d0 %b0%d0%b2%d0%b0%d0%bb%d0%b0%d1 %86%d0%b0_%d1%99%d1%83%d0%b4%d1 %81%d0%ba%d0%b8%d1%85_%d0%bc%d1 %80%d0%b3%d0%b0%d0%bd%d0%b0_64_1 0.pdf
Bulgaria				
<i>General</i>	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	1. Constitution of the Republic of Bulgaria, Amendment SG. 18/25, Article 29 (2015) (Bulgarian): http://www.government.bg/cgi-bin/e-cms/vis/vis.pl?p=0159&n=000007 2. Oviedo Convention on Human Rights and Biomedicine (2003) 3. Law Ratifying the Additional Protocol on Biomedical Research (2006) (Bulgarian): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsija-zashtita-pravata-na_choveka_29-08-2006.pdf 4. Healthcare Act, Articles 197 and 206 (2013) 5. Law on Medicinal Products in Human Medicine (2015): http://en.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf		
<i>Drugs and Devices</i>	<i>Drugs</i>			
	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 (2015): http://en.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf	Regulation No. 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice (2012) (Bulgarian): http://www.bda.bg/images/stories/documents/regulations/naredbi/naredba31.pdf	
	<i>Devices</i>			
	Bulgarian Drug Agency (BDA) (Bulgarian): http://en.bda.bg/	Medical Devices Act (2016): http://www.bda.bg/images/stories/documents/regulations/zakoni/ZMI_2	Ordinance No. 10 of 2008 on the Documents Required from the Principal/Coordinating	Various: http://www.bda.bg/index.php?option=com_content&view=category&layout=blog&id=60&Itemid=

Country	Key Organizations	Legislation	Regulations	Guidelines
		0160308.pdf	Investigator or Sponsor for Obtaining an Ethics Committee Statement and on the Procedure for Safety Monitoring of Medical Devices During Clinical Investigations and Assessment of the Clinical Data Collected During such Investigations: http://en.bda.bg/images/stories/documents/legal_acts/Ordinance_Clinical_investigations_MD_EN.pdf	mid=117&lang=en
<i>Research Injury</i>	Bulgarian Drug Agency (BDA): http://en.bda.bg/	Medicinal Products in Human Medicine Act, 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) (Bulgarian): http://www.bda.bg/images/stories/documents/regulations/naredbi/naredba31.pdf	
<i>Privacy/Data Protection</i>	1. Bulgarian Commission for Personal Data Protection: https://www.cdpd.bg/en/index.php?p=rubric&aid=2 2. Ombudsman: www.ombudsman.bg	Law for Protection of Personal Data (2013): https://www.cdpd.bg/en/index.php?p=element&aid=373		
<i>Human Biological Materials:</i>	1. Executive Agency for Transplantation (Bulgarian): http://bgtransplant.bg/ 2. Council of Ministers, Ethics Committee for Transplantation	1. Law on Transplantation of Organs, Tissues, and Cells (2013) (Bulgarian): http://bgtransplant.bg/iat/regulations.php 2. Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006) (Bulgarian): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifikatsiya-protokol-konventsia-zashtita-pravata-na-choveka-29-08-2006.pdf	Regulation No. 13 of 4 April 2007 for the Terms and Conditions of Informing Bulgarian Citizens on the Activities regarding the Transplantation of Organs, Tissues and Cells	
<i>Embryos, Stem Cells, and Cloning</i>	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	1. Law on Transplantation of Organs, Tissues, and Cells (2013) (Bulgarian): http://bgtransplant.bg/iat/regulations.php		

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006) (Bulgarian): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifikatsiya-protokol-konventsija-zashtita-pravata-na_choveka_29-08-2006.pdf		
Croatia Note: All websites and documents are in Croatian. For an overview of human subject protections standards in Croatia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Croatia%20definitive%20Updated.pdf				
<i>General</i>		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. Patient Protection Act, Article 20 (2008): http://www.zakon.hr/z/255/Zakon-o-za%C5%A1titi-prava-pacijenata		
<i>Drugs and Devices</i>	<i>Drugs</i>			
	1. Ministry of Health (MZSS): http://www.zdravlje.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.almp.hr/#	1. Medicinal Product Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html 2. Rule Book on Amendments to Medicinal Product Act (2014): http://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html	MZSS: Ordinance on Clinical Trials and Good Clinical Practice (2015): http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html	
	<i>Devices</i>			
	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		

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Research Injury</i>	1. Agency for Medicinal Products and Medical Devices of Croatia: http://www.almp.hr/ 2. Ministry of Health: http://www.zdravlje.hr/ 3. Croatian Health Insurance Fund: http://www.hzzo.hr/en/	1. Law on Mandatory Health Insurance (2013): http://www.hzzo.hr/wp-content/uploads/2013/10/ZOZO_PR_OCISCENI_TEKSTv2.pdf?6d8ad4 2. Medicinal Product Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html 3. Rule Book on Amendments to Medicinal Product Act (2014): http://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html	Ordinance on Clinical Trials and Good Clinical Practice, Articles 11 and 16, Act 5.8., 6.8. and 8.2.5 (2015): http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html	
<i>Privacy/Data Protection</i>	Croatian Personal Data Protection Agency: http://www.azop.hr/	1. Personal Data Protection Act (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_09_106_2300.html 2. Law about the Right to Access Personal Information (2015): http://www.zakon.hr/z/126/Zakon-o-pravu-na-pristup-informacijama		
<i>Human Biological Materials</i>	Ministry of Health: http://www.zdravlje.hr/	1. Law about Blood and Blood Products (2006): http://narodne-novine.nn.hr/clanci/sluzbeni/2006_07_79_1916.html 2. Rule Book on Amendments to Law about Blood and Blood Products (2011): http://narodne-novine.nn.hr/clanci/sluzbeni/2011_11_124_2476.html 3. Law on the Implementation of Human Tissues and Cells (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3070.html 4. Law on Transplantation of Human Organs for the Purpose of Treatment: http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3071.html	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	
<i>Embryos, Stem Cells, and Cloning</i>	Ministry of Health: http://www.zdravlje.hr/	1. Additional Protocol to the Convention for the Protection of	Ordinance on the Conditions of Space, Professional Workers,	

Country	Key Organizations	Legislation	Regulations	Guidelines
		<p>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</p> <p>2. Medical Fertilization Act, Article 32: (2012): http://www.hzzo-net.hr/dload/zakoni/20_01.pdf</p> <p>3. Law on the Implementation of Human Tissues and Cells (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_1_2_144_3070.html</p>	<p>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</p>	
<p>Cyprus</p>				
<p>For an overview of human subject protections in Cyprus, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Cyprus%20definitive%20Updated.pdf</p>				
<i>General</i>		<p>1. Law No. 31 (III)/2001: Oviedo Convention on Human Rights and Biomedicine</p> <p>2. The Safeguarding and Protection of Patients' Rights Law (2004): http://www.bioethics.gov.cy/Moh/cnbc/cnbc.nsf/All/745717D26F068582C2257CCA003B350F/\$file/Patients%20Rights%20Law-English%20translation.pdf</p>		
<i>Drugs and Devices</i>	<p>1. Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/Moh/phs/phs.nsf/dmlindex_en/dmlindex_en?opendocument</p> <p>2. Ministry of Health, National Bioethics Committee: http://www.bioethics.gov.cy/moh/cnbc/cnbc.nsf/index_en/index_en?OpenDocument</p>	<p>Law for Good Clinical Practice (2004)</p>		
<i>Research Injury</i>	<p>Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/moh/moh.nsf/ind</p>	<p>Legislation Concerning Medicinal Products of Human Use (Good Clinical Practice)</p>		

Country	Key Organizations	Legislation	Regulations	Guidelines
	ex_en/index_en?OpenDocument	No. 452/2004, Regulation No. 11 (8)		
<i>Privacy/Data Protection</i>	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. 2003 Amendments: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/\$FILE/37(I)-2003_en.pdf		
<i>Embryos, Stem Cells, and Cloning</i>		Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002)		
Czech Republic				
For an overview of human subject protections in the Czech Republic, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRreportFiles/Czech%20definitive%20Updated.pdf				
<i>General</i>	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		
<i>Drugs and Devices</i>	<i>Drugs</i> 1. Ministry of Health (MOH) (Czech): http://www.mzcr.cz 2. State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lred=1	Act No. 378/2007 Collection on Pharmaceuticals	MOH: Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products	SUKL: Various: http://www.sukl.cz/medicinal-products-clinical-trials-guidelines-1

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	<i>Devices</i> State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lred=1	1. Act No 268/2014 Coll., on Medical Devices and on Amendment to Act. 634/2004 Coll., on Administrative Fees 2. Decree No 62/2015 Coll. Implementing Certain Provisions of the Act on Medical Devices	Various: http://www.sukl.cz/medical-devices?highlightWords=501%2F2000	Various: http://www.sukl.cz/medical-devices-guidelines
<i>Research Injury</i>		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		
<i>Privacy/Data Protection</i>	Office for Personal Data Protection: http://www.uoou.cz/uoou.aspx	Act No. 101/2000 Coll., On Protection of Personal Data and Amending Certain Laws, As Amended (2015) (Czech): 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	
<i>Embryos, Stem Cells, and Cloning</i>	1. Ministry of Education, Youth, and Sport: http://www.msmt.cz/index.php?lchan=1&lred=1 2. Research and Development Council, Bioethical Commission: http://www.vyzkum.cz/FrontClanek.aspx?idsekce=15908	Act of 26 April 2006 on Research on Human Embryonic Stem Cells No. 227/2006 Sb. (Coll.)		
Denmark				
For an overview of human subject protections in Denmark, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Denmark%20definitive.pdf				
<i>General</i>	National Committee on Health Research Ethics (NVK): http://dnvk.dk/CVK/Home/English.aspx	Act on Research Ethics Review of Health Research Projects (2011): http://www.dnvk.dk/English/actona_biomedicalresearch.aspx	Executive Order No. 710 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects (2004) (Danish): http://www.dnvk.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.dnvk.dk/English/guidelinesaboutnotification.aspx
<i>Drugs and Devices</i>	Danish Medicines Agency: http://www.dkma.dk	1. Medicinal Product Act No. 506 (2013) 2. Act on Clinical trials on Medical Products No. 620 (2016)	1. Executive Order on Clinical Trials on Medicinal Products, Human Use (2004) 2. Executive Order No. 710 on Informed Consent from Patients	

Country	Key Organizations	Legislation	Regulations	Guidelines
			in Biomedical Trials (2016) 3. Danish Guideline on Notification of Clinical Trials of Medicinal Products in Humans (2016)	
<i>Research Injury</i>	Patient Compensation Association: http://patienterstatningen.dk/en.aspx	1. Liability for Damages Act (2007): http://patienterstatningen.dk/Patient skader/Love-og-regler/Lov-om-klage-og-erstatningsadgang/Behandlingsskader 2. Danish Act on the Right to Complain and Receive Compensation within the Health Service No. 904 (2013): http://patienterstatningen.dk/Patient skader/Love-og-regler/Lov-om-klage-og-erstatningsadgang/Laegemiddelskader		
<i>Privacy/Data Protection</i>	Danish Data Protection Agency (DPA): http://www.datatilsynet.dk/english/	Act on Processing of Personal Data (Act No. 429) (2007): http://www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/	Executive Order on Health Law, No. 1188, Chapter 9 (2016)	DCE: Protection of Sensitive Personal Information
<i>Human Biological Materials</i>	National Committee on Health Research Ethics: http://www.dnvk.dk/CVK/Home/English.aspx	1. Health Law (2014) 2: Act on Processing of Personal Data (31.5.200) http://www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/ 3. Act on Research Ethics Review of Health Research Projects (2011): http://www.dnvk.dk/English/actona biomedicalresearch.aspx	Executive Order on Health Law, No. 1188 (2016)	
<i>Genetic Research</i>	National Committee on Health Research Ethics: http://www.dnvk.dk/CVK/Home/English.aspx	Act on Research Ethics Review of Health Research Projects: http://www.dnvk.dk/English/actona biomedicalresearch.aspx		Guidelines on Health Research Projects Involving Genome Research (Danish): http://www.dnvk.dk/~media/Files/cvk/forskere/Hvordan%20soeger%20jeg/Retningslinjer%20genom%20Version%205%20DOR10040S.aspx

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Embryos, Stem Cells, and Cloning</i>	Danish Council of Ethics: http://www.etiskraad.dk/da-DK.aspx?sc_lang=en	Act on Danish Council of Ethics No. 440 (2004)	Executive Order on Medically Assisted Procreation No. 93 (2015)	
Estonia				
For an overview of human subject protections in Estonia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Estonia%20definitive.pdf				
<i>General</i>	Estonian Council on Bioethics: http://www.eetikakeskus.ut.ee/en	1. Oviedo Convention on Human Rights and Biomedicine (2002) 2. Constitution of the Republic of Estonia, Paragraph 18 (2016): https://www.riigiteataja.ee/en/eli/521052015001/consolide		Code of Ethics of Estonian Scientists: http://www.akadeemia.ee/repository/File/ALUSDOKUD/Code-ethics.pdf
<i>Drugs and Devices</i>	<i>Drugs:</i> 1. State Agency of Medicines: http://www.sam.ee/en/clinical-trials-medical-products-estonia 2. Minister of Social Affairs (MSA): https://www.sm.ee/en	Medicinal Products Act, Chapter 5 (2015): https://www.riigiteataja.ee/en/eli/ee/525112013005/consolide/current	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): https://firstclinical.com/regdocs/doc/?db=INT_Estonia_Regulation_23	
	<i>Devices:</i> Estonian Health Board: http://www.terviseamet.ee/en/medical-devices.html			Same as above.
<i>Research Injury</i>	1. Minister of Social Affairs (MSA): https://www.sm.ee/en 2. Estonian Health Insurance Fund: https://www.haigekassa.ee/en	Medicinal Products Act, Section 90: https://www.riigiteataja.ee/en/eli/ee/525112013005/consolide/current	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-medical-products-estonia	
<i>Privacy/Data Protection</i>	Estonian Data Protection Inspectorate: http://www.aki.ee/en/inspectorate	Personal Data Protection Act (2016): https://www.riigiteataja.ee/en/eli/ee/512112013011/consolide/current		
<i>Genetic Research</i>		Human Genes Research Act (RT I 2000, 104, 685) (2014):		

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Embryos, Stem Cells, and Cloning</i>		https://www.riigiteataja.ee/en/eli/ee/518062014005/consolide 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) (Estonian): 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/ee/530102013057/consolide/current		
Finland				
For an overview of human subject protections in Finland, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Finland%20definitive%20Updated.pdf				
<i>General</i>	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	Medical Research Act No. 488/1999 (Amended 295/2004, 794/2010, and 143/2015): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488	1. Decree on the National Research Ethics Council of Finland No. 1347/2002 2. Decree on Medical Research Nos. 986/1999, 313/2004, and 65/2016 3. Decree on the National Committee on Medical Research Ethics No. 820/2010 4. Decree on Fees, No. 1168/2014	TUKIJA: 1. Report on Children in Medical Research (2003) 2. Report on Ethical Evaluation of Research in Finland (2006) 3. Operating Procedures of the National Committee on Medical Research Ethics (2016) Access: http://tukija.fi/en/publications1
<i>Drugs and Devices</i>	<i>Drugs</i>	Medicines Act No. 395/1987 (Finnish): http://www.finlex.fi/fi/laki/smur/1987/19870395	1. Decree on Clinical Trials on Medicinal Products No. 841/2010 2. Other Decrees: http://www.finlex.fi/fi/laki/smur/1987/19870395#nojalla FIMEA: 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	TUKIJA: 1. Consent to Participate in the Clinical Trial 2. Templates for Clinical Trial Information Leaflet and Consent Form (2016) Access: http://tukija.fi/en/publications1

Country	Key Organizations	Legislation	Regulations	Guidelines
	<p><i>Devices</i></p> <p>National Supervisory Authority for Welfare and Health (VALVIRA): http://www.valvira.fi/en/licensing/medical_devices</p>	<p>Medical Devices Act No. 629/2010 (Finnish): http://www.finlex.fi/fi/laki/kokoelma/2010/20100085.pdf</p>	<p>1. Decree (Decision) on Clinical Investigations (2010) (Finnish): http://www.finlex.fi/data/normit/39644-maarays_3_2010_kliininen_laitetutkimus.pdf 2. Various: http://www.valvira.fi/en/licensing/medical_devices/legislation</p>	
<i>Research Injury</i>	<p>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/</p>	<p>Patient Injuries Act No. 585/1986 (Finnish): http://www.finlex.fi/fi/laki/ajantasa/1986/19860585</p>		<p>Pharmaceutical Injuries Insurance: General Terms and Conditions (2016): http://www.laakevahinko.fi/in-english/terms-and-conditions/</p>
<i>Privacy/Data Protection</i>	<p>Office of the Data Protection Ombudsman: http://www.tietosuoja.fi/1560.htm</p>	<p>Personal Data Act No. 523/1999 (Finnish): http://www.finlex.fi/fi/laki/ajantasa/1999/19990523</p>		
<i>Human Biological Materials</i>	<p>National Supervisory Authority for Welfare and Health: http://www.valvira.fi/web/en</p>	<p>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</p>	<p>1. Decree on Consent for Biobank No. 643/2013 (Finnish and Swedish): http://www.finlex.fi/fi/laki/alkup/2013/20130643 2. Decree on information on Biobank No. 649/2013 (Finnish and Swedish): http://www.finlex.fi/fi/laki/alkup/2013/20130649</p>	
<i>Genetic Research</i>	<p>1. National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en 2. Board for Gene Technology http://www.geeniteknikanlautakunta.fi/en</p>	<p>1. Medical Research Act No. 488/1999 (Amended 295/2004 and 794/2010): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488 2. Gene Technology Act No. 377/1995: https://www.finlex.fi/fi/laki/ajantasa/1995/19950377</p>		
<i>Embryos, Stem Cells, and Cloning</i>	<p>1. National Supervisory Authority for Welfare and Health: http://www.valvira.fi/web/en 2. National Committee on Medical Research Ethics (TUKIJA) http://www.tukija.fi/en</p>	<p>1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)</p>		<p>TUKIJA: Report on Stem Cells, Cloning, and Research (2005): http://tukija.fi/documents/1481661/1546647/2005cells.pdf/c14b7dd0-11b4-428d-bdae-539566ade614</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
	3. National Advisory Board on Research Ethics (TENK): http://www.tenk.fi/en/index.html 4. National Advisory Board on Social Welfare and Health Care Ethics (ETENE): http://www.etene.fi/en	2. Medical Research Act No. 488/1999 (amended 295/2004, 749/2010, and 143/2015): 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		

France				
For an overview of human subject protections in France, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/France%20definitive%20Updated.pdf				
<i>General</i>	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/en/type_publication/avis
<i>Drugs and Devices</i>	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/	Decision on Good Clinical Practices: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT00000819256	CCNE: 1. Phase I Trials in Cancer (2002) 2. Transposition into French Law of the European Directive Relating to Clinical Trials on Medicinal Products: A New Ethical Framework for Human Research (2003)
<i>Privacy/Data Protection</i>	1. National Commission of Information and Liberty (CNIL): http://www.cnil.fr/english/ 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr	Law 2004-801 of August 6, 2004 Modifying Law 78-17 of January 6, 1978 Relating to the Protection of Data Subjects as Regards the Processing of Personal Data	CNIL: Decree No. 2005-1309 of 20 October 2005 Enacted for the Application of Act No. 78-17 of 6 January 1978 on Data Processing, Files and Individual Liberties (Amended by Decree 2007-451 of 25 March 2007): http://www.cnil.fr/fileadmin/documents/en/Decree%202005-1309.pdf	CCNE: 1. Ethical Questions Arising from the Transmission of Scientific Information Concerning Research in Biology and Medicine (1995) 2. Biometrics, Identifying Data and Human Rights (2007)
<i>Human Biological Materials</i>	National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): 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/		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,”

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Public Health Code Articles L1241-1 and following sections: (2010) (French): http://www.legifrance.gouv.fr/initRechCodeArticle.do		“Biolibraries” (2003)
<i>Genetic Research</i>	National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr	Civil Code Articles 16-10 to 16-13 (French): http://www.legifrance.gouv.fr/affichCode.do?sessionId=D2DE023194483D3384DE19DE8959BDDA.tpdjo17v_3?idSectionTA=LEGISCTA000006136513&cidTexte=LEGITEXT000006070721&dateTexte=20131006		Various: http://www.ccne-ethique.fr/en/type_publication/avis
<i>Embryos, Stem Cells, and Cloning</i>	National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): 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	Decree N° 2015-155 of 11 February, 2015 Public Health Code on Research on Embryos Article R2151-1 and Following Sections: http://legifrance.gouv.fr/affichCode.do?idArticle=LEGIARTI000030233469&idSectionTA=LEGISCTA000006190409&cidTexte=LEGITEXT000006072665&dateTexte=20151015	1. Commercialization of Human Stem Cells and Other Cell Lines (2006) 2. Opinion on the Ethical Reflection Concerning Research on Human Embryonic Cells and on Human Embryos in Vitro (2010) Access: http://www.ccne-ethique.fr/en/type_publication/avis
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				
<i>General</i>	Bioethics and Health Law Studies Society: http://www.patientsrights.ge/index.php?page=385&lang=geo	1. Law on Health Care, Chapter XIX (1997) (Georgian): http://rama.moh.gov.ge/res/docs/janmrtebobis.pdf 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)		
<i>Drugs and Devices</i>	State Regulation Agency for Medical Activities (LEPL) of the Ministry of Labor, Health, and Social Affairs: http://www.moh.gov.ge/index.php?sec_id=10&lang_id=ENG	1. Drug and Pharmacy Law No. 659 (1997) (Georgian): http://rama.moh.gov.ge/res/docs/wamali.pdf 2. Licenses and Approvals Law (2005)	Regulation about the Rules and Conditions of Issuing of the Approval of Clinical Trials Approved #176 (2005) (Georgian): http://rama.moh.gov.ge/res/docs/2016	Order of Health Minister about Implementation of “ICH: E6 Good Clinical Practice: Consolidated Guidance” (1996) including WMA: Declaration of Helsinki (2010) (Georgian): http://rama.moh.gov.ge/res/docs/9539N233.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Law of Medicines and Pharmaceutical Activity (2009) (Georgian): http://rama.moh.gov.ge/res/docs/wa_mali.pdf	0809105943176.pdf	
<i>Research Injury</i>		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
<i>Privacy/Data Protection</i>	Office of the Personal Data Protection Inspector: https://personaldata.ge/en/data-protection-day-event-2014/177	Law on Data Protection (2014): https://personaldata.ge/manage/res/docs/unofficial%20translations/PDP%20LAW%20ENG%20%20-.pdf		
<i>Embryos, Stem Cells, and Cloning</i>		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 the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Germany%20definitive%20Updated.pdf				
<i>General</i>	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: http://www.ethikrat.org/?set_language=en 5. Federal Ministry of Health: http://www.bmg.bund.de/ministerium/english-version.html			BÄK: (Model) Professional Code for Physicians in Germany, Article 15 (2011) (German): http://www.bundesaerztekammer.de/downloads/MBOen2012.pdf
<i>Drugs and Devices</i>	<i>Drugs</i> 1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_no_de.html 2. Federal Ministry of Education and Research (BMBF):	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	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

Country	Key Organizations	Legislation	Regulations	Guidelines
	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		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/gcpv/gesamt.pdf BMBF: Principles and Responsibilities When Carrying Out Clinical Studies (2013) (German): http://www.gesundheitsforschung-bmbf.de/media/Grundsaeetze_und_Verantwortlichkeiten_20130424.pdf	
	<i>Devices</i>			
	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	
<i>Clinical Trials Registry</i>	German Clinical Trials Register: https://drks-neu.uniklinik-freiburg.de/drks_web/			FAQs: https://drks-neu.uniklinik-freiburg.de/drks_web/navigate.do?navigationId=faq&messageDE=FAQ&messageEN=FAQ
<i>Research Injury</i>		Medicinal Products Act, Sections Section 40, Sub-section 3 (2014): http://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p0917		
<i>Privacy/Data Protection</i>	Federal Commissioner for Data Protection and Freedom of Information (German): http://www.bfdi.bund.de/DE/Home/home_node.html	Federal Data Protection Act, as Amended (2009): http://www.gesetze-im-internet.de/englisch_bdsgr/		
Note: The 16 German states also have data protection laws (German): http://www.datenschutzz-bayern.de/infoquel/ds-				

Country	Key Organizations	Legislation	Regulations	Guidelines
inst/deutschland.html <i>Human Biological Materials</i>	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): http://www.dizg.de/en/institute.html			1. Ethical Code (2000) 2. Common Standards: Tissues and Cell Banking (2004)
<i>Genetic Research</i>	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/gesamt.pdf		Various: http://www.pei.de/DE/service/linklisten/links-gentherapie/links-thema-gentherapie-node.html
	German Society of Human Genetics: http://www.gfhev.de/en/gfh/			1. 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 2. Position Paper of the German Society of Human Genetics (2007) (German)

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Embryos, Stem Cells, and Cloning</i>	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 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	http://www.medgenetik.de/sonderdruck/2007_gfh_positionspapier.pdf
	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): http://www.rki.de/EN/Content/Institute/DepartmentsUnits/StemCell/StemCell_node.html			
Greece				
<i>General</i>	National Bioethics Commission (NBC): http://www.bioethics.gr/			1. Research Ethics for Biological Sciences (2008): http://www.bioethics.gr/index.php/en/gnomes/

Country	Key Organizations	Legislation	Regulations	Guidelines
				86-research-ethics-in-biological-sciences 2. A Guide for Research Ethics Committees for Biological Research (2008): http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/guide.pdf 3. Conflict of Interest in Biomedical Research (2011): http://www.bioethics.gr/images/pdf/EKDOSEIS/OPINIONS_AND_REPORTS_2008-2013_EN.pdf 4. Incidental Findings in Research and Clinical Practice (2015): http://www.bioethics.gr/index.php/en/gnomes/983-incidentalfindingsinresearchandclinicalpractice
<i>Drugs and Devices</i>	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	1. Ministerial Decision ΔΥΤ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC 2. Ministerial Decision ΔΥΤ 3 α/79602/2007: Harmonization of the Greek Legislation with EU Legislation, according to the Directive 2005/28/EC	NBC: 1. Recommendation on Clinical Trials: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/recom_clinical_trials_en.pdf 2. Control of Non-Invasive Clinical Trials for Drugs (2013) (Greek): http://www.bioethics.gr/index.php/en/gnomes/532-control-of-non-invasive-clinical-trials-for-drugs
<i>Research Injury</i>	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	1. Ministerial Decision ΔΥΤ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC 2. Ministerial Decision ΔΥΤ 3 α/79602/2007 Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2005/28/EC:	
<i>Privacy/Data Protection</i>	Hellenic Data Protection Authority (Greek): http://www.dpa.gr/	1. Greek Constitution 1975/1986/2001 Article 9.1 2. Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998) 3. Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by		

Country	Key Organizations	Legislation	Regulations	Guidelines
		<p>Laws 2819/2000 and 2915/2000) (Greek): http://www.dpa.gr/Documents/Eng/2472engl_all.doc 4. Act 3418/2005 Code on Medical Ethics</p>		
<i>Genetic Research</i>	<p>National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3</p>	<p>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/pls/portal/docs/PAGE/APDPX/ENGLISH_INDEX/LEGAL%20FRAMEWORK/LAW%202472-97-NOV2013-EN.PDF 4. Act 3418/2005 Code on Medical Ethics</p>		<p>1. Recommendation on Banks of Biological Material of Human Origin (Biobanks) in Biomedical Research: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/biobanks_recom_eng.pdf 2. Recommendation on the Collection and Use of Genetic Data: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/recom_genetic_data_eng.pdf 3. Opinion on Prenatal and Pre-Implantation Diagnosis and Embryo Treatment: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/1_pd_pg_d_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 5. Opinion on Incidental Findings in Research and Clinical Practice (2015): http://www.bioethics.gr/images/pdf/GNOMES/OPINION_Incidental_Findings_FINAL_.pdf</p>
<i>Embryos, Stem Cells, and Cloning</i>	<p>1. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3 2. National Authority for Medically Assisted Reproduction (Greek)</p>	<p>1. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 2. Civil Code (Act 3089/2002, Medically Assisted Reproduction) 3. Act 3305/2005 Application of Medically Assisted Reproduction</p>		<p>NBC: 1. Recommendation on the Use of Stem Cells in Biomedicine and Clinical Medicine 2. Recommendation on Human Reproductive Cloning 3. Opinion on Prenatal and Pre-implantation Diagnosis and Embryo Treatment Access: http://www.bioethics.gr/index.php/gnomes</p>

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Hungary	For an overview of human subject protections in Hungary, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Hungary%20definitive%20Updated.pdf			
<i>General</i>	1. Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Research Ethics Committees (KFEB, TUKEB, HRB) (Hungarian): http://www.ett.hu/	1. Fundamental Law of Hungary, Articles II-III 2. Act CLIV of 1997 on Health Care, Chapters VIII and IX 3. Act VI. of 2002 on the Promulgation of the Oviedo Convention on Human Rights and Biomedicine 4. Act LXXXI of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research 5. Act C of 2012 on the Criminal Code, Chapter XVI Medical Procedures and Criminal Offenses Against the Order of Research, Sections 168-175	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 35/2005 (VIII.26.) of the Minister of Health on the Clinical Trials of Investigational Medicinal Products for Human Use and on the Application of Good Clinical Practice 3. 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	
<i>Drugs and Devices</i>	<i>Drugs</i> 1. National Institute of Pharmacy and Nutrition: http://www.ogvei.gov.hu 2. Medical Research Council, Ethics Clinical Pharmacology Ethics Committee (KFEB) (Hungarian): http://www.ett.hu/kfeb.htm	<i>Clinical Trials:</i> 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 <i>Non-Interventional Trials:</i> Act CLIV of 1997 on Health Care, Chapter VIII, Section 164/A: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV	<i>Clinical Trials:</i> Decree 35/2005 (VIII. 26) of the Minister of Health on the Clinical Trial and Application of Correct Clinical Practices of Investigational Medicinal Products Intended for Use in Humans: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM&celpara=#xcelparam <i>Non-Interventional Trials:</i> 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	

Country	Key Organizations	Legislation	Regulations	Guidelines
			gi?docid=A0200023.EUM&celpara=#xcelparam	
	<p><i>Devices</i></p> <p>1. Authority for Medical Devices, Health Registration and Training Center: http://www.enkk.hu/index.php/hun/</p> <p>2. Medical Research Council, Ethics Committee for Clinical Pharmacology: http://www.ett.hu/kfeb/kfeb.htm</p>	<p>Act CLIV of 1997 on Health Care, Chapter VIII, Section 159: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV</p>	<p><i>Clinical Trials:</i> 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</p> <p><i>Non-Interventional Trials:</i> 1. 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</p> <p>2. 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</p>	
<i>Research Injury</i>	<p>National Institute of Pharmacy and Nutrition: http://www.ogyei.gov.hu</p>	<p>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</p>		
<i>Privacy/Data Protection</i>	<p>Hungarian National Authority for Data Protection and Freedom of Information: http://www.naih.hu/general-information.html</p>	<p>1. Act XLVII of 1997 on the Handling of Medical and Other Related Data: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700047.TV&celpara=#xcelparam</p> <p>2. Act CXII of 2011 on Right of Informational Self-Determination and Freedom of Information: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A1100112.TV&cel</p>		

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Human Biological Materials</i>	Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberieroforrasok-miniszteriuma	para=#xcelparam 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	
<i>Genetic Research</i>	1. Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberieroforrasok-miniszteriuma 2. Medical Research Council, Committee for Human Reproduction (HRB) (Hungarian): http://www.ett.hu/hrb.htm	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
<i>Embryos, Stem Cells, and Cloning</i>	1. Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberieroforrasok-miniszteriuma 2. Medical Research Council, Research Ethics Committees (KFEB, TUKEB, HRB) (Hungarian): http://www.ett.hu/	1. Act CLIV of 1997 on Health Care, Chapter IX 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 Regarding Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam
Iceland				
For an overview of human subject protections in Iceland, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Iceland%20definitive%20Updated.pdf				
<i>General</i>	1. Ministry of Welfare (MOW): http://eng.velferdarraduneyti.is/ 2. National Bioethics Committee (NBC): http://www.vsn.is/en	1. Act on the Rights of Patients No. 74/1997, Article 10 (2009): http://eng.velferdarraduneyti.is/medi/a/acrobat-enskar_sidur/Patients-Rights-Act-No-74-1997.pdf 2. The Act on Scientific Research in the Health Sector No 44/2014: http://eng.velferdarraduneyti.is/medi/a/acrobat-enskar_sidur/Health-Sector-Research-Act-No-44-2014.pdf 3. Oviedo Convention on Human Rights and Biomedicine (2004)		NBC: 1. Vulnerable Groups Including Children: http://www.vsn.is/en/content/vulnerable-groups-including-children 2. Informed Consent: http://www.vsn.is/en/content/informed-consent 3. Withdrawal of Consent: http://www.vsn.is/en/content/withdrawal-consent 4. Duty to Report Unexpected Events: http://www.vsn.is/en/content/duty-report-unexpected-events 5. Advertising to Recruit Participants: http://www.vsn.is/en/content/advertising-recruit-participants

Country	Key Organizations	Legislation	Regulations	Guidelines	
<i>Drugs and Devices</i>	<i>Drugs</i>	1. Icelandic Medicines Agency (MCA): http://www.ima.is/ 2. National Bioethics Committee (NBC): www.visindasidanefnd.is	Medicinal Products Act No. 93/1994 (2013): http://eng.velferdarraduneyti.is/acts-of-Parliament/nr/20128	MCA: Regulation on Clinical Trials of Medicinal Products in Humans No. 443/2004 (2010): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Medicinal-Products-Act-NoMedicinal-Products-Act-No-93-1994-as-amended.pdf	NBC: Various: http://www.vsn.is/en/content/clinical-trials
	<i>Devices</i>	Ministry of Welfare: http://eng.velferdarraduneyti.is/	Act on Medical Devices No 16/2001 (2011): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/16012012_Act-on-Medical-Devices-No-16-2001-as-amended.pdf	1. Regulation on Medical Devices No. 934/2010 (2010): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/16012012_Act-on-Medical-Devices-No-16-2001-as-amended.pdf 2. Regulation on Active Implantable Medical Devices No. 320/2011 (Icelandic): http://www.stjornartidindi.is/Advert.aspx?ID=c50d676c-4651-46c2-83b5-ad946f3decaa 3. Regulation on In Vitro Diagnostic Medical Devices No. 936/2011 (Icelandic): http://stjornartidindi.is/Advert.aspx?ID=f20b3e4e-ab25-44d3-8e32-e5f42a7b02f0	
<i>Research Injury</i>	Icelandic Health Insurance Agency (MCA): http://www.sjukra.is/english	1. Act on Patient Insurance No. 111/2000 (2011): https://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act-on-Patient-Insurance-as-amended.pdf 2. Act on Health Insurance No. 112/2008 (2012): https://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act-on-Health-Insurance-No-112-2008-16.pdf	Regulation on Clinical Trials of Medicinal Products in Humans No 443/2004 (2010): http://eng.velferdarraduneyti.is/media/Reglugerdir-enska/Regulation-on-clinical-trials-of-medicinal-products-in-humans-no-443-2004-as-amended.pdf		
<i>Privacy/Data Protection</i>	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/			

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Human Biological Materials</i>	1. Ministry of Welfare: http://eng.velferdarraduneyti.is/ 2. National Bioethics Committee (NBC): www.visindasidanefnd.is/en	Biobanks Act No. 110/2000 (2009): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Biobanks-Act-as-amended.pdf	Regulations on the Keeping and Utilization of Biological Samples in Biobanks No. 134 (2001)	NBC: 1. Access to and Utilisation of Health Data and Bio-Samples: http://www.vsn.is/en/content/access-and-utilisation-health-data-and-bio-samples 2. Biobanks: http://www.vsn.is/en/content/biobanks
<i>Embryos, Stem Cells, and Cloning</i>		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2004) 2. 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				
For an overview of human subject protections in Ireland, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Ireland%20definitive.pdf ; and see this summary on Clinical Trials Involving Medical Products: http://health.gov.ie/blog/policy/clinical-trials-involving-medicinal-products/				
<i>General</i>	Department of Health: http://health.gov.ie/			1. Operational Procedures for Research Ethics Committees: Guidance 2004: http://health.gov.ie/wp-content/uploads/2014/07/Operational_Procedures1.pdf 2. Health Service Executive National Consent Policy, Part 3: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Policy/
<i>Drugs and Devices</i>	1. Department of Health: http://health.gov.ie/ 2. Health Products and Regulatory Authority: https://www.hpra.ie/	European Communities (Clinical Trials on Medicinal Products for Human Use) Amendment 2004 (S.I. No. 190 of 2004): http://www.irishstatutebook.ie/eli/2004/si/190/made/en/print	European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004): http://www.irishstatutebook.ie/eli/2004/si/190/made/en/html	Various: https://www.hpra.ie/homepage/site-tools/search?query=clinical%20trials
<i>Research Injury</i>	Health Products and Regulatory Authority: https://www.hpra.ie/		European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004,	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Section 13(6)(k) and Schedule 1, Part 2, Paragraph 4 (S.I. No. 190 of 2004): http://www.irishstatutebook.ie/eli/2004/si/190/made/en/html	
<i>Privacy/Data Protection</i>	Data Protection Commissioner: http://www.dataprotection.ie/docs/Home/4.htm	Data Protection Act (1988), as Amended (2003): http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html		
<i>Human Biological Materials</i>	Health Products and Regulatory Authority: https://www.hpra.ie/			Human Biological Material: Recommendations for Collection, Use, and Storage in Research (2005): http://health.gov.ie/wp-content/uploads/2014/07/Human_Biological_Material1.pdf
<i>Genetic Research</i>	Health Products and Regulatory Authority: https://www.hpra.ie/			Guidelines for Pharmacogenetic Research (2006): http://lenus.ie/hse/bitstream/10147/96983/1/Pharmacogenetic06.pdf
Italy				
For an overview of human subject protections in Italy, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Italy%20definitive%20Updated.pdf				
<i>General</i>	1. National Bioethics Committee (CNB): http://www.governo.it/bioetica/eng/index.html 2. National Monitoring Center for Clinical Trials (OSS): http://oss-sper-clin.agenziafarmaco.it/		OSS: Ministerial Decree of 12 May 2006: Terms of Reference for the Establishment and the Functioning of Ethics Committees	CNB: Various: http://www.governo.it/bioetica/eng/opinions.html
<i>Drugs and Devices</i>	<i>Drugs</i> 1. National Monitoring Center for Clinical Trials: http://www.agenziafarmaco.com/en/content/national-monitoring-centre-clinical-trials 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) 3. Legislative Decree No. 200: Transposition of Directive	1. Ministerial Decree of 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 of 31 March 2008: Definition of the Minimum Requirements that Contract Research Organisations (CROs) Shall Satisfy in Order to	

Country	Key Organizations	Legislation	Regulations	Guidelines
		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	Work within Clinical Trials on Medicinal Products	
	<i>Devices</i>			
	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	Administrative Procedures Concerning the Conduction of Clinical Investigations with CE-Marked Medical Devices (2007)
<i>Research Injury</i>	Ministry of Labour and Social Policy (Italian): www.lavoro.gov.it		Ministerial Decree 14 of July 2009: Minimum Requirements for Insurance Policies Which Safeguard Participants to Clinical Trials of Medicinal Products	
<i>Privacy/Data Protection</i>	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%2FI+Codice+in+materia+di+protezione+dei+dati+personali	1. Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000) 2. Regulation for the Implementation of Articles No. 20 and 21 of the Legislative Decree No. 196 of June 30, 2003 3. Ministerial Decree No. 277 (2007)	
<i>Genetic Research</i>	1. Istituto Superiore di Sanita (ISS): http://www.iss.it/chis/?lang=2 2. Italian Society of Human Genetics (SIGU): http://www.sigu.net/			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: Various: http://www.sigu.net/show/documenti/5/1/linea%20guida

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Embryos, Stem Cells, and Cloning</i>		Regulation of Medically Assisted Reproduction, Law No. 40, Article 13 (2004)		

Latvia				
For an overview of human subject protections in Latvia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Latvia%20definitive.pdf				
<i>General</i>	Central Medical Ethics Committee		Statutes of Central Medical Ethics Committees (1998) (Latvian): http://likumi.lv/doc.php?id=46597	
<i>Drugs and Devices</i>	<i>Drugs</i>			
	1. State Agency of Medicines: http://www.zva.gov.lv/?setlang=en&large 2. Central Medical Ethics Committee	1. Law on Pharmacy, Section 26 (2013): http://www.zva.gov.lv/?id=355&top=333&large=0 2. Law on the Rights of Patients, Section 11 (2013) http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Law_On_the_Rights_of_Patients.doc	Cabinet Regulation No. 289: Regulations Regarding the Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal Products, Labelling of Investigational Medicinal Products and the Procedures for Assessment of Conformity of Clinical Trial of Medicinal Products with the Requirements of Good Clinical Practice: http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab_Reg_No_289_-_Procedures_for_Conduct_of_Clinical_Trials_and_Non-interventional_Trials_of_Medicinal_Products.doc	
	<i>Devices</i>			
	State Agency of Medicines: http://www.zva.gov.lv/?setlang=en&large =	Medical Treatment Law, Section 34 (2006): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Medical_Treatment_Law.pdf	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	
<i>Research Injury</i>	State Agency of Medicines: http://www.zva.gov.lv/?setlang=en&large =		<i>Drugs:</i> Cabinet Regulation No. 289: Regulations Regarding the Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal	

Country	Key Organizations	Legislation	Regulations	Guidelines
			<p>Products, Labelling of Investigational Medicinal Products and the Procedures for Assessment of Conformity of Clinical Trial of Medicinal Products with the Requirements of Good Clinical Practice, Sections 22, 31.6, 54.10, 55.9, and 61.14 (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab.Reg.No.289 - Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal Productsx.doc</p> <p><i>Devices:</i> Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for Human Use, Sections 42.7 and 62.5 (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab.Reg.No.891 - Procedures for the Clinical Trial of Medical Devices.doc</p>	
<i>Privacy/Data Protection</i>	1. Data State Inspectorate: http://www.dvi.gov.lv/en/ 2. Central Medical Ethics Committee	1. Personal Data Protection Law (2010): http://www.dvi.gov.lv/en/wp-content/uploads/legal-acts/Personal_Data_Protection_Law.doc 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		
<i>Human Biological Materials</i>	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_Decea	Cabinet Regulation No. 1176 (2013) Procedures for Use of Human Tissues and Cells (Latvian): http://likumi.lv/ta/id/261810-cilveka-audu-un-sunu-izmantosanas-kartiba	

Country	Key Organizations	Legislation	Regulations	Guidelines
		sed Human Beings and the Use of Human Tissues and Organs in Medicine.doc		
<i>Genetic Research</i>	1. Ministry of Health: http://www.vm.gov.lv/en/ 2. Data State Inspectorate: http://www.dvi.gov.lv/en/ 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) (Latvian): http://likumi.lv/doc.php?id=92330	
<i>Embryos, Stem Cells, and Cloning</i>	1. Ministry of Health: http://www.vm.gov.lv/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				
Note: All standards are in Lithuanian. For an overview of human subject protections in Lithuania, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Lithuania%20definitive%20Updated.pdf				
<i>General</i>	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/treaties/html/164.htm 2. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL	1. Decree No. V-405 on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage, and Providing Information on Biomedical Research (2010): http://www3.lrs.lt/pls/inter3/dokpaies.ka.showdoc_1?p_id=372121&p_query=&p_tr2= 2. Government of the Republic of Lithuania: Decree No. 1458 on State Fees (2015): https://www.e-tar.lt/portal/lt/legalAct/TAR.E3A145C8DD49/CQWiEHsWLL 3. Decree on the Procedure for Calculating and Paying Compensation for the Expenses Incurred Due to Participation in Biomedical Research and the Time Spent (2016): https://www.e-	

Country	Key Organizations	Legislation	Regulations	Guidelines
			<p>tar.lt/portal/lt/legalAct/2a0242a0b5fe11e5a6588fb85a3cc84b</p> <p>4.V-28, Decree on the Detailed Requirements for the Content of a Person's Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent (2016): https://www.e-tar.lt/portal/lt/legalAct/0f2f1b70b9db11e5a6588fb85a3cc84b</p> <p>5. V-1483, Decree on the List of Interventional Methods of Biomedical Research Causing a Slightly Detrimental and Temporary Impact on the Subject's Health (2014): http://www3.lrs.lt/pls/inter3/dokpaies.ka.showdoc_1?p_id=1002481&p_tr2=2</p> <p>6. V-235/A1-83, Decree on the Procedure for a Minor's Participation in Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/104c2540d3e711e583a295d9366c7ab3</p>	
	<p>Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1073108465</p>		<p>1. Decree on the Detailed Requirements for the Content of a Person's Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent, No. V-28 (2016): https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/b9895bf0ba3811e5be9bf78e07ed6470?positionInSearchResults=0&searchModelUUID=a4086949-b1f3-429e-8197-870c6122d393</p> <p>2. Decree on the Procedure to Conduct Biomedical Research on Medical Documents, No. V-28</p>	<p>Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical Research of the LBEC (2010): bioetika.sam.lt/get_file.php?file=Y3BUSHk1YWhrNlZ1bTJKbXhwZlprYWNOB3ltVF R5cHhxMnBlZGxhU2V4cFdTbHA5cFoyMm pscGFjbTNDWm1LR2F4cGJVbXBPWHJwck 14SjNjcFhIS25kYVlZV2FlYTU5cW81cWFjV 0tkYm1XYWFEJOXR5TWfY2NtYm1lZDZjY TZzcWNaU1xcHBtMmFpeUtTYm5acWFtO DlseFpyRm01cHR6NVNlbDZodzJKcURuVl NWYUhCbmttZWJWWEZnblc2WWdaYVRh NXlaVjJtb3g0R2JqWnFGbDhySXBHYXRhY WFTbk1tb2JsQ2VwV3JDWmRXyTJzaWdjT mpEcUphaW10UESxNVNUazVOeVoyS1VsM k5zbEpla204U1puR3VmbWclM0QIM0Q=</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
			<p>(2011): https://www.e-tar.lt/portal/lt/legalAct/TAR.480CDD584ADB 3. V-7, Decree on the Sample Form of the Biomedical Research Protocol, Summary of the Protocol and the CV of Investigator (2016): https://www.e-tar.lt/portal/lt/legalAct/352d55b0c44111e583a295d9366c7ab3 4. V-24, Decree on the Procedure for Submission of the Documents to the Lithuanian Bioethics Committee to Issue Favorable Opinion to Conduct a Clinical Trial on Medicinal Products or Approval to Conduct Biomedical Research by the Sponsor of the Clinical Trial on Medicinal Product or Other Type of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/3790a050be7e11e5a6588fb85a3cc84b 5. V-4, Decree on the Request to Issue Approval to Conduct Biomedical Research, the Application Form and the Biomedical Research Ethical Assessment Form (2016): https://www.e-tar.lt/portal/lt/legalAct/f6caecd0be8511e5a6588fb85a3cc84b</p>	
<i>Drugs and Devices</i>	<p><i>Drugs</i></p> <p>1. Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG 2. State Medicines Control Agency (SMCA): http://www.vvkt.lt/lit/English</p>	<p>1. Law on Ethics of Biomedical Research (2016): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=477235 2. Law on Pharmacy (2013): https://www.e-tar.lt/portal/lt/legalAct/TAR.FF33B3BF23DD/FjrKXzkZsb</p>	<p>1. Decree No. 320 on the Rules of Good Clinical Practice (1998): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=58549&p_query=&p_tr2= 2. Corrections of GCP Terminology in Lithuanian (2006) http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=287288 3. Decree No. 435 on the</p>	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Procedure for Issuing a Favorable Opinion to Conduct Clinical Trials on Medicinal Product, Approval for Clinical Trials on Medicinal Product, and Conducting and Controlling Clinical Trials (2016): http://www3.lrs.lt/pls/inter3/dokpaies.ka.showdoc_l?p_id=277308&p_query=&p_tr2=	
	Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?-1073108465		V-6, Decree on the Sample Form of the Request to Issue Favorable Opinion to Conduct Clinical Trial on Medicinal Product Form and the Ethical Assessment Form (2016): https://www.e-tar.lt/portal/lt/legalAct/b65b5ca0c44011e583a295d9366c7ab3	Guidelines to Advertise Clinical Trials, Adopted by the Group of Experts on Biomedical Research of the LBEC (2007)
	<i>Devices</i>			
	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 (2016): http://www3.lrs.lt/pls/inter3/dokpaies.ka.showdoc_l?p_id=312804	
	State Health Care Accreditation Agency Under the Ministry of Health (SHCA): http://www.vaspvt.gov.lt/en	Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL	Decree No. T1-1064 on the Procedure to Issue Recommendation to Conduct Clinical Trial on Medical Device (2010): https://e-tar.lt/acc/legalAct.html?documentId=TAR.B2013F6F31B9&lang=lt	
<i>Research Injury</i>	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL	MOH: Decree No. 745 on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor (2015): http://www3.lrs.lt/pls/inter3/dokpaies.ka.showdoc_l?p_id=116634&p_query=&p_tr2=	
<i>Privacy/Data Protection</i>	State Data Protection Inspectorate: https://www.ada.lt/go.php/lit/English	Law on Legal Protection of Personal Data (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.5368B592234C/IGOrBAvuZc		

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Human Biological Materials</i>	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL		
<i>Embryos, Stem Cells, and Cloning</i>	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	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): http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/168 2. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL	1. Decree No. V-660 on the Procedure to Issue Authorization for the Transit of Tissues of Human Embryonic Tissue, Embryonic Stem Cells and their Lines, Fetal Tissue, and Fetal Stem Cells throughout the Territory of the Republic of Lithuania (2007): http://www3.lrs.lt/pls/inter3/dokpaies.ka.showdoc_l?p_id=302906&p_query=&p_tr2= 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 (2015): http://www3.lrs.lt/pls/inter3/dokpaies.ka.showdoc_l?p_id=302907&p_query=&p_tr2=	
Luxembourg For an overview of human subject protections in Luxembourg, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Luxembourg%20definitive%20Updated.pdf Note: All websites and documents are available in French.				
<i>General</i>	National Ethics Consultative Commission: http://www.cne.public.lu/fr/commission/statut.html			Various: http://www.cne.public.lu/fr/publications/avis.html
<i>Drugs and Devices</i>	1. Ministry of Health: http://www.ms.public.lu and http://www.sante.lu 2. National Research Ethics Committee: http://www.cner.lu 3. Division of Pharmacy and Medicines of the Ministry of Health: http://www.sante.public.lu/fr/politique-	Hospitals Act of 1998, Article 25 (2010): http://www.legilux.public.lu/leg/a/archives/1998/0078/a078.pdf	Grand-Ducal Decree of May 30, 2005 on the Conduct of Clinical Trials on Medicinal Products for Human Use: http://www.legilux.public.lu/leg/a/archives/2005/0084/2005A15161.html	

Country	Key Organizations	Legislation	Regulations	Guidelines
	sante/ministere-sante/direction-sante/div-pharmacie-medicaments/index.html			
<i>Privacy/Data Protection</i>	National Commission for Data Protection: 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 2, 1992 on the Use of Personal Medical Data in IT Processing: http://www.legilux.public.lu/leg/a/arc_hives/1992/0074/a074.pdf#page=12	
Macedonia				
Note: All websites and documents are in Macedonian.				
<i>Drugs and Devices</i>	<i>Drugs</i> 1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Drug and Devices Register: https://lekovi.zdravstvo.gov.mk/ 3. Drug Agency http://malmed.gov.mk/	Law on Medicinal Products and Medical Devices (Official Gazette No.106/2007) and Laws Amending and Supplementing the Law (2010-2016): Click on file folder 1., then open sub-folders: https://lekovi.zdravstvo.gov.mk/documents/2	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/81732562?t:ac=1/1 1.1. Rulebook on Amending and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2010): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/879452170?t:ac=1/1 1.2. Rulebook on Amending and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2012): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/880033320?t:ac=1/1 1.3. Rulebook on Amending and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents and Annex No.3 (Guideline for the Clinical Trial	Guideline for the Clinical Trial Applicant (Annex 3) (2012): https://lekovi.zdravstvo.gov.mk/documents/1/1 (Sub-folder 23.2)

Country	Key Organizations	Legislation	Regulations	Guidelines
			<p>Applicant) (Document No. 23.3) (2012): https://lekovi.zdravstvo.gov.mk/documents/1/1</p> <p>1.4. Rulebook on Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2016) (Document No. 23.4): https://lekovi.zdravstvo.gov.mk/documents/1/1</p> <p>2. 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:downloadfile/880287913?t:ac=1/1</p>	
<i>Devices</i>				
	<p>1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/</p> <p>2. Drug and Devices Register: https://lekovi.zdravstvo.gov.mk/</p> <p>3. Drug Agency http://malmed.gov.mk/</p>	<p>Law on Medicinal Products and Medical Devices (Official Gazette No.106/2007) and Laws Amending and Supplementing the Law (2010-2016): Click on file folder 1., then open sub-folders: https://lekovi.zdravstvo.gov.mk/documents/2</p>	<p>1. 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 (Official Gazette No. 62/2010): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/844338380?t:ac=1/2</p> <p>2. Rulebook on the Manner of Reporting Adverse Effects During the Use of Medical Devices, Types of Reactions they Cause, the Actions of Health Workers and Suppliers, As Well as the Manner of Organizing the System of Monitoring Adverse Effects and Reactions to Medical Devices (Official Gazette No.100/2016) (Document No.8):</p>	

Country	Key Organizations	Legislation	Regulations	Guidelines
			https://lekovi.zdravstvo.gov.mk/documents/1/2	
<i>Research Injury</i>	1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Drug Agency: http://malmed.gov.mk/		Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and Documentation Contents (2009): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/817325622?t:ac=1/1	
<i>Privacy/Data Protection</i>	Directorate for Personal Data Protection: www.dzlp.mk	1. Law on Personal Data Protection, Consolidated (2016): http://www.dzlp.mk/sites/default/files/u4/ZZLP_konsolidiran_tekst_2016.pdf 2. 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 3. 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	Regulations on Protection of Personal Data: http://www.dzlp.mk/mk/podzakonski_akti	
<i>Human Biological Materials</i>	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: (Official Gazette No. 43/2012) and Laws Amending and Supplementing the Law (2012-2015): http://zdravstvo.gov.mk/zakon-za-zdravstvenata-zashtita/ 2. Law on Taking and Transplanting of Human Body Organs (Official Gazette No. 47/2011) and Laws Amending and Supplementing the Law (2011-2015): http://zdravstvo.gov.mk/zakon-za-zemanje-i-presaduvanje-na-delovi-	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 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

Country	Key Organizations	Legislation	Regulations	Guidelines
		na-chovechkoto-telo-zaradi-lekuvanje/ 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		
<i>Genetic Research</i>	Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/	Law on Patient Rights Protections, Article 21: Action on Human Genome: http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-zastita-na-pravata-na-pacientite-precisten.pdf		
<i>Embryos, Stem Cells, and Cloning</i>	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		
Malta				
For an overview of human subject protections in Malta, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Malta%20definitive%20Updated.pdf				
<i>General</i>	Bioethics Committee: http://health.gov.mt/en/regcounc/Bioethics-Committee/Pages/CommitteeMembers.aspx			Various: http://health.gov.mt/en/regcounc/Bioethics-Committee/Pages/Opinions.aspx

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	<p>px</p> <p><i>Drugs</i></p> <p>Medicines Authority: http://medicinesauthority.gov.mt/</p>	<p>1. Medicines Act, 2003: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8924&l=1</p> <p>2. Subsidiary Legislation, 458.43, Clinical Trials Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11281&l=1</p> <p>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</p>		<p>Guidance Notes on Good Clinical Practice (2010): http://medicinesauthority.gov.mt/clinicaltrials.htm</p>
	<p><i>Devices</i></p> <p>1. Medicines Authority: http://medicinesauthority.gov.mt/</p> <p>2. Malta Competition and Consumer Affairs Authority, Technical Regulations Division, Regulatory Affairs Directorate: http://www.mccaa.org.mt/en/regulatory-affairs-directorate</p>	<p>1. Product Safety Act, 2001: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8893&l=1</p> <p>2. Subsidiary Legislation, 427.16, <i>In Vitro</i> Diagnostic Medical Devices Regulations, 2003 http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10756&l=1</p> <p>3. Subsidiary Legislation, 427.44, Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10781&l=1</p> <p>4. Subsidiary Legislation, 427.10, Active Implantable Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10781&l=1</p>		

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Privacy/Data Protection</i>	Office of the Information and Data Protection Commissioner: http://idpc.gov.mt/index.aspx	d=10753&l=1 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.				
<i>General</i>	Ministry of Health, National Committee for Ethical Expertise of Clinical Trials: http://ms.gov.md/?q=comitetul-national-etica	Oviedo Convention on Human Rights and Biomedicine (2002)		
<i>Drugs and Devices</i>	1. Ministry of Health , National Committee for Ethical Expertise of Clinical Trials: http://ms.gov.md/?q=comitetul-national-etica 2. Medicines and Medical Devices Agency: http://www.amed.md/	1. Law No. 1409 Dated 17.12.1997 on Medicines, Articles 11 and 12: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311586 2. Law No. 263 Dated 27.10.2005 on Patients’ Rights and Responsibilities. Articles 9, 10, 11, 12, 13, and 14: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=313060	MOH: 1. Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Expertise of Clinical Trial: http://lex.justice.md/md/362783/ 2. Order No.648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in the Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf	
<i>Research Injury</i>	Ministry of Health (MOH): http://www.ms.gov.md/	Law No. 411-XIII Dated 28.03.1995 on Health: http://lex.justice.md/viewdoc.php?action=view&view=doc&id=312823&lang=1	1. Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Expertise of Clinical Trials: http://lex.justice.md/md/362783/ 2. Order No. 648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in the Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf	
<i>Privacy/Data Protection</i>	National Center for Personal Data Protection of the Republic of Moldova: http://www.datepersonale.md/en/start/	1. Convention No. 108 for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981):	Decision of Government No. 1123 Dated 14.12.2010 on the Approval of the Requirements for the Assurance of Personal Data	

Country	Key Organizations	Legislation	Regulations	Guidelines
		<p>http://datepersonale.md/en/international003/</p> <p>2. Decision of Parliament No. 483-XIV Dated 02.07.1999 on Ratification of Convention No. 108:</p> <p>http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=309121</p> <p>3. Law No. 982 Dated 11.05.2000 on Access to Information:</p> <p>http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311759</p> <p>4. Law No.133 Dated 08.07.2011 on the Protection of Personal Data:</p> <p>http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=340495</p>	<p>Security at their Processing within the Information Systems of Personal Data:</p> <p>http://www.datepersonale.md/file/hotariri/cerinte_securitate%20eng_101228.pdf</p>	
<i>Human Biological Materials</i>	<p>1. Ministry of Health (MOH): http://www.ms.gov.md/</p> <p>2. Transplant Agency http://lex.justice.md/md/334622</p>	<p>Law No. 42 Dated 06.03.2008 on Transplantation of Organs, Tissues and Human Cells:</p> <p>http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=327709</p>	<p>MOH: Order No.648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in Republic of Moldova:</p> <p>http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf</p>	
<i>Embryos, Stem Cells, and Cloning</i>	<p>1. Ministry of Health (MOH): http://www.ms.gov.md/</p> <p>2. National Commission on Biological Security: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=303353</p>	<p>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)</p> <p>2. Law No. 42 Dated 06.03.2008 on Transplantation of Organs, Tissues and Human Cells:</p> <p>http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=327709</p>		
Montenegro				
<i>Drugs and Devices</i>	<p>1. Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat</p>	<p>1. Law on Medicines (“Official Gazette of Montenegro”, No.</p>	<p>Rulebook on More Detailed Conditions and Documentation</p>	

Country	Key Organizations	Legislation	Regulations	Guidelines
	<p>2. Agency for Medicines and Medical Devices: https://www.calims.me/Portal/faces/glavn_a?_adf.ctrl-state=rsbe35pln_83</p>	<p>56/2011), Articles 60 – 83: https://www.calims.me/Portal/faces/servlet1?putanja=Law%2520on%2520medicines%2520Montenegro%2520202011.pdf&_afWindowMode=0&_afLoop=13118320360550956&_adf.ctrl-state=vn1r9i5df_417</p> <p>2. Law on Medical Devices (“Official Gazette of Montenegro” No. 79/2004), Articles 46 – 50: https://www.calims.me/Portal/faces/servlet1?putanja=Law%2520on%2520medical%2520devices%25202004.pdf&_afWindowMode=0&_afLoop=13119103630157953&_adf.ctrl-state=vn1r9i5df_799</p> <p>3. Law on Amendments to the Law on Medical Devices (“Official Gazette of Montenegro”, No. 53/2009), Articles 34 – 38: https://www.calims.me/Portal/faces/servlet1?putanja=Law%2520on%2520amendments%2520to%2520the%2520Law%2520on%2520medical%2520devices_2009.pdf&_afWindowMode=0&_afLoop=13119388662995839&_adf.ctrl-state=vn1r9i5df_809</p>	<p>Required for Approval and Conduct of Clinical Trials of Medicines for Human Use (2013): https://www.calims.me/Portal/faces/servlet1?_afLoop=26656243505641585&_afWindowMode=0&putanja=Rulebook%2520on%2520Clinical%2520trials.pdf&_adf.ctrl-state=wdqo8wvwo_214</p>	
<i>Research Injury</i>	<p>1. Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat</p> <p>2. Agency for Medicines and Medical Devices: https://www.calims.me/Portal/faces/glavn_a?_adf.ctrl-state=rsbe35pln_83</p>	<p>1. Law on Medicines (“Official Gazette of Montenegro”, No. 56/2011), Article 77: https://www.calims.me/Portal/faces/servlet1?putanja=Law%2520on%2520medicines%2520Montenegro%2520202011.pdf&_afWindowMode=0&_afLoop=13118320360550956&_adf.ctrl-state=vn1r9i5df_417</p> <p>2. Law on Medical Devices (“Official Gazette of Montenegro” No. 79/2004), Article 47: https://www.calims.me/Portal/faces/servlet1?putanja=Law%2520on%2520medical%2520devices%25202004.pdf&_afWindowMode=0&_afLoop=13119388662995839&_adf.ctrl-state=vn1r9i5df_799</p>		

Country	Key Organizations	Legislation	Regulations	Guidelines
		oop=13119103630157953&_adf.ctrl-state=vn1r9i5df_799		
<i>Privacy/Data Protection</i>	National Security Agency: http://www.anb.gov.me/en/Home?alphabet=lat	Law on the Protection of Personal Data (Official Gazette of Montenegro No. 79/08, 70/09, 44/12)		
<i>Human Biological Materials</i>	Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat	Law on the Collection and Use of Biological Samples (Official Gazette of Montenegro No. 14/2010)		
<i>Genetics</i>	Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat	Law on the Protection of Genetic Data (Official Gazette of Montenegro No. 25/2010)		
<i>Embryos, Stem Cells, and Cloning</i>	Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat		Rulebook on the Collection, Storage, and Use of Stem Cells (2012)	
Netherlands				
For an overview of human subject protections in the Netherlands, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Netherlands%20definitive%20Updated.pdf				
<i>General</i>	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/en/	1. Population Screening Act (1996): http://wetten.overheid.nl/BWBR0005699/geldigheidsdatum_24-09-2015 2. Medical Research Involving Human Subjects Act (2012): 2006 English version: 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)	Various (Dutch): http://www.ccmo.nl/en/publications-of-the-ccmo
<i>Drugs and Devices</i>	1. Ministry of Health, Welfare, and 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://english.cbg-meb.nl/	Medicines Act (2007) (Dutch): http://wetten.overheid.nl/BWBR0021505	VWS: 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	CCMO: 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
<i>Clinical Trials Registry</i>	Netherlands Trial Register (Dutch): http://www.trialregister.nl/trialreg/index.asp			

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Research Injury</i>	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): https://zoek.officielebekendmakingen.nl/stb-2014-477.html	
<i>Privacy/Data Protection</i>	1. Federation of Biomedical Scientific Societies (FMWV) (Dutch): http://www.federa.org/ 2. Dutch Data Protection Authority: https://cbpweb.nl/en	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/bijlagn/coreon/code_of_conduct_for_medical_research_1.pdf 2. Explanatory Report Accompanying the Code (2004): http://www.federa.org/sites/default/files/bijlagn/coreon/explanatory_report1.pdf
<i>Human Biological Materials</i>	Federation of Biomedical Scientific Societies (FMWV) (Dutch): http://www.federa.org/	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/bijlagn/coreon/codepropersecondaryuseofhumantissue1_0.pdf
<i>Genetic Research</i>	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=
<i>Embryos, Stem Cells, and Cloning</i>	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		
Norway				
For an overview of human subject protections in Norway, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Norway%20definitive%20Updated.pdf				
<i>General</i>	National Committee for Medical and Health Research Ethics (NEM): http://www.etikkom.no/en/In-English/Committee-for-Medical-and-Health-Research/	1. Oviedo Convention on Human Rights and Biomedicine (2006) 2. Law regarding Ethics and Integrity in Research (2006): http://www.ub.uio.no/ujur/ulovdata/lov-20060630-056-eng.pdf		1. Guidelines for Research on Persons with Impaired Informed Consent Capacity (2005) 2. Payment for Research Participants in Medical and Health Research (2009) 3. Guidelines for Research Ethical and

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Act on Health Care Research (2008) (Norwegian): http://www.lovdatal.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&		Scientific Evaluation of Qualitative Research Projects in Medical and Health Research (2009) (Norwegian): https://www.etikkom.no/forskningsetiske-retningslinjer/Medisin-og-helse/Kvalitativ-forskning/
	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/
<i>Drugs and Devices</i>	<i>Drugs</i>			
	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
	<i>Devices</i>			
	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/ikbVier/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): https://helsedirektoratet.no/Documents/Medisinsk%20utstyr/Guidance%20for%20completing%20the%20Notification%20form.pdf
<i>Research Injury</i>		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2007)		
<i>Privacy/Data Protection</i>	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)	
<i>Human Biological Materials</i>	1. Ministry of Health and Care Services (MHCS):	1. Act on Biobanks (February 21, 2003, No. 12):	MHCS: Guidelines for the Norwegian Act	

Country	Key Organizations	Legislation	Regulations	Guidelines
	https://www.regjeringen.no/en/dep/hod/id/421/ 2. Ministry of Education and Research (MER): http://www.regjeringen.no/en/dep/kd.html?id=586	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=helseforskingslov*&	on Biobanks (2003)	
<i>Genetic Research</i>	1. Ministry of Health and Care Services (MHCS): https://www.regjeringen.no/en/dep/hod/id/421/ 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): https://www.regjeringen.no/globalassets/upload/kilde/hod/red/2005/0081/ddd/pdfv/242718-biotechnology_act_master.pdf		
<i>Embryos, Stem Cells, and Cloning</i>	Directorate for Health and Social Affairs: http://www.helsedirektoratet.no/kvalitet-planlegging/bio-og-enteknologi/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		
Poland				
For an overview of human subject protections in Poland, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Poland%20definitive.pdf				
<i>General</i>	1. Ministry of Health, Bioethics Appeals Commission (MOH): http://www.mz.gov.pl/en 2. Center of Bioethics, Polish Chamber of Physicians and Dentists (NIL) (Polish): http://www.nil.org.pl/dzialalnosc/oro-dek-bioetyki	1. Constitution of the Republic of Poland, Article 39 (1997) 2. Medical Profession Act, Articles 21-29 (1997): http://isap.sejm.gov.pl/Download?id=WDU19970280152&type=3	MOH: Order of the Minister of Health and Social Welfare on How to Establish, Finance, and the Mode of Action of Bioethics Committees (1999) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU19990470480	NIL: Code of Medical Ethics, Chapter II (2003): http://www.nil.org.pl/dokumenty/kodeks-etyki-lekarskiej

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Drugs and Devices</i>	<i>Drugs</i>	<p>1. Pharmaceutical Law (2015): isap.sejm.gov.pl/Download?id=WDU20011261381&type=3</p> <p>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)</p>	<p>1. Order of the Minister of Health in the Matter of Central Register of Clinical Trials (2004)</p> <p>2. Decree of the Minister of Health on Clinical Trials on Minors (2004) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20041041108</p> <p>3. March 11, 2005 Order of the Minister of Health Concerning Detailed Requirements of Good Clinical Practice (2005) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20120000489</p> <p>4. February 16, 2016 Regulation of the Minister of Health on Detailed Requirements for Planning, Conducting, Monitoring, and Documenting the Clinical Study of a Medical Device: http://isap.sejm.gov.pl/DetailsServlet?id=WDU20160000209</p>	
	<i>Devices</i>	<p>Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products: http://en.urpl.gov.pl/general-information</p>	<p>1. Act on Medical Devices (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20101070679</p> <p>2. Act Amending the Act on Medical Devices and Certain Other Acts: isap.sejm.gov.pl/DetailsServlet?id=WDU20150001918</p>	<p>1. Regulation of the Minister of Health on Detailed Conditions to be Met for Clinical Evaluation of Medical Devices or Active Implantable Medical Devices (2011) (Polish): isap.sejm.gov.pl/DetailsServlet?id=WDU20110630331</p> <p>Various (Polish): http://www.urpl.gov.pl/</p>
<i>Research Injury</i>		<p>Pharmaceutical Law, Chapter 36b(2)(6) (2008)</p>	<p>1. Order of the Minister of Finance Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2004) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20041011034</p> <p>2. Order of the Minister of Finance Amending the Regulation</p>	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2005) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20051010845 3. Order of the Minister of Finance Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors in Clinical Trials of Medicinal Products (2010) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20101941290	
<i>Privacy/Data Protection</i>	Inspector General for the Protection of Personal Data: http://www.giodo.gov.pl/168/j/en/	Act on the Protection of Personal Data (2006): http://www.giodo.gov.pl/data/filemager_en/61.doc		
<i>Human Biological Materials</i>		1. Act of 26 October 1995 on the Collection and Transplantation of Cells 2. Act of 22 August 1997 on the Public Blood Service 3. July 1, 2005 Act Regarding Sampling, Storage and Transplanting of Cells, Tissues and Organs		

Portugal				
For an overview of human subject protections in Portugal, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Portugal%20definitive%20Updated.pdf				
<i>General</i>	National Council of Ethics for the Life Sciences: http://www.cneqv.gov.pt/cneqv/en/	Oviedo Convention on Human Rights and Biomedicine (2001)		Various: http://www.cneqv.gov.pt/cneqv/en/opinions/
<i>Drugs and Devices</i>	<i>Drugs</i> 1. National Institute of Pharmacy and Medicines: http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH 2. Ethics Commission for Clinical Research (CEIC): http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/CEIC	1. Approval of the Applicable Legal Standards for the Conduct of Clinical Trials of Medicines for Human Use, Law No. 46/2004 2. Approval of the Composition, Operations, and Financing of the Ethics Commission for Clinical Research, Decree No. 57/2005 (Portuguese):	Decree-Law No. 102/2007 of April 2	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/portaria_57-2005.pdf		
	<i>Devices</i>			
	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
<i>Research Injury</i>		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
<i>Privacy/Data Protection</i>	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		
<i>Genetic Research</i>	Ministry of Health: http://www.portugal.gov.pt/en/the-ministries/ministry-of-health.aspx	Law 12/2005		
<i>Embryos, Stem Cells, and Cloning</i>	National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/	1. 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)		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 the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Romania%20definitive%20Updated.pdf				
<i>General</i>	Ministry of Health (MOH) (Romanian): http://www.ms.ro/	Oviedo Convention on Human Rights and Biomedicine (2001)	Ordinance No. 57/16.08.2002 (2002): http://www.research.ro/ro/articol/1021/despre-ancs-legislatie	

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Drugs and Devices</i>	1. Ministry of Health (MOH) (Romanian): http://www.ms.ro/ 2. National Agency for Medicines and Medical Devices: http://www.anm.ro/anmdm/en/index.html 3. National Bioethics Committee for Medicines and Medical Devices (Romanian): http://www.bioetica-medicala.ro/		MOH: Order 904/25 July 2006 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 Access: http://www.anm.ro/anmdm/med_legislatie_ordine.htm	MOH: Guideline for Clinical Trials in Pediatric Populations (CPMP/ICH/2711/99) (1999)
<i>Research Injury</i>	1. National Agency for Medicines and Medical Devices: http://www.anm.ro/anmdm/en/index.html 2. National Bioethics Committee for Medicines and Medical Devices (Romanian): http://www.bioetica-medicala.ro/	Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
<i>Privacy/Data Protection</i>	National Supervisory Authority for Personal Data Processing: http://www.dataprotection.ro/index.jsp?page=documents&lang=en	Law No. 667/2001 On the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data: http://www.dataprotection.ro/servlet/ViewDocument?id=174		
<i>Human Biological Materials</i>	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/Lege-2006-95.pdf	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	
<i>Embryos, Stem Cells, and Cloning</i>		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2001)		

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Law No. 301 from 2004 Penal Code – Chapter IV – Crimes and Felonies Regarding Genetic Manipulation: http://www.codpenal.ro/legislatie/document/lege-301-din-2004-codul-penal-capitol-4-crime-si-delicte-privind-manipularea-genetica-1260-63259.html		
Russia				
For an overview of human subject protections in Russia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Russia%20definitive%20Updated.pdf				
<i>General</i>	1. Ministry of Healthcare of the Russian Federation (MOH): http://www.rosminzdrav.ru 2. Federal Service on Surveillance in Healthcare (Roszdravnadzor): (Russian): http://www.roszdravnadzor.ru/ 3. Russian Committee for Bioethics: http://www.bioethics.ru/eng/	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): http://acto-russia.org/en/index.php?option=com_content&task=view&id=105 3. Federal Law #FZ55 “On Introduction of Changes in FZ “On Foundations of Protection of Citizens’ Health in the Russian Federation” with Regard to Questions of Organization of Medical Aid Administered in the Course of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation” (2015) (Russian): http://www.consultant.ru/document/cons_doc_LAW_176159		MOH: 1. Ministry of Health Order 433n (July 10, 2015) “On Adoption of the Regulations on Organization of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation (Including Order of Patients’ Assignment for Administering Such Medical Help), Standard Form of Protocol for Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment, and Rehabilitation” (Russian): http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=183847 2. Ministry of Health Order 435h (July 10, 2015) “On Ethics Committee of the Ministry of Health of the Russian Federation” (Russian): http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=183677
<i>Drugs and Devices</i>	1. Council of Ethics of the Ministry of Healthcare of the Russian Federation (MOH) (Russian): http://www.grls.rosminzdrav.ru/ 2. Association of Clinical Trials Organizations: http://acto-russia.org/en/ 3. Federal Agency for Technical Regulation and Metrology (GOST):	Federal Law #61FZ “On Circulation of Medicines” (2011): http://acto-russia.org/files/zakon_ob_obr_ls_en.docx	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.	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Main">http://www.gost.ru/wps/portal/pages.en>Main		774n (August 31, 2010) “On Council of Ethics” (Russian): http://www.rg.ru/2013/02/22/etika-dok.html 3. Ministry of Health Order of April 1, 2016 № 200n "On Approval of the Rules of Good Clinical Practice: http://acto-russia.org/files/prikaz_200n.docx 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	
<i>Research Injury</i>		Federal Law #61FZ “On Circulation of Medicines” (2011), Art. 38-44: http://acto-russia.org/files/zakon_ob_obr_ls_en.docx		
<i>Privacy/Data Protection</i>		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 Personal Data (2006): http://base.garant.ru/12148567/		
<i>Genetic</i>	Interdepartmental 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	
<i>Embryos, Stem Cells, and Cloning</i>		Federal Law #30-FZ “On Introduction of Change in Art. 1		

Country	Key Organizations	Legislation	Regulations	Guidelines
		of the Federal Law “On Temporary Ban on Human Cloning” (2010) (Russian): http://base.garant.ru/184467/		
San Marino				
<i>General</i>	San Marino Bioethics Committee (Italian): http://www.sanita.sm/online/home/comitato-bioetica/comitato-sammarinese-di-bioetica.html	Oviedo Convention on Human Rights and Biomedicine (1998)		
<i>Research Injury</i>		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1999)		
Serbia				
For an overview of human subject protections in Serbia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRportFiles/Serbia%20definitive%20Updated.pdf				
<i>Drugs and Devices</i>	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: 1. 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 2. Regulation on Amendment to Regulation on Content of Requests and Documents for Approval of Clinical Trials and Procedures for Conducting Clinical Trials, Official Gazette of RS, 60/2016 (Serbian): http://www.alims.gov.rs/ciril/files/2016/07/KI-60-16-izmena.pdf	
<i>Research Injury</i>	1. Ministry of Health (MOH): http://www.zdravlje.gov.rs/index.php? 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: 1. 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/	

Country	Key Organizations	Legislation	Regulations	Guidelines
			archive/files/lat/pdf/zakoni/2013/1283-13Lat.pdf	
<i>Privacy/Data Protection</i>	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 (Serbian): http://www.minrzs.gov.rs/files/doc/porodica/ostali/Zakon%20o%20zastiti%20podataka%20o%20licnosti.pdf		
<i>Genetics</i>	Ministry of Health (MOH): http://www.zdravlje.gov.rs/index.php?	Law on the Prevention and Diagnosis of Genetically Conditioned Diseases, Genetically Caused Anomalies and Rare Diseases (2015) (Serbian): http://www.parlament.gov.rs/upload/archive/files/lat/pdf/zakoni/2015/2245-14%20lat.pdf		
<i>Embryos, Stem Cells, and Cloning</i>	National Health Insurance Fund: http://www.rfzo.rs/	1. Law on Organ Transplantation, Official Gazette No. 72/2009 (Serbian): http://www.rfzo.rs/download/zakoni/Zakon_transplantacija.pdf 2. Law on Cells and Tissues, Official Gazette No. 72/2009 (Serbian): http://www.rfzo.rs/download/zakoni/Zakon_celije_tkiva.pdf		
Slovakia				
For an overview of human subject protections in Slovakia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Slovakia%20definitive%20Updated.pdf				
<i>General</i>	1. Ministry of Health (Slovak): http://www.health.gov.sk/ 2. Institute of Medical Ethics and Bioethics: http://www.bioethics.sk/	1. Oviedo Convention on Human Rights and Biomedicine (1998) 2. Additional Protocol on Biomedical Research (2005) 3. Act No. 576/2004 Coll on Health Care, as amended by Acts No. 350/2005, 282/2006, 662/2007, 345/2009 Coll.		
<i>Drugs and Devices</i>	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.	

Country	Key Organizations	Legislation	Regulations	Guidelines
			148/2009 Coll.	
<i>Research Injury</i>		Law 277/1994 on Health Care, Section 44		
<i>Privacy/Data Protection</i>	Office for Personal Data Protection: https://dataprotection.gov.sk/uouu/en	Act No. 428/2002 Coll. on Protection of Personal Data, as amended by Act No. 90/2005 Coll.		
<i>Human Biological Materials</i>		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	
<i>Embryos, Stem Cells, and Cloning</i>		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (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 the EFGCP Report: <http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Slovenia%20definitive%20Updated.pdf>
Note: All websites and documents are in Slovenian.

<i>General</i>	Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/	1. Oviedo Convention on Human Rights and Biomedicine (1998) 2. Additional Protocol on Biomedical Research (2006) 3. Patient Rights Act, Official Gazette No. 15/2008: http://www.uradni-list.si/1/objava.jsp?sop=2008-01-0455 4. Mental Health Act, Official Gazette Nos. 77/2008 and 46/2015: http://www.uradni-list.si/1/objava.jsp?sop=2008-01-3448 and http://www.uradni-list.si/1/objava.jsp?sop=2015-01-1881		Slovenian Code of Medical Deontology, Articles 47-50 (1997)
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Country	Key Organizations	Legislation	Regulations	Guidelines	
<i>Drugs and Devices</i>	<i>Drugs</i>	<p>1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/</p> <p>2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/</p>	<p>1. Medicinal Products Act, Official Gazette No. 17/2014: http://www.uradni-list.si/1/objava.jsp?sop=2014-01-0539</p> <p>2. Rules on Clinical Testing of Medicinal Products, Official Gazette, No. 54/2006: http://www.uradni-list.si/1/objava.jsp?sop=2006-01-2304</p>	<p>NMEC:</p> <p>1. Statutory Notes (1998)</p> <p>2. On the Ethical Review of Phase IV Clinical Studies (2003): http://www.mf.uni-lj.si/kme-nmec/Docu/Ocenjevanje_klin_studij_IV_faze.pdf</p> <p>3. Rules on the Composition, Duties, Responsibilities, and Working Methods of the Commission for Medical Ethics, Official Gazette Nos. 30/1995 and 69/2009</p>	
	<i>Devices</i>	<p>1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/</p> <p>2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/</p>	<p>1. Act on Medical Devices, Official Gazette No. 98/2009: http://www.uradni-list.si/1/objava.jsp?sop=2009-01-4284</p> <p>2. Rules on Medical Devices, Official Gazette Nos. 37/2010 and 66/2012: http://www.uradni-list.si/1/objava.jsp?sop=2010-01-1842 and http://www.uradni-list.si/1/objava.jsp?sop=2012-01-2622</p>		
<i>Research Injury</i>	<p>Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/</p>	<p>1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1999)</p> <p>2. Additional Protocol Concerning Biomedical Research, Article 13, CETS No. 195 (2007)</p>			
<i>Privacy/Data Protection</i>	<p>Information Commissioner of the Republic of Slovenia: http://www.ip-rs.si/</p>	<p>Personal Data Protection Act No. 94/2007: http://www.uradni-list.si/1/objava.jsp?sop=2007-01-4690</p>			
<i>Human Biological Materials</i>	<p>1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/</p> <p>2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/</p>	<p>1. Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin (2006)</p> <p>2. Act on Quality and Safety of</p>	<p>On Interventions into the Human Corpse Which are Not Part of the Routine Autopsy and on Handling with Biologic Material of Human Origin (2004): http://kme-</p>	<p>Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999)</p>	

Country	Key Organizations	Legislation	Regulations	Guidelines
		<p>Human Tissues and Cells, for the Purposes for Medical Treatment, Official Gazette No. 61/2007: http://www.uradni-list.si/1/objava.jsp?sop=2007-01-3297</p> <p>3. Rules on Donation and Procurement of Human Tissues and Cells, Official Gazette Nos. 70/2008, 67/2014, and 79/2014</p> <p>4. Act Regulating the Collection and Transplantation of Human Body Parts for the Purposes of Medical Treatment, Official Gazette No. 56/2015: http://www.uradni-list.si/1/objava.jsp?sop=2015-01-2357</p>	<p>nmec.sazu.si/Docu/O_truplih_Isis.pdf</p>	
<i>Genetic</i>	<p>Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/</p>	<p>Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes (2009)</p>		
<i>Embryos, Stem Cells, and Cloning</i>	<p>1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/</p> <p>2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/</p>	<p>1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998)</p> <p>2. Infertility Treatment and Procedures of Biomedically-Assisted Procreation Act, Official Gazette No. 70/2000, Section 9 (Slovenian): http://www.uradni-list.si/1/objava.jsp?sop=2000-01-3307</p> <p>3. Act on Quality and Safety of Human Tissues and Cells, for the Purposes for Medical Treatment, Official Gazette No. 61/2007 (Slovenian): http://www.uradni-list.si/1/objava.jsp?sop=2007-01-3297</p>		

Country	Key Organizations	Legislation	Regulations	Guidelines
		3297 4. Rules on Donation and Procurement of Human Tissues and Cells, Official Gazette Nos. 70/2008, 67/2014, and 79/2014		
Spain For an overview of human subject protections in Spain, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Spain%20definitive%20Updated.pdf Note: Many of the 17 Spanish autonomous regions have their own laws and regulations on human subject protections.				
<i>General</i>	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.catedraderechoygenoma humano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
<i>Drugs and Devices</i>	<i>Drugs</i> Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/investigacionClinica/medicamentos/home.htm	1. Royal Decree 1015/2009: Drug Availability for Special Purposes (Spanish): http://www.boe.es/boe/dias/2009/07/20/pdfs/BOE-A-2009-12002.pdf 2. Royal Decree 577/2013, Regulating Pharmacovigilance in Human Use Medicines: http://www.boe.es/diario_boe/txt.php?id=BOE-A-2013-8191 3. 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 4. Royal Decree 1/2015 of Guarantees and Rational Use of Medicines and Health Products (Spanish): http://www.boe.es/diario_boe/txt.php?id=BOE-A-2015-10000	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/rc1_2007_270.pdf 2. Order SCO/362/2008 that Modifies Order SCO/256/2007 (Spanish): http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rc1_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	

Country	Key Organizations	Legislation	Regulations	Guidelines
		<p>p?id=BOE-A-2015-8343 5. Royal Decree 1090/2015, of 4 December, Regulating Clinical Trials with Medicinal Products, Ethics Committees for Investigation with Medicinal Products and the Spanish Clinical Studies Registry: https://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/Royal-Decree-1090-2015_4-December.pdf</p>		
	<i>Devices</i>			
	<p>Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/investigacionClinica/productosSanitarios/home.htm</p>	<p>Royal Decree 1591/2009, Regulating Sanitary Devices: http://www.ont.es/infesp/Legislacion/RD_1591_2009.pdf</p>	<p>Various (Spanish): http://www.aemps.es/actividad/pschb/implantables1.htm#circulares</p>	
<i>Research Injury</i>	<p>Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/home.htm</p>	<p>1. Law 14/2007 on Biomedical Research, Article 18: http://www.catedraderechogenoma humano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.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 3. Royal Decree 1090/2015, of 4 December, Regulating Clinical Trials with Medicinal Products, Ethics Committees for Investigation with Medicinal Products and the Spanish Clinical Studies Registry: https://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/Royal-Decree-1090-2015_4-December.pdf</p>		
<i>Privacy/Data Protection</i>	<p>Spanish Data Protection Authority (Spanish): https://www.agpd.es/portalweb/index-ides-</p>	<p>1. Organic Law 15/1999 of December 13 on the Protection of Personal Data:</p>	<p>1. Royal Decree 1720/2007 (Spanish): http://www.davara.com/documentos/</p>	

Country	Key Organizations	Legislation	Regulations	Guidelines
	idphp.php	<p>http://www.legislationline.org/documents/id/9044</p> <p>2. Law 14/2007 on Biomedical Research, Title I, Article 5: http://www.catedraderechogenoma humano.es/images/novedades/SpainLawonBiomedicalResearchEnglish.pdf</p>	<p>relacionados/proteccion/RD_1720-2007_english.pdf</p> <p>2. Royal Decree of 19 January 2008</p>	
<i>Human Biological Materials</i>	<p>Ministry of Health and Consumption: http://www.msc.es/en/home.htm</p>	<p>1. Royal Decree 2070/1999 of December 30, Regarding Activities of Collection and Clinical Use of Human Organs for Organ Transplants and Tissues</p> <p>2. Royal Decree 1301/2006 of November 10 Regarding the Use of Cells and Human Tissue</p> <p>3. Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: http://www.catedraderechogenoma humano.es/images/novedades/SpainLawonBiomedicalResearchEnglish.pdf</p> <p>4. Royal Decree 1716/2011 on Biobanks: http://www.comitedebioetica.es/normativa/docs/RD%201716_2011_de%20autorizacion%20y%20funcionamiento%20de%20los%20biobancos.pdf</p> <p>5. Royal Decree 9/2014, of July 4 on Quality and Security Rules Regarding Donating, Gathering, Evaluation, Processing, Storage, Preservation and Distribution of Human Cells and Tissues and Rules Regarding Coordination and Functioning of their Use in Human Beings: http://www.boe.es/buscar/doc.php?id=BOE-A-2014-7065</p>	<p>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</p>	
<i>Genetic</i>	<p>Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US</p>	<p>Law 14/2007 of July 3 on Biomedical Research, Title I, Articles 6-9; Title V:</p>		

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.catedraderechoygenoma humano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
<i>Embryos, Stem Cells, and Cloning</i>	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 4. National Stem Cell Bank: http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/fd-organizacion/fd-estructura-directiva/fd-subdireccion-general-investigacion-terapia-celular-medicina-regenerativa/fd-centros-unidades/banco-nacional-lineas-celulares.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 3. Law 14/2007 of July 3 on Biomedical Research, Title III: http://www.catedraderechoygenoma humano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf 4. Royal Decree 1527/2010, of November 15, By Which the Guarantees Commission for the Donation and Use of Human Cells and Tissues and Registration Research Projects is Regulated: http://www.boe.es/diario_boe/txt.php?id=BOE-A-2010-18654		
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				
<i>General</i>	Central Ethical Review Board: http://www.epn.se/en/start/	Act No. 460 on the Ethical Review of Research Involving Humans (2003): http://www.epn.se/media/2348/the_ethical_review_act.pdf	1. Ordinance No. 615 Concerning the Ethical Vetting of Research Involving Humans (2003): http://www.epn.se/media/1204/2003_615.pdf 2. Statute No. 2007:1068 Containing Instructions for the Central Ethical Review Boards (2007): http://www.epn.se/media/1202/1068.pdf 3. Statute No. 2007:1069 Containing Instructions for	Information for Research Participants

Country	Key Organizations	Legislation	Regulations	Guidelines
			Regional Ethical Review Boards (2007): http://www.epn.se/media/1203/1069.pdf	
	Swedish Research Council: http://www.vr.se/english		Regulations and General Counsel VRFS 2012:1 on Ethical Vetting of Human Subjects Research (Swedish): http://www.vr.se/download/18.7ef696713734483870280/1340207447175/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 (2011): https://publikationer.vr.se/en/product/good-research-practice/
<i>Drugs and Devices</i>	<i>Drugs</i>			
	Medical Products Agency: https://lakemedelsverket.se/english/	1. Pharmaceuticals Act No. No 2015:315 (Swedish): http://www.notisum.se/rnp/sls/lag/20150315.htm 2. Pharmaceuticals Ordinance 2015:458 (Swedish): http://www.notisum.se/rnp/sls/lag/20150458.htm	MPA Regulations on Clinical Trials in Humans -- LVFS 2011:19 (Swedish): http://www.lakemedelsverket.se/upload/lvfs/LVFS_2011_19.pdf	
	<i>Devices</i>			
	Medical Products Agency: http://www.lakemedelsverket.se/english/product/Medical-devices/Clinical-Investigations/	1. Swedish Medical Devices Act (SFS 1993:584): http://www.notisum.se/rnp/sls/lag/19930584.htm 2. Medical Devices Ordinance (SFS1993:876)	Swedish Implementation of Directive 93/42/EEC -- LVFS 2003:11 with Amendment LVFS 2004:11: https://lakemedelsverket.se/upload/lvfs/konsoliderade/LVFS_2003_11_konsoliderad_tom_2011_13.pdf	
<i>Privacy/Data Protection</i>	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 (Swedish): 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 (Swedish): 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 (2003) (Swedish): http://www.vr.se/download/18.6b2f98a910b3e260ae28000342/Personuppgifter_7.pdf
<i>Human Biological Materials</i>	1. National Board of Health and Welfare (SOS):	1. Biobanks in Medical Care Act No. 297 (2002):	SOS: Consolidated regulations	SRC: Research Ethics Guidelines for Using

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.socialstyrelsen.se/english 2. Swedish Research Council (SRC): http://www.vr.se/english 3. BBMRI Sweden: http://bbmri.se/en/	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	(Swedish): http://www.socialstyrelsen.se/sosfs/2002-11	Biobanks (Swedish) (2003) http://www.vr.se/download/18.6b2f98a910b3e260ae28000350/Riktlinjer_Biobanker_11.pdf
<i>Genetic Research</i>	1. Ministry of Health and Social Affairs: http://www.sweden.gov.se/sb/d/2061 2. National Board of Health and Welfare: 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)
<i>Embryos, Stem Cells, and Cloning</i>	Swedish Research Council (SRC): http://www.vr.se/english	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 (Swedish): 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 (Swedish): http://www.socialstyrelsen.se/sosfs/2009-32	SRC: Guidelines for Ethical Vetting of Human Stem Cell Research (2004) (Swedish): http://www.vr.se/download/18.6b2f98a910b3e260ae28000362/human_stamcellsforskning_16.pdf
Switzerland				
For an overview of human subject protections in Switzerland, see: http://kofam.ch/en/home/				
<i>General</i>	1. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en 2. Federal Office of Public Health, Portal for Human Research (FOPH): http://kofam.ch/en/home/ 3. National Advisory Commission on Biomedical Ethics (NEK-CNE): http://www.nek-cne.ch/en/homepage/ 3. Swiss Ethics Committees on Research Involving Humans: 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/Coimmun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=EN 2. Federal Constitution of the Swiss Confederation of 18 April, 1999, RS 101, Article 118b: http://www.admin.ch/opc/en/classified-compilation/19995395/index.html	1. Ordinance of 20 September 2013 on Clinical Trials in Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO), RS 810.305: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html 3. Ordinance of 20 September	Swiss Clinical Trial Organisation, 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

Country	Key Organizations	Legislation	Regulations	Guidelines
		<p>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</p>	<p>2013 on Organizational Aspects of the Human Research Act (HRA Organisational Ordinance, OrgO-HRA), RS 810.308: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html</p>	
<i>Drugs and Devices</i>	<i>Drugs</i>	<p>1. Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), RS 812.21, Articles 53-54: http://www.admin.ch/opc/en/classified-compilation/20002716/index.html</p> <p>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</p>	<p>1. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Article 7 (2014): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html</p> <p>2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO), RS 810.305: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html</p> <p>3. Ordinance of 20 September 2013 on Organisational Aspects of the Human Research Act (HRA Organisational Ordinance, OrgO-HRA), RS 810.308, Articles 6-7: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html</p>	
	<i>Devices</i>	<p>1. Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), RS 812.21, Articles 1-2, 45-67: https://www.admin.ch/opc/en/classified-compilation/20002716/index.html</p> <p>2. Federal Act of 30 September 2011 on Research involving Human Beings, (Human</p>	<p>1. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Article 7: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html</p> <p>2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials</p>	<p>Swissmedic Guide to the Regulation of Medical Devices: https://www.swissmedic.ch/medizynprodukte/0287/index.html?lang=en</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
		Research Act, HRA), RS. 810.30: https://www.admin.ch/opc/en/classified-compilation/20061313/index.html	Ordinance, ClinO), RS 810.305 articles 20, 32, 37, 42-45 and Annexes 1, 3 and 4: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html 3. Ordinance of 20 September 2013 on Organisation Aspects of the Human Research Act (HRA Organisation Ordinance, OrgO-HRA), RS 810.308, Articles 6-7: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html	
<i>Clinical Trials Registry</i>	Swiss National Clinical Trials Portal: http://kofam.ch/en/swiss-clinical-trials-portal/	Federal Act on Research Involving Human Beings, Articles 56, 64, 65, and 67 (2011)		
<i>Research Injury</i>	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: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	1. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Articles 8, 12, 13, and 15, and Annexes 1-2: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance ClinO), RS 810.305, Articles 7, 10-13, 25, and 71, and Annexes 2-3: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html	
<i>Privacy/Data Protection</i> Note: Most Swiss cantons have enacted laws regarding data collection in the public sector that are	Federal Data Protection and Information Commissioner (FDPIC): http://www.edoeb.admin.ch/index.html?lang=en	1. Federal Act of 19 June 1992 on Data Protection (FADP), RS 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	1. 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, 24-34, 37-39, 41, and 44-45, and Annex 2: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html	

Country	Key Organizations	Legislation	Regulations	Guidelines
similar to the FADP.		810.30, Articles 2, 3, 8, 16-18, 31-35, 41-45, 47, 49, 58-60, and 63: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305 Articles 5, 7, 9, 12, 16-18, and 25, and Annexes 2-3: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html	
<i>Human Biological Materials</i>	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, 41-43, 45, 47, 49, and 63: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	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 Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301 Articles 5 - 8, 10, 15, 21, 24-30, 33-34, 37 - 39, 41, 44-45 and Annex 2): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 3. 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	SAMS: Biobanks: Obtainment, Preservation and Utilization of Human Biological Material (2006): http://www.samw.ch/en/Ethics/Guidelines/Archive.html
<i>Genetic Research</i>	Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en	1. Federal 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 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	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 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	

Country	Key Organizations	Legislation	Regulations	Guidelines
		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	3. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials 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	
<i>Embryos, Stem Cells, and Cloning</i>	Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE): http://www.nek-cne.ch/en/homepage/	<i>Embryos in Vivo:</i> 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 <i>Others:</i> Federal Act of 19 December 2003 on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), RS 810.31: http://www.admin.ch/opc/en/classified-compilation/20022165/index.html	<i>Embryos in Vivo:</i> 1. 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 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 3. 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	NEK-CNE: 1. Pre-Implantation Genetic Diagnosis, 2007/9 (French): 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 (German): http://www.nek-cne.ch/fileadmin/nek-cne-dateien/Themen/Stellungnahmen/PID_II_d.pdf Access: http://www.nek-cne.ch/en/topics/opinions/
Ukraine				
<i>General</i>	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		
<i>Drugs and Devices</i>	1. Ministry of Health of Ukraine State Expert Center: http://www.dec.gov.ua 2. National Academy of Sciences Bioethics Committee: http://biomed.nas.gov.ua/index-	1. Ministry of Health Act On Procedure of Clinical Trials and Basic Statute of Ethics Commission 23.09/2009 No. 690 (2014) (Ukrainian): http://zakon5.rada.gov.ua/laws/show/	1. Ukrainian Ministry of Health Order No. 95 About Approval of Documents Related to the Quality Assurance of Medicines (2009) (Ukrainian): http://zakon5.rada.gov.ua/rada/show/	Bioethics Committee: 1. Information Letters on Ethics Questions of Clinical Trials and Implementation of Medicines (2006) 2. Ethics Expertise of Clinical Trials Medicines (2007)

Country	Key Organizations	Legislation	Regulations	Guidelines
	en/bioethics-committee	w/z1010-09 2. On Medicines, Articles 7 and 8 No. 123/96BP (2014): http://zakon4.rada.gov.ua/laws/show/z123/96-%D0%B2%D1%80	v0095282-09 2. Ministry of Health Act 14.12.2009 N 944 on Approval of the Clinical Trial and Expertise of Clinical Trials (Ukrainian): http://zakon4.rada.gov.ua/laws/show/z0053-10	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
<i>Research Injury</i>	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/z123/96-%D0%B2%D1%80		
<i>Privacy/Data Protection</i>	1. State Service of Ukraine on Personal Data Protection 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 of Personal Data Act, 01.06.2010 with changes from 13.05.2014: http://zakon3.rada.gov.ua/laws/show/z2297-17		
<i>Human Biological Materials</i>	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	1. Cabinet Ministry of Ukraine Act № 286 on 02.03.2016 License Conditions on Providing Activities of Banks of Cord Blood and Other Human Tissues and Cells (Ukrainian): http://zakon2.rada.gov.ua/laws/show/z286-2016-%D0%BF 2. Ministry of Health Act 20.04.12 No. 276 On Approving the List of Human Tissues and Cells, Allowing the Use of Banks of Cord Blood and Other Human Tissues and Cells (Ukrainian):	Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) with Changes from 23.09.2009 No. 690 (Ukrainian): http://zakon1.rada.gov.ua/laws/show/z1206-07	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://zakon3.rada.gov.ua/laws/show/z1124-12		
<i>Genetic Research</i>	Academy of Medical Sciences of the Ukraine			Medical and Ethical Guidelines for Genetic Investigations in Humans
<i>Embryos, Stem Cells, and Cloning</i>	1. National Academy of Sciences Bioethics Committee: http://biomed.nas.gov.ua/index-en/bioethics-committee 2. Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	1. Act on the Banning of Human Reproductive Cloning (2004) (Ukrainian): http://zakon0.rada.gov.ua/laws/show/2231-15 2. Act on Organs and Other Human Materials Transplantology No. 1007-XIV (2007) (Ukrainian): http://zakon0.rada.gov.ua/laws/show/1007-14	1. Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) (Ukrainian): 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	

United Kingdom

Unless otherwise noted, all laws, regulations, and guidelines listed for England apply to the entire United Kingdom.

For an overview of clinical research regulations in the United Kingdom, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=226

<i>General</i>	<i>England:</i>			
	Health Research Authority (HRA): http://www.hra.nhs.uk/	Care Act (2014): http://www.legislation.gov.uk/ukpga/2014/23/contents/enacted/data.htm		1. Directory of HRA Guidance: http://www.hra.nhs.uk/resources/ 2. Integrated Research Application System: https://www.myresearchproject.org.uk/
	Department of Health (DH): https://www.gov.uk/government/organizations/department-of-health	1. Mental Capacity Act (2005) (England and Wales only): http://www.legislation.gov.uk/ukpga/2005/9/contents 2. Health and Social Care Act (2012): http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted	1. Research Governance Framework for Health and Social Care (2005) https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition 2. Governance Arrangements for NHS Research Ethics Committees (2012): https://www.gov.uk/government/publications/health-research-ethics-committees-governance-arrangements	
	Medical Research Council (MRC):			1. Good Research Practice: Principles and

Country	Key Organizations	Legislation	Regulations	Guidelines
	https://www.mrc.ac.uk/			Guidelines (2012): http://www.mrc.ac.uk/research/research-policy-ethics/good-research-practice/ 2. Research Involving Human Participants in Developing Societies (2004): http://www.mrc.ac.uk/news/publications/research-involving-human-participants-in-developing-societies/ 3. Medical Research Involving Children (2004): https://www.mrc.ac.uk/documents/pdf/medical-research-involving-children/ 4. Medical Research involving Adults Who Cannot Consent (2007): http://www.mrc.ac.uk/documents/pdf/medical-research-involving-adults-who-cannot-consent/
	<i>Scotland:</i>			
	1. NHSScotland, Chief Scientist Office (CSO): http://www.cso.scot.nhs.uk/ 2. NHS Research Scotland: http://www.nhsresearchscotland.org.uk/	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.hmsso.gov.uk/legislation/scotland/ssi2002/20020190.htm	CSO: 1. Research Governance Framework for Health and Community Care (2006): http://www.cso.scot.nhs.uk/wp-content/uploads/2013/02/RGF-Second-Edition-February-06.pdf
	<i>Wales:</i>			
	Health and Care Research Wales: http://www.healthandcareresearch.gov.wales/			Research Governance Framework for Health and Social Care in Wales Second Edition (2009): http://www.wales.nhs.uk/sites3/Documents/952/Research%20Governance%20Framework%202009%20%28English%291.pdf
	<i>Northern Ireland:</i>			
	1. Department of Health, Social Services and Public Safety: http://www.dhsspsni.gov.uk/ 2. Office for Research Ethics Committees Northern Ireland: http://www.hscbusiness.hscni.net/orecni.htm			Research Governance Framework for Health and Social Care (Northern Ireland) (2007): https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/research-governance-framework-2007.pdf
<i>Drugs and Devices</i>	<i>Drugs</i>			
	1. Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/organizations/medicines-and-healthcare-products-regulatory-agency 2. Administration of Radioactive Substances Advisory Committee	Medicines Act (1968): http://www.legislation.gov.uk/ukpga/1968/67/contents	1. Ionising Radiation (Medical Exposure) Regulations IR(ME)R (2000): http://www.legislation.gov.uk/uksi/2000/1059/contents/made <i>Amended by:</i> IR(ME)R (Amendment)	Consultation Letter on the Medicines for Human Use (Clinical Trials) Regulations (2003): http://www.mhra.gov.uk/home/groups/comms-ic/documents/websitesources/con007629.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
	(ARSAC) (UK): https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee		Regulations (2006) http://www.legislation.gov.uk/ukxi/2006/2523/contents/made IR(ME)R (Amendment) Regulations (2011) http://www.legislation.gov.uk/ukxi/2011/1567/made 2. Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004): http://www.legislation.gov.uk/ukxi/2004/1031/contents/made 3. Amendment Regulations (SI 2006/1928) http://www.legislation.gov.uk/uksi/2006/1928/contents/made 4. 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/ukxi/2006/2984/pdfs/ukxi_20062984_en.pdf 5. SI 2008 No.941 The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment Regulations 2008: http://www.legislation.gov.uk/ukxi/2008/941/contents/made	
	Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk			Guidelines for Phase I Clinical Trials (2012): http://www.abpi.org.uk/our-work/library/guidelines/Pages/phase-1-trials-2012.aspx
	National Institute for Health Research: http://www.nihr.ac.uk/			Clinical Trials Toolkit: http://www.ct-toolkit.ac.uk/
	Health Research Authority (HRA): http://www.hra.nhs.uk/			Clinical Trials of Investigational Medicinal Products (CTIMPs) – Resource page: http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/clinical-trials-of-investigational-medicinal-products/

Country	Key Organizations	Legislation	Regulations	Guidelines
	<p><i>Devices</i></p> <p>Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/collections/regulatory-guidance-for-medical-devices</p> <p>Health Research Authority (HRA): http://www.hra.nhs.uk/</p>		<p>1. Medical Devices Regulations (2002): http://www.opsi.gov.uk/si/si2002/20020618.htm</p> <p>2. Medical Devices (Amendment) Regulations 2008 No 2936: http://www.legislation.gov.uk/ukSI/2008/2936/contents/made</p>	<p>1. Clinical Trials for Medical Devices: https://www.gov.uk/government/collections/regulatory-guidance-for-medical-devices</p> <p>2. Notify MHRA About a Clinical Investigation for a Medical Device: https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device</p> <p>Medical Devices Guidance: http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/medical-devices-research-2/</p>
<i>Clinical Trials Registry</i>	<p>1. ISRCTN: http://www.isrctn.com/</p> <p>2. Health Research Authority (HRA): http://www.hra.nhs.uk/</p>			<p>ISRCTN: FAQs: http://www.isrctn.com/page/faqs</p> <p>HRA: Transparency, Registration, and Publication: http://www.hra.nhs.uk/resources/during-and-after-your-study/transparency-registration-and-publication/</p>
<i>Research Injury</i>	<p>Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency</p> <p>Department of Health (DH): https://www.gov.uk/government/organisations/department-of-health</p> <p>Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk</p>		<p>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.legislation.gov.uk/ukSI/2004/1031/contents/made</p>	<p>NHS Indemnity Arrangements for Clinical Negligence Claims in the NHS: www.nhs.uk/clinicalnegligence/claims/Documents/NHS%20Indemnity.pdf</p> <p>1. Insurance and Compensation in the Event of Injury in Phase I Clinical Trials (2012): http://www.abpi.org.uk/our-work/library/guidelines/Pages/clinical-trials-insurance.aspx</p> <p>2. Clinical Trial Compensation Guidelines (2014): http://www.abpi.org.uk/our-work/library/guidelines/Pages/ct-compensation.aspx</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
	Association of the British Healthcare Industry (ABHI): http://www.abhi.org.uk/			Clinical Investigations Compensation Guidelines (2014): http://www.abhi.org.uk/multimedia/groups/clinical-investigations/ci_compensationguidelines.doc
Privacy/Data Protection	<i>United Kingdom:</i>			
	Information Commissioner's Office: https://ico.org.uk/	Data Protection Act (1998): http://www.legislation.gov.uk/ukpga/1998/29/contents		
	Medical Research Council (MRC): http://www.mrc.ac.uk/			1. Personal Information in Medical Research (2003): http://www.mrc.ac.uk/documents/pdf/personal-information-in-medical-research/ 2. Use of Personal Health Information in Medical Research General Public Consultation Final Report (2007) https://www.mrc.ac.uk/documents/pdf/the-use-of-personal-health-information-in-medical-research-june-2007/ 3. Data and Tissues Tool Kit: http://www.dt-toolkit.ac.uk/home.cfm
	<i>England and Wales:</i>			
1. Health Research Authority (HRA) (England): http://www.hra.nhs.uk/ 2. Confidentiality Advisory Group (CAG): http://www.hra.nhs.uk/about-the-hra/our-committees/section-251	Health Service (Control of Patient Information) Regulations 2002 (HS (CPI) Regs): http://www.legislation.gov.uk/uksi/2002/1438/made?view=plain		1. Ethical Review of Research Databases: http://www.hra.nhs.uk/documents/2013/09/ethical-review-of-research-databases.pdf 2. Section 251 and the Confidentiality Advisory Group (CAG): http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/	
Human Biological Materials	<i>United Kingdom:</i>			
	Human Tissue Authority (HTA): http://www.hta.gov.uk/	1. Human Tissue Act (2004): http://www.legislation.gov.uk/ukpga/2004/30/contents (Applies to England, Wales, and Northern Ireland. Section 45 also applies in Scotland.) 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 (Applies to England, Wales, and Northern Ireland.)		Guidance for Professionals: https://www.hta.gov.uk/guidance-professionals

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Statutory Instrument 2006 No. 1659: The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (<i>Different provisions apply to England, Wales, Northern Ireland, and/or Scotland.</i>): http://www.legislation.gov.uk/uksi/2006/1659/contents/made		
	Medical Research Council (MRC): https://www.mrc.ac.uk/			Human Tissue and Biological Samples for Use in Research (2014)
	<i>Scotland:</i> Healthcare Improvement Scotland: http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/human_tissue_banks.aspx	Human Tissue (Scotland) Act 2006: http://www.legislation.gov.uk/asp/2006/4/contents		
	Medical Research Council (MRC): https://www.mrc.ac.uk/			1. Human Tissue and Biological Samples for Use in Research (2014) http://www.mrc.ac.uk/publications/browse/human-tissue-and-biological-samples-for-use-in-research/ 2. Data and Tissues Tool Kit: http://www.dt-toolkit.ac.uk/home.cfm
<i>Genetics Research</i>	1. Public Health Genetics Foundation: http://www.phgfoundation.org/ 2. Gene Therapy Advisory Committee: http://www.hra.nhs.uk/resources/applying-to-recs/gene-therapy-advisory-committee-gtac/			
<i>Embryos, Stem Cells, and Cloning</i>	1. Human Fertilisation and Embryology Authority: http://www.hfea.gov.uk/ 2. Human Tissue Authority (HTA): https://www.hta.gov.uk/regulated-sectors	1. Human Fertilisation and Embryology Act (1990): http://www.legislation.gov.uk/ukpga/1990/37/contents 2. HFE Act (2008): http://www.hfea.gov.uk/134.html	Human Fertilisation and Embryology Regulation and Chronology: http://www.hfea.gov.uk/1319.html	HFEA Code of Practice 8th Edition (2016): http://www.hfea.gov.uk/docs/CoP_2016_Final.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
ASIA/PACIFIC				
Australia				
<i>General</i>	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Australian Research Council (ARC): http://www.arc.gov.au	National Health and Medical Research Council Act 1992 (2014): http://www.comlaw.gov.au/Details/C2014C00364	National Health and Medical Research Regulation 2016: https://www.legislation.gov.au/Details/F2016L00682	NHMRC: 1. Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) http://www.nhmrc.gov.au/guidelines/publications/e52 2. Keeping Research on Track: A Guide for Aboriginal and Torres Strait Islander Peoples about Health Research Ethics (2006): http://www.nhmrc.gov.au/guidelines/publications/e65 NHMRC, ARC, and Universities Australia: 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 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72
	Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS): http://aiatsis.gov.au/			Guidelines for Ethical Research in Australian Indigenous Studies (2012): http://www.aiatsis.gov.au/research/ethics/GERAIS.html
<i>Drugs and Devices</i>	<i>Drugs</i> Therapeutic Goods Administration (TGA): http://www.tga.gov.au	Therapeutic Goods Act 1989 (2016): https://www.legislation.gov.au/Details/C2016C00269	Therapeutic Goods Regulations 1990 (2016): https://www.legislation.gov.au/Details/F2016C00801	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): https://www.tga.gov.au/sites/default/files/clinical-trials-handbook.pdf NHMRC, ARC, and UA: 1. National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72

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
	<i>Devices</i>			
	Therapeutic Goods Administration: http://www.tga.gov.au/industry/devices.htm	Therapeutic Goods Act 1989 (2016): https://www.legislation.gov.au/Details/C2016C00269	Therapeutic Goods (Medical Devices) Regulations 2002 (2016): https://www.legislation.gov.au/Details/F2016C00801	Australian Regulatory Guidelines for Medical Devices (ARGMD) (2011): http://www.tga.gov.au/industry/devices-argmd.htm
<i>Clinical Trials Registry</i>	1. National Health and Medical Research Council and the Department of Industry, Innovation, and Science: https://www.australianclinicaltrials.gov.au/ 2. Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/			1. National Statement on Ethical Conduct in Human Research, 3.3.12 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72 2. FAQs: http://www.anzctr.org.au/Faq.aspx
<i>Research Injury</i>	1. Therapeutic Goods Administration (TGA): http://www.tga.gov.au/ 2. Medicines Australia https://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): https://www.tga.gov.au/publication/note-guidance-good-clinical-practice Medicines Australia: Industry Standard Compensation Guidelines, Section 4 (2012): https://medicinesaustralia.com.au/policy/clinical-trials/indemnity-and-compensation-guidelines/ NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research. Paragraphs 3.3.24 and 3.3.25 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72
<i>Privacy/Data Protection</i>	Office of the Australian Information Commissioner: http://www.oaic.gov.au/	Privacy Act 1988 (2016): https://www.legislation.gov.au/Details/C2016C00838	1. Australian Privacy Principles Guidelines (2014): http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles 2. Guidelines under Section 95 of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr1	1. Australian Privacy Principles Guidelines (2014): http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles 2. Guidelines under Section 95 of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr1
	Note: All Australian states and territories have privacy/data protection laws: http://www.oaic.gov.au			

Country	Key Organizations	Legislation	Regulations	Guidelines
/privacy/other-privacy-jurisdictions/state-and-territory-privacy-law			3. Guidelines Approved under Section 95A of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr2 4. Guidelines Approved under Section 95AA of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr3 5. Privacy Regulation 2013 (2016): https://www.legislation.gov.au/Details/F2016C00599	3. Guidelines Approved under Section 95A of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr2 4. Guidelines Approved under Section 95AA of the Privacy Act 1988 (2014): http://www.nhmrc.gov.au/guidelines/publications/pr3
<i>Human Biological Materials</i> 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 (TGA): http://www.tga.gov.au/			NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research (2015): 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
<i>Genetic Research</i>	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 (2016): https://www.legislation.gov.au/Details/C2016C00792	Gene Technology Regulations 2001 (2016): https://www.legislation.gov.au/Details/F2016C00615	NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research, Chapter 3.5 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72
<i>Embryos, Stem Cells, and Cloning</i>	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. National Health and Medical Research Council: Embryo Research Licensing Committee https://www.nhmrc.gov.au/about/nhmrc-committees/embryo-research-licensing-committee	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 (2015): 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

Country	Key Organizations	Legislation	Regulations	Guidelines
Bangladesh				
<i>General</i>	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			
<i>Drugs and Devices</i>	Bangladesh Directorate of Drug Administration: http://www.dgda.gov.bd/	1. The Drugs Act (1964) 2. Drugs (Control) Ordinance 1982, Ordinance No. VIII: http://bdlaws.minlaw.gov.bd/pdf_parrt.php?id=623		
<i>Human Biological Materials</i>	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			Guidelines for Transfer of Human Biological Materials Abroad for Research Purposes (2004)
Burma (Myanmar)				
<i>General</i>	1. Department of Medical Research (DMR): http://www.dmrlm.gov.mm/ 2. Ministry of Health National Ethics Committee on Clinical Research: www.moh.gov.mm			DMR: Operational Guidelines for Institutional Ethical Review Committee (2005)
<i>Drugs and Devices</i>	Ministry of Health, Food and Drug Administration: http://www.fdamyanmar.gov.mm/index.php/en/	National Drug Law (1992)		
<i>Human Biological Materials</i>		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 an overview of clinical research regulations in China, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=44				
<i>General</i>	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC): http://en.nhfpc.gov.cn 2. Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/	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 NHFPC, CFDA, and State Administration of TCM: Management Guidelines for Conducting Clinical Research at Medical/Health Institutions (Mandarin) (2014):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.nhfpc.gov.cn/yzygj/s3593g/201410/9bd03858c3aa41ed8aed17467645fb68.shtml
<i>Drugs and Devices</i>	<p data-bbox="346 199 420 224"><i>Drugs</i></p> <p data-bbox="346 228 716 310">Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/</p>	<p data-bbox="783 228 1136 367">Drug Administration Law of the People's Republic of China (2001): http://eng.sfda.gov.cn/WS03/CL0766/61638.html</p>	<ol data-bbox="1161 228 1528 1159" style="list-style-type: none"> 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): http://eng.sfda.gov.cn/WS03/CL0768/61646.html 4. Provisions for Drug Registration (2007): 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 	<ol data-bbox="1556 228 2009 570" style="list-style-type: none"> 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
	<p data-bbox="346 1170 436 1195"><i>Devices</i></p> <p data-bbox="346 1200 716 1281">Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/</p>		<p data-bbox="1161 1200 1528 1370">CFDA and NHFPC: Good Clinical Practice on Medical Device Clinical Trials (2016) (Mandarin): http://www.sda.gov.cn/WS01/CL0053/148101.html</p>	<p data-bbox="1556 1200 2009 1370">CFDA: Guiding Principles of the Clinical Trail Technology on In Vitro Diagnostic (IVD) Reagents (2014) (Mandarin): http://www.sda.gov.cn/WS01/CL0087/106241.html</p> <p data-bbox="1556 1406 2009 1490">Templates for Medical Device Clinical Trials (Mandarin): 1. Ethical Review Application And</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
				Review Form 2. Informed Consent Form 3. CRF Template 4. Protocol Template 5. Report Template 6. Required Documents List Access: http://www.sda.gov.cn/WS01/CL0087/148126.html
<i>Clinical Trials Registry</i>	Chinese Clinical Trial Registry: http://www.chictr.org.cn/index.aspx			FAQs: http://www.chictr.org.cn/question.aspx
<i>Privacy/Data Protection</i>	<i>Hong Kong:</i> Office of the Privacy Commissioner for Personal Data: http://www.pcpd.org.hk	Personal Data (Privacy) Ordinance (2013): http://www.legislation.gov.hk/blis.pdf.nsf/6799165D2FEE3FA94825755E0033E532/B4DF8B4125C4214D482575EF000EC5FF/\$FILE/CAP_486_e_b5.pdf		
<i>Research Injury</i>	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Chinese Food and Drug Administration (CFDA): 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/qijys/s3581/200804/b9f1bfec4ab344ec892e68097296e2a8.shtml 2. Regulations on Recall of Medical Devices (Interim), Article 37 (2011) (Mandarin): http://www.gov.cn/flfg/2011-06/13/content_1882686.htm CFDA and NHFPC: Good Clinical Practice on Medical Device Clinical Trials (2016), Articles 10, 22, 33, and 48; (Mandarin): http://www.sda.gov.cn/WS01/CL0053/148101.html	SFDA: 1. Guideline on Vaccine Clinical Trials, Part 6 (2004) (Mandarin): http://www.sda.gov.cn/WS01/CL0844/10307.html 2. Guideline on Ethical Review of Drug Clinical Trials, Appendix 1, Section 6.10 (2010) (Mandarin): http://www.sda.gov.cn/WS01/CL0058/55613.html
<i>Genetic Research</i>	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/		NHFPC and MOST: 1. Interim Measures for the Administration of Human Genetic Resources (1998) (Mandarin): http://www.most.gov.cn/bszn/new/rly	MOST: Service Guidelines for the Collection, Selling, Export and Admission Application of Human Genetic Resources

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of Science and Technology of the People's Republic of China (MOST): http://www.most.cn/eng/		c/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	(2015) (Mandarin): http://www.most.gov.cn/tztg/201507/t20150703_120547.htm
<i>Embryos, Stem Cells, and Cloning</i>	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/s3589/201308/0c579ba3babf47de8f0e811810d438a2.shtml NHFPC and CFDA Interim Measures for the Management of Stem Cell Clinical Research (2015) (Mandarin): http://www.nhfpc.gov.cn/qjjys/s3581/201508/28635ef99c5743e294f45e8b29c72309.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
	<i>Hong Kong:</i> Legislative Council of the Hong Kong Special Administrative Region of the People's Republic of China: http://www.legco.gov.hk/index.htm		Human Reproductive Technology Ordinance, Chapter 561 (2007): http://www.legislation.gov.hk/blis_pdf.nsf/6799165D2FEE3FA94825755E0033E532/795C7496522C8237482575EF001B5A45?OpenDocument&bt=0	
India				
For an overview of the clinical research regulations in India, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=100				
<i>General</i>	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 (no date):

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Drugs and Devices</i>	<i>Drugs</i>			http://www.icmr.nic.in/ethics_SOP.pdf
	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	Schedule Y of the Drugs and Cosmetics Act (2005): http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf	DCGI: 1. Good Clinical Practices for Clinical Research in India (2001): http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf 2. Permission for Clinical Trials: General Statutory Rules 63(E) 3. Ethics Committee Registration: General Statutory Rules 72(E) 4. A/V Consent – General Statutory Rules 611 (E) (2015) 5. Phytopharmaceutical Drug: General Statutory Rules 918(E) 6. Exemption for Academic Research and Animal Toxicity: General Statutory Rules 313(E) (2016)	ICMR: Ethical Guidelines for Biomedical Research on Human Participants: Chapter IV. Drug Trials and Vaccine Trials (2006)
	<i>Devices</i>			
	1. Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): http://cdsco.nic.in 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Drugs & Cosmetics Act, 1940 (2005): http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf	1. Rules: Schedule D & K (2014): http://www.cdsco.nic.in/writereaddata/GSR%20690(E),%2025th%20Sep,%202014.pdf 2. Rules: Schedule MIII (2016): http://www.cdsco.nic.in/writereaddata/GSR%20640%20(E)%20dated%2029_06_2016%20-%20Copy.pdf	ICMR: Ethical Guidelines for Biomedical Research on Human Participants: Clinical Trials with Surgical Procedures/Medical Devices: http://www.icmr.nic.in/ethical_guidelines.pdf
<i>Clinical Trials Registry</i>	Clinical Trials Registry – India: http://ctri.nic.in/			Clinical Trials Registry – India: FAQs: http://ctri.nic.in/Clinicaltrials/faq.php Office of Drugs Controller General: Registration of Clinical Trial in ICMR Clinical Trial Registry: http://www.cdsco.nic.in/writereaddata/CTRegistration.doc
<i>Research Injury</i>	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	Drugs & Cosmetics Act, 1940 (2005): http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf	DCGI: Compensation: General Statutory Rules 53 (E): http://www.manupatra.com/manufeed/contents/PDF/634969625902580076.pdf	ICMR: Ethical Guidelines for Biomedical Research on Human Participants: Chapter III, Section VI (2006): http://www.icmr.nic.in/ethical_guidelines.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			<p>CDSCO:</p> <p>1. Compensation and Reporting of SAE timelines GSR 889 (E) 2014 (scroll down to see English version): http://www.cdsc.nic.in/writereaddata/Notification%20on%20Compensation%20on%20clinical%20trial%20(1).pdf</p> <p>2. Compensation in Case of Injury or Death During Clinical Trial, Schedule Y, Appendix XII (2013) (Scroll down to see English version): http://www.pharmamedtechbi.com/~media/Supporting%20Documents/Pharmasia%20News/2013/February/Clinical%20Trials%20Compensation%20Guidelines.pdf</p> <p>3. Compensation Formula for Clinical Trial Injury Other than Death (2014) : http://www.cdsc.nic.in/writereaddata/ORDER%20and%20Formula%20to%20Determine%20the%20quantum%20of%20compensation%20in%20the%20cases%20of%20Clinical%20Trials%20related%20serious%20Adverse%20Events(SAEs)%20of%20Injury%20other%20than%20Death.pdf</p>	
<i>Human Biological Materials</i>	Ministry of Health and Family Welfare: http://mohfw.nic.in/		Govt. of India Office Memorandum (O.M. No.19015/53/1997 - IH Pt.) 19 th 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 (1997): http://icmr.nic.in/ihd/ihd.htm
<i>Genetic Research</i>	1. Department of Biotechnology (DBT): http://dbtindia.nic.in/ 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Environmental Protection Act (1986)		DBT: 1. Recombinant DNA Safety Guidelines (1990) 2. Ethical Policies on the Human Genome, Genetic Research, and Services (2002) ICMR: Ethical Guidelines for Biomedical Research on Human Subjects: Statement

Country	Key Organizations	Legislation	Regulations	Guidelines
				of Specific Principles for Human Genetics and Genomics Research (2006): http://www.icmr.nic.in/ethical_guidelines.pdf
<i>Embryos, Stem Cells, and Cloning</i>	1. Department of Biotechnology (DBT): http://dbtindia.nic.in/ 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			DBT and ICMR: Guidelines for Stem Cell Research, Revised (2013): http://www.icmr.nic.in/guidelines/NGSCR%202013.pdf
Indonesia				
<i>General</i>	Ministry of Health, National Institute of Health Research and Development: http://indonesia.go.id/en	Indonesian Health Act No. 23/1992 Section on Health Research, Article 69	Regulation No. 39/1995 on Health Research & Development	National Guidelines on Ethics in Health Research (2003)
<i>Drugs and Devices</i>	National Agency of Drug and Food Control: http://www.pom.go.id/index.php/home/en		Guidelines on Good Clinical Practice (2001)	
<i>Human Biological Materials</i>			National Guidelines on Use of Stored Biological Materials (2005)	
Japan				
<i>General</i>	1. Ministry of Education, Culture, Sports, Science, and Technology (MEXT): http://www.mext.go.jp/english/ 2. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html			MEXT and MHLW: Ethics Guidelines for Medical and Health Research Involving Human Subjects (2014): http://www.lifescience.mext.go.jp/files/pdf/n1500_01.pdf
<i>Drugs and Devices</i>	<i>Drugs</i>			
	1. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html 2. Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html	Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (Revised Pharmaceutical Affairs Law, (2015) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html	MHLW: Ministerial Ordinance on Good Clinical Practice for Drugs (2014) (Japanese): http://law.e-gov.go.jp/htmldata/H09/H09F03601000028.html	MHLW: Guidance for the Ministerial Ordinance on Good Clinical Practice for Drugs (2013) (Japanese): http://www.jmacct.med.or.jp/plan/files/gcp130404.pdf
	<i>Devices</i>			
	1. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html 2. Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/english/index.html	Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (Revised Pharmaceutical Affairs Law, (2015) (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	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

Country	Key Organizations	Legislation	Regulations	Guidelines
		html	English (2009 version): https://www.pmda.go.jp/files/000153732.pdf	
<i>Clinical Trials Registry</i>	Japan Primary Registries Network:* http://rctportal.niph.go.jp/			FAQs (Japanese): http://rctportal.niph.go.jp/qa
<i>Privacy/Data Protection</i>	Personal Information Protection Commission: http://www.ppc.go.jp/en/	Amended Act on the Protection of Personal Information (2015): http://www.ppc.go.jp/files/pdf/280222_amendedlaw.pdf		
<i>Research Injury</i>	Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html	Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (2015) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html	1. Ministerial Ordinance on Good Clinical Practice for Drugs, Article 14 (2014): http://www.pmda.go.jp/files/000152996.pdf 2. Ministerial Ordinance on Good Clinical Practice for Medical Devices, Article 14 and 23 (2014)	Ethics Guidelines for Medical and Health Research Involving Human Subjects, Chapter 2, No. 5, 1-(3) and No. 6, 2-(2) (2014): http://www.lifescience.mext.go.jp/files/pdf/n1500_01.pdf
<i>Human Biological Materials</i>	Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html			On Research and Development Utilizing Human Tissues Removed by Surgery and Other Procedures (1998) (Japanese) http://www1.mhlw.go.jp/shingi/s9812/s1216-2_10.html
<i>Genetic Research</i>	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): http://www.mext.go.jp/english/ 3. Ministry of Health, Labor, and Welfare (MHLW): http://www.mhlw.go.jp/english/index.html 4. Ministry of Economy, Trade, and Industry (METI): http://www.meti.go.jp/english/			CSTP: Fundamental Principles of Research on the Human Genome (2000): http://www.lifescience.mext.go.jp/files/pdf/43137.pdf MEXT, MHLW, and METI: Ethics Guidelines for Human Genome/Gene Analysis Research (2014) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1432_01_01.pdf English (2008 version): http://www.lifescience.mext.go.jp/files/pdf/n796_00.pdf MHLW: Guidelines for Clinical Research in Gene Therapy and Others (2015) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/150812_rinrison.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Embryos, Stem Cells, and Cloning</i>	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): http://www.mext.go.jp/english/	1. Act on Regulation of Human Cloning Techniques (2014) (Japanese): http://law.e-gov.go.jp/htmldata/H12/H12HO146.html English (2000 version): http://www.cas.go.jp/jp/seisaku/hourei/data/htc.pdf 2. Act on Safety of Regenerative Medicine (2013) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000030847.pdf	1. Ordinance for Enforcement of Act on Regulation of Human Cloning Techniques (2009): http://www.lifescience.mext.go.jp/files/pdf/n1564_01.pdf 2. Ordinance for Enforcement of Act on Safety of Regenerative Medicine (2014) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000065532.pdf	CSTP: Fundamental Philosophy on Handling of Human Embryo (2004) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/6_28.pdf MEXT: 1. Guidelines on the Handling of a Specified Embryo (2009): http://www.lifescience.mext.go.jp/files/pdf/n1564_02.pdf 2. Guidelines on the Derivation of Human Embryonic Stem Cells (2014): http://www.lifescience.mext.go.jp/files/pdf/n1553_01.pdf 3. Guidelines on the Distribution and Utilization of Human Embryonic Stem Cells (2014): http://www.lifescience.mext.go.jp/files/pdf/n1553_02.pdf 4. Guidelines on Research on Producing Germ Cells from Human Induced Pluripotent Stem Cells or Human Tissue Stem Cells (2015) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1492_01.pdf English (2010 version): http://www.lifescience.mext.go.jp/files/pdf/n1567_02.pdf MEXT and MHLW: Ethical Guidelines for Research on Assisted Reproductive Technology to Develop Human Fertilized Embryos (2015) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1492_03.pdf English (2010 version): http://www.lifescience.mext.go.jp/files/pdf/n1567_01.pdf
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				
<i>General</i>	Ministry of Healthcare and Social Development, Central Commission on Research Ethics:			1. Guidelines on Ethics in Health Research. (2007) 2. Local Ethics Committees: Policy, Rules

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.mzsr.gov.kz/en			and Procedures (2014) 3. Guidelines on Ethics in Biomedical Research (2015)
<i>Drugs and Devices</i>	Ministry of Healthcare and Social Development, Control Committee of Medical and Pharmacy Activity: https://www.mzsr.gov.kz/en/taxonomy/term/674	Code of the Republic of Kazakhstan "On People's Health and the Health Care System" (18.09.2009 No.193-IV), Articles 74 and 180 (2015): http://online.zakon.kz/Document/?doc_id=30479065#pos=1;-8	1. Order of the MHSD of the RK Dated 12.11.2009 No. 697 on the Approval of Regulations on the Medical-Biological Experiments, Preclinical (Non-Clinical) and Clinical Trials 2. Order of the MHSD of the RK dated 19.11.2009 No. 744 on the Approval of Regulations on the Conduct of Clinical Trials and/or Trials on Pharmaceutical and Drug Products, Medical Devices, and Medical Equipment 3. Order of the MHSD Dated 20.05.2014 No.272 on the Approval of Regulations on the Implementation of the New Methods of Diagnostic, Treatment, and Rehabilitation	Guidelines on Clinical Trials in Kazakhstan (2003)
<i>Privacy/Data protection</i>	Ministry of Healthcare and Social Development: http://www.mzsr.gov.kz/en	Code of the Republic of Kazakhstan "On People's Health and the Health Care System" (18.09.2009 No.193-IV), Article 24 (2015): http://online.zakon.kz/Document/?doc_id=30479065#pos=1;-8		
Korea				
Note: All documents are in Korean.				
<i>General</i>	Ministry of Health and Welfare: http://english.mw.go.kr/	Bioethics and Safety Act No. 12844 (2014): http://www.law.go.kr/lsInfoP.do?lsiSeq=162503#0000	1. Enforcement Decree of Bioethics and Safety Act No. 25840 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=164877#0000 2. Enforcement Rule of Bioethics and Safety Act No. 283 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=166794#0000	

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Drugs and Devices</i>	<i>Drugs</i>	1. Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/ 2. Ministry of Food and Drug Safety (MFDS) (2013): http://www.mfds.go.kr/eng	Pharmaceutical Affairs Act No. 13320 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=170970#0000 MOHW: 1. Enforcement Decree of Pharmaceutical Affairs Act No. 26544 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=175075#0000 2. Enforcement Rule of Pharmaceutical Affairs Act No. 337 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=173445#0000 MFDS: Enforcement Rule of Medicinal Product Safety No. 1194 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=175272#0000	MFDS: 1. Guidelines on Human Research Protection Program (2014): http://www.mfds.go.kr/index.do?x=0&searchkey=title:contents&mid=1161&searchDivision=&searchClass=&searchword=hrpp&y=0&searchSubDivision=&pageNo=1&seq=7877&cmd=v 2. IND regulations No 2015-22 (2015): http://www.law.go.kr/admRulLsInfoP.do?admRulSeq=2100000018982
	<i>Devices</i>			
	Ministry of Food and Drug Safety: http://www.mfds.go.kr/eng	Medical Device Act No. 13320 (2015): http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyCode=125&page=1&mode=view&boardSeq=67030	1. Enforcement Decree of the Medical Device Act (2015): http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyCode=125&page=1&mode=view&boardSeq=66026 2. Enforcement Regulations of the Medical Device Act (2105): http://www.mfds.go.kr/eng/eng/index.do?nMenuCode=46&searchKeyCode=125&page=1&mode=view&boardSeq=66026	
<i>Clinical Trials Registry</i>	Clinical Research Information Service: https://cris.nih.go.kr/cris/en/use_guide/cris_introduce.jsp			
<i>Research Injury</i>	Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng		Enforcement Rule of Medicinal Product Safety No. 1194 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=175272#0000	Guidelines for Clinical Trial Indemnity and Its Process (2013): http://www.mfds.go.kr/index.do?x=0&searchkey=title:contents&mid=1161&searchDivision=&searchClass=&searchword=입상시험피해자&y=0&searchSubDivision=&pageNo=1&seq=7205&cmd=v
<i>Privacy/Data Protection</i>	1. Ministry of the Interior (MOI): http://www.moi.go.kr/eng/a01/engMain.do	MOI: Personal Information Protection Act No.13423 (2015):	MOI: 1. Enforcement Rules to Personal Information Protection Act No. 1	MOI: Guidelines on Standard Personal Information Protection (2011):

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/	http://www.law.go.kr/lsInfoP.do?lsiSeq=173223#0000 MOHW: Bioethics and Safety Act No. 12844 (2014): http://www.law.go.kr/lsInfoP.do?lsiSeq=162503#0000	(2014): http://www.law.go.kr/lsInfoP.do?lsiSeq=163788#0000 2. Enforcement Decrees to Personal Information Protection Act No. 26140 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=169145#0000 MOHW: Enforcement Rule of Bioethics and Safety Act No. 283 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=166794#0000	http://www.law.go.kr/admRulLsInfoP.do?admRulSeq=2000000064994
<i>Human Biological Materials</i>	1. Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/ 2. Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng	MOHW: Bioethics and Safety Act No. 12844 (2014): http://www.law.go.kr/lsInfoP.do?lsiSeq=162503#0000	1. Enforcement Decree of Bioethics and Safety Act No. 25840 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=164877#0000 2. Enforcement Rule of Bioethics and Safety Act No. 283 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=166794#0000	MFDS: Guideline for human tissue management (2014): http://www.mfds.go.kr/index.do?searchkey=title:contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=인체&x=0&mid=1161&pageNo=1&seq=8094&cmd=v
<i>Genetic Research</i>	1. Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/ 2. Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng	MOHW: MOHW: Bioethics and Safety Act No. 12844 (2014): http://www.law.go.kr/lsInfoP.do?lsiSeq=162503#0000	MOHW: MOHW: 1. Enforcement Decree of Bioethics and Safety Act No. 25840 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=164877#0000 2. Enforcement Rule of Bioethics and Safety Act No. 283 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=166794#0000	MFDS: Guideline on the Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (2005): http://www.mfds.go.kr/index.do?searchkey=title:contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=유전자&x=0&mid=1161&pageNo=2&seq=4662&cmd=v
<i>Embryos, Stem Cells, and Cloning</i>	1. Ministry of Health and Welfare (MOHW): http://english.mw.go.kr/ 2. Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng	Bioethics and Safety Act No. 12447 (2014)	MOHW: 1. Enforcement Decree of Bioethics and Safety Act No. 25840 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=164877#0000 2. Enforcement Rule of Bioethics and Safety Act No. 283 (2015): http://www.law.go.kr/lsInfoP.do?lsiSeq=166794#0000	MFDS: Guideline on Sponsor-Investigator Trials of Cell Therapy Products for Academic Purpose (2014): http://www.mfds.go.kr/index.do?searchkey=title:contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=세포&x=0&mid=1161&pageNo=1&seq=8730&cmd=v

Country	Key Organizations	Legislation	Regulations	Guidelines
Kyrgyzstan				
Note: All websites and documents are in Russian.				
<i>General</i>	1. Government of the Kyrgyz Republic: http://www.gov.kg 2. Ministry of Health: http://www.med.kg 3. Ministry of Justice of the Kyrgyz Republic: http://cbd.minjust.gov.kg	1. Constitution of Kyrgyz Republic, Chapter II, Article 22 (2010): http://www.gov.kg/?page_id=263 2. Law on Health Protection of the Kyrgyz Republic (Sept. 1, 2005, No. 6): Articles 34 and 73: http://www.pharm.kg/ru/legislation	1. Code of Professional Ethics of Medical Worker of the Kyrgyz Republic (2004): http://www.med.kg/index.php/dokumenty-2/kodex-prof-etiki-2.html 2. Code of Administrative Responsibility of the Kyrgyz Republic №114 from 04.08.1998r. (Updated June 11, 2008 N 115 and June 23, 2008 N 136) Chapters 7 and 10: http://www.pharm.kg/ru/legislation/	
<i>Drugs and Devices</i>	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee 3. Pharmaceutical Union of Kyrgyzstan, Ethics Committee: http://farmunion.kg/o-nas/eticheskij-komitet/	Law on Drugs of the Kyrgyz Republic (30.04.2003 No. 91) Chapter VII, Articles 25-29 (2003): http://www.pharm.kg/ru/legislation	DDMDP: 1. National Standard KMC 1195:2010: Medical Devices: Rules for Clinical Trials (2010): http://www.pharm.kg/ru/legislation/ 2. 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/	
<i>Research Injury</i>	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 Drugs of the 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 for Clinical Trials, Paragraphs 3, 4, and 6 (2010): http://www.pharm.kg/ru/legislation/	
<i>Human Biological Materials</i>	1. Ministry of Health, Department of Drug and Medical Devices Provision: http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on Health Protection of the Kyrgyz Republic (09.01.2005 No. 6): Article 39: http://www.pharm.kg/ru/legislation	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/	
<i>Privacy/Data Protection</i>	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 Health Protection of the Kyrgyz Republic (09.01.2005 No. 6): Article 91: http://www.pharm.kg/ru/legislation	DDMDP: 1. National Standard KMC 1195:2010: Medical Devices, Rules for Clinical Trials, Paragraphs 3, 4, and 6 (2010): http://www.pharm.kg/ru/legislation/ 2. Technical Regulations on the Safety of Medical Products for	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Medical Application, Approved by the Governmental Order #74 from February 1, 2012: http://www.pharm.kg/ru/legislation/	
Malaysia				
<i>Drugs and Devices</i>	National Committee for Clinical Research: http://www.nccr.gov.my/			1. Guidelines for Ethical Review of Clinical Research or Research Involving Human Subjects (2006): http://www.nccr.gov.my/view_file.cfm?fileid=16 2. Malaysian Guidelines of Good Clinical Practice (2011): http://www.nih.gov.my/mrec/documents/Malaysian%20GCP.pdf
<i>Privacy/Data Protection</i>		Act 709: Personal Data Protection Act 2010: http://www.pdp.gov.my/images/LAWS_OF_MALAYSIA_PDPA.pdf		
<i>Human Biological Materials</i>	National Committee for Clinical Research: http://www.nccr.gov.my/	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 September 2009	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
<i>Genetic Research</i>	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
<i>Embryos, Stem Cells and Cloning</i>	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				
<i>General</i>	Nepal Health Research Council, Ethical Review Board: http://www.nhrc.org.np/	Nepal Health Research Council Act, 1991, Section 3(1): http://www.lawcommission.gov.np/en/documents/2015/08/nepal-health-research-council-act-2047-1991.pdf		1. National Ethical Guidelines for Health Research in Nepal and Standard Operating Procedure (2011): http://nhrc.org.np/guidelines 2. Guidelines for Institutional Review Committees (IRCs) for Health Research in Nepal (2016): http://nhrc.org.np/guidelines
<i>Drugs and Devices</i>	Nepal Health Research Council: http://www.nhrc.org.np/			National Guidelines on Clinical Trials with the Use of Pharmaceutical Products (2005): http://nhrc.org.np/guidelines

Country	Key Organizations	Legislation	Regulations	Guidelines
New Zealand				
<i>General</i>	<p>1. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/</p> <p>2. National Ethics Advisory Committee (NEAC): http://www.neac.health.govt.nz/</p> <p>3. Ministry of Health (MOH): http://www.moh.govt.nz/</p> <p>4. Health and Disability Commissioner (HDC): http://www.hdc.org.nz/</p> <p>5. Health and Disability Ethics Committees: http://www.ethics.health.govt.nz/</p> <p>6. Ministry of Business, Innovation and Employment: http://www.mbie.govt.nz/</p>	<p>1. Health Research Council Act 1990, Sections 24 and 25</p> <p>2. New Zealand Bill of Rights Act, Article 10 (1990)</p> <p>3. Health and Disability Commissioner Act 1994</p> <p>4. New Zealand Public Health and Disability Act 2000, Section 16</p> <p>5. Accident Compensation Act 2001</p> <p>Access: All New Zealand acts, bills, and regulations can be found here: http://www.legislation.govt.nz/</p>	<p>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</p>	<p>HRC: 1. Guidelines for Researchers on Health Research Involving Māori (2010)</p> <p>2. HRC Guidance Notes on Research Ethics (2014)</p> <p>3. Pacific Health Research Guidelines (2014)</p> <p>Access: http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval</p> <p>NEAC: 1. Goals, Objectives, and Desired Outcomes of an Ethical Review System (2003)</p> <p>2. Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (2012)</p> <p>3. Ethical Guidelines for Intervention Studies (2012)</p> <p>Access: http://www.neac.health.govt.nz/moh.nsf/indexm/neac-resources-publications</p> <p>MOH: Standard Operating Procedures for Health and Disability Ethics Committees (2012): http://www.ethics.health.govt.nz/operating-procedures</p>
<i>Drugs and Devices</i>	<i>Drugs</i>			
	<p>1. New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz</p> <p>2. Medicines New Zealand: http://www.medicinesnz.co.nz/</p> <p>3. Health Research Council (HRC), Standing Committee on Therapeutic Trials: http://www.hrc.govt.nz/about-us/committees/standing-committee-therapeutic-trials-scott</p>	<p>1. Accident Compensation Act 2001, Section 32 (2010)</p> <p>2. Medicines Act 1981(2012)</p>	<p>Medsafe: Medicines Regulations 1984 http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM95668.html</p>	<p>Medsafe: Good Clinical Research Practice and Obtaining Approval for Clinical Trials (2013): http://www.medsafe.govt.nz/medicines/clinical-trials.asp</p> <p>Medicines New Zealand: Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial (2015): https://ethics.health.govt.nz/system/files/documents/pages/2015-medicines-new-zealand-</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
				compensation-guidelines.pdf
	<i>Devices</i>			
	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
<i>Clinical Trials Registry</i>	Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/			FAQs: http://www.anzctr.org.au/Faq.aspx
<i>Privacy/Data Protection</i>	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	
<i>Human Biological Materials</i>	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
<i>Genetic Research</i>	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)		
<i>Embryos, Stem Cells, and Cloning</i>	1. Ministry of Health: http://www.moh.govt.nz/ 2. Advisory Committee on Assisted Reproductive Technology (ACART): http://acart.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

Country	Key Organizations	Legislation	Regulations	Guidelines
	3. Ethics Committee on Assisted Reproductive Technology (ECART): http://ecart.health.govt.nz/			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				
<i>General</i>	Pakistan Medical Research Council, National Bioethics Committee (NBC): http://nbcPakistan.org.pk/			Various: http://nbcPakistan.org.pk/?page_id=61
<i>Drugs and Devices</i>	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
<i>Embryos, Stem Cells, and Cloning</i>	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				
<i>General</i>	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): http://www.doh.gov.ph/ 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/	PHREB: Memorandum: Registration and Accreditation of all Ethics Review Committees in the Philippines (2015): http://www.ethics.healthresearch.ph/index.php/orders-and-memorandums/10-orders-and-memos/226-phreb-memo 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 2. Administrative Order 001 Series 2008: Registration of All Ethics Review Committee at the PHREB (2008):	PHREB: National Ethical Guidelines for Health Research (2011): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:public-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
			<p>http://ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/111-ao-001</p> <p>3. PCHRD Special Order No. 146 Series of 2013: Reactivation and Amendment of Functions of the National Ethics Committee http://nec.pchrd.dost.gov.ph/components/com_ethics/pdf_files/nec_so.pdf</p> <p>DOH: Department Circular No. 2015-0059: Research Ethics Review Committees Registration and Accreditation: http://www.ethics.healthresearch.ph/index.php/orders-and-memorandums/10-orders-and-memos/217-doh-circular</p> <p>CHED: 1. Memo 34 Series 2007: Policy Requirement in the Conduct of Health Research involving Human Subjects: http://www.ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/130-ched-memorandum 2. Memorandum from the CHED Chairperson: Philippine Health Research Ethics Board – Registration and Accreditation of All Ethics Review Committees: http://www.ethics.healthresearch.ph/index.php/orders-and-memorandums/10-orders-and-memos/225-ched-memo</p>	
<i>Drugs and Devices</i>	<i>Drugs</i> Food and Drug Administration (FDA): http://www.fda.gov.ph/		<p>FDA: 1. 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</p>	Ethical Guidelines for Clinical Trials on Drugs, Devices, and Diagnostics (2006): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:public-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
			<p>Order No. 47-a) (2001)</p> <p>2. FDA Circular 2015-026: Adoption of the ICH Harmonised Tripartite Guideline, Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products Q5C: http://www.fda.gov.ph/attachments/article/118205/FC2013-026.pdf</p> <p>DOST, DOH, CHED, and UPM: Joint Memorandum Order 001 Series of 2012: http://www.ethics.healthresearch.ph/index.php/component/content/article/10-orders-and-memos/215-joint-memo-01</p> <p>DOST, DOH, CHED, and UPM-NIH: Joint Administrative Order No. 001: The Implementing Rules and Regulations of Republic Act 10532 Otherwise Known as “The Philippine National Health Research System Act of 2013:” http://www.ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/214-implementing-rules-of-pnhrs</p>	
	<p><i>Devices</i></p> <p>Food and Drug Administration: http://www.fda.gov.ph/</p>			<p>FDA Guidelines: Regulation of Clinical Trials in the Philippines http://www.pcrp.org.ph/pdf/GuidelinesversionLR.PDF</p>
<i>Clinical Trials Registry</i>	<p>Philippine Health Research Registry: http://registry.healthresearch.ph/</p>			<p>FAQs: http://registry.healthresearch.ph/index.php?option=com_content&view=article&id=7&Itemid=185</p>
<i>Research Injury</i>	<p>1. Department of Science and Technology (DOST): http://www.dost.gov.ph/</p> <p>2. Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph</p>			<p>PHREB: National Ethical Guidelines for Health Research, pages 19-20 (2011): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:public-ethics-guidelines-2011</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Embryos, Stem Cells, and Cloning</i>	Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph			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:public-ethics-guidelines-2011
Singapore				
<i>General</i>	<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 1. Medical Registration Act (Cap. 174) (1985): http://statutes.agc.gov.sg/ 2. Human Biomedical Research Bill No. 25/2015: http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev.loadTime;page=0;query=Id%3A1f615627-01d3-4250-a720-de776cd4f794;rec=0 	MOH: Directive of June 25, 1998: Hospital Ethics Committees	MOH: <ol style="list-style-type: none"> 1. Governance Framework for Human Biomedical Research (2007): https://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Human%20Biomedical%20Research/2007/Governance%20Frwk%20for%20HBR_14-12-07_formatted.pdf 2. Operational Guidelines for IRBs (2007): https://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Human%20Biomedical%20Research/2007/IRB%20Operational%20Guidelines_14-12-07_formatted.pdf 3. Code of Ethical Practice in Human Biomedical Research (2009): https://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Human%20Biomedical%20Research/2009/Code%20of%20Ethical%20Practice%20in%20Human%20Biomedical%20Research_Apr%2009_final.pdf NMEC: Ethical Guidelines on Research Involving Human Subjects (1997): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines/1997/nmec_ethical_guidelines_on_research_involving_human_subjects.html BAC: <ol style="list-style-type: none"> 1. Research Involving Human Subjects: Guidelines for IRBs (2004): http://www.bioethics-singapore.org/index/publications/reports/172-research-involving-human-subjects-guidelines-for-irbs.html 2. Ethics Guidelines for Human Biomedical Research (2015):

Country	Key Organizations	Legislation	Regulations	Guidelines	
				http://www.bioethics-singapore.org/index/publications/reports/86-reports/ethics-guidelines-for-human-biomedical-research.html	
<i>Drugs and Devices</i>	<i>Drugs</i>	<p>1. Health Sciences Authority of Singapore (HSA): http://www.hsa.gov.sg</p> <p>2. Ministry of Health, National Medical Ethics Committee (NMEC): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines.html</p>	<p>Medicines Act (1975): http://statutes.agc.gov.sg/</p>	<p>Medicines (Clinical Trials) Regulations (2000): http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev.loadTime;page=0;query=Id%3A7e3c748b-8089-4699-a4b2-9f66af6f7820;rec=0</p>	<p>HSA: Singapore Guideline for Good Clinical Practice (1990): http://www.pacra.org/dev-pacra/images/pdf-files/singapore/sg-gcp.pdf</p> <p>NMEC: Recommendations on Clinical Trials: Update Focusing On Phase I Trials (2007): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines/2007.html</p>
	<i>Devices</i>	<p>1. Health Sciences Authority (HSA): http://www.hsa.gov.sg</p> <p>2. National Environment Agency, Centre For Radiation Protection And Nuclear Science: http://www.nea.gov.sg/anti-pollution-radiation-protection/radiation-protection</p>	<p>1. Health Products Act (2007): http://statutes.agc.gov.sg/</p> <p>2. Radiation Protection Act (2007): http://statutes.agc.gov.sg/</p>	<p>1. Health Products (Medical Device) Regulations (2010): http://www.emergogroup.com/sites/default/files/file/singapore-health-products-medical-devices-regulations-2010.pdf</p> <p>2. Radiation Protection Regulations (2014): http://www.nea.gov.sg/anti-pollution-radiation-protection/radiation-protection/regulatory/summary-of-radiation-protection-(amendment)-act-2014</p>	
<i>Research Injury</i>	<p>1. Health Sciences Authority: http://www.hsa.gov.sg</p> <p>2. Ministry of Health, National Medical Ethics Committee (NMEC): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines.html</p>	<p>1. Medicines Act (1975): http://statutes.agc.gov.sg/</p> <p>2. Radiation Protection Act (2007): http://statutes.agc.gov.sg/</p>	<p>Medicines (Clinical Trials) Regulations (2000): http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev.loadTime;page=0;query=Id%3A7e3c748b-8089-4699-a4b2-9f66af6f7820;rec=0</p>	<p>HSA: Singapore Guideline for Good Clinical Practice (1999): http://www.pacra.org/dev-pacra/images/pdf-files/singapore/sg-gcp.pdf</p> <p>NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)</p>	
<i>Privacy/Data Protection</i>	<p>1. Ministry of Communications and Information (MCI): http://www.mci.gov.sg/web</p> <p>2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org</p>	<p>1. Computer Misuse Act (Cap. 50A) (1993): http://statutes.agc.gov.sg/</p> <p>2. Personal Data Protection Act (2012): http://statutes.agc.gov.sg/</p>		<p>BAC: Personal Information in Biomedical Research (2007): http://www.bioethics-singapore.org/index/publications/reports/170-personal-information-in-biomedical-research.html</p>	

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Human Biological Materials</i>	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Health Sciences Authority: http://www.hsa.gov.sg 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/ 3. Human Biomedical Research Bill No. 25/2015, Part 6: http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev.loadTime;page=0;query=Id%3A1f615627-01d3-4250-a720-de776cd4f794;rec=0	Medicines (Clinical Trials) Regulations (2000): http://statutes.agc.gov.sg/aol/search/display/view.w3p;orderBy=date-rev.loadTime;page=0;query=Id%3A7e3c748b-8089-4699-a4b2-9f66af6f7820;rec=0	BAC: Human Tissue Research (2002): http://www.bioethics-singapore.org/index/publications/reports/173-human-tissue-research.html
<i>Genetic Research</i>	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): https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national_medical_ethics_committee_guidelines/2001.html BAC: Genetic Testing and Genetic Research (2005): http://www.bioethics-singapore.org/index/publications/reports/171-genetic-testing-and-genetic-research.html
<i>Embryos, Stem Cells, and Cloning</i>	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): http://www.bioethics-singapore.org/index/publications/reports/86-reports/174-stem-cell-research.html 2. Donation of Human Eggs for Research (2008): http://www.bioethics-singapore.org/index/publications/reports/86-reports/168-donation-of-human-eggs-for-research.html 3. Human-Animal Combinations in Stem-Cell Research (2010): http://www.bioethics-singapore.org/index/publications/reports/86-reports/167-human-animal-combinations-in-stem-cell-research.html
Sri Lanka				
<i>Drugs and Devices</i>	Cosmetics, Devices, and Drugs Regulatory Authority, Subcommittee on Clinical Trials:	National Medicines Regulatory Authority Act of 2015: http://www.cdda.gov.lk/images/stori		Guidelines for the Conduct of Clinical Trials in Sri Lanka (2014): http://www.cdda.gov.lk/images/pdf/clinical%2

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.cdda.gov.lk/index.php?option=com_content&view=article&id=78&Itemid=115&lang=en	es/new/pdf/legislations/5e_nmdra.pdf		Otrials%20guidelines_oct2014.pdf
<i>Clinical Trials Registry</i>	Sri Lanka Clinical Trials Registry: http://www.slctr.lk/			FAQs: http://slctr.lk/faq
Taiwan				
<i>General</i>	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 (2014): 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): http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0020023 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): http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp 5. Informed Consent Exemptions for Human Research (2012): http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp 6. Expedited Review Categories for Human Research (2012): http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp 7. Partial Amended Articles of Enforcement Rules of Medical Care Act (2016) http://gazette.nat.gov.tw/egFront/eng/EngIndex.jsp	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
<i>Drugs and Devices</i>	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/EN/index.aspx	MOHW: Medical Care Act (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020021 FDA: Pharmaceutical Affairs Act	MOHW: 1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162 2. Pharmaceutical Affairs Act Enforcement Rules (2012): http://law.moj.gov.tw/Eng/LawClass	

Country	Key Organizations	Legislation	Regulations	Guidelines
		(2015): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L003001	/LawContent.aspx?pcode=L0030002 3. Regulations for Drug Safety Monitoring (2013) http://mohwlaw.mohw.gov.tw/Chi/EngContent.asp?msgid=516&KeyWord ≡ 4. Guideline for Good Clinical Practice (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0030056 5. Regulations for Governing the Management of Medical Devices (2014): http://mohwlaw.mohw.gov.tw/Chi/EngContent.asp?msgid=528&KeyWord ≡ 6. Regulations for Bioavailability and Bioequivalence Studies (2015): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0030065	
<i>Research Injury</i>	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 (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020021	FDA: Guideline for Good Clinical Practice (2014): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0030056	
<i>Privacy/Data Protection</i>	Ministry of Justice: http://www.moj.gov.tw/mp095.html	Personal Information Protection Act (2015): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=I0050021		
<i>Human Biological Materials</i>	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. Human Biobank Management Act (2012): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020164	1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162 2. Administrative Regulations on the Establishment of Human Biobanks (2011) http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020173	1. Good Tissue Practice (2002) (Chinese): http://www.fda.gov.tw/TC/includes/GetFile.aspx?id=1153&chk=342a5c73-c206-4756-ade9-9c63265c859d&mid=46&name=fdContent 2. Guidelines for Collection and Use of Human Specimens for Research (2006) (Chinese): http://www.fda.gov.tw/TC/includes/GetFile.aspx?id=1598&chk=6056f7dd-eb0a-48bf-ae7e-8a2a5875e6e0&mid=46&name=fdContent

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Medical Care Act (2015): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020021		
<i>Genetic Research</i>	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. Ministry of Science and Technology: https://www.most.gov.tw/en/public	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 Biobanks (2010) (Chinese): http://law.moj.gov.tw/LawClass/LawContentIf.aspx?PCODE=L0020170 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/FLAWDAT0202.asp
<i>Embryos, Stem Cells, and Cloning</i>	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		
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				
Note: All websites and documents are in Russian.				
<i>General</i>	Ministry of Public Health: http://www.health.tj/		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	
Thailand				
For an overview of the clinical research regulations in Thailand, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=213				
<i>General</i>	1. National Research Council of Thailand (NCRT): http://en.ncrt.go.th/en/home.aspx 2. Medical Council of Thailand (MCT): http://www.tmc.or.th/en_home.php 3. Forum for Ethical Review Committees in Thailand (FERCIT) (Thai): http://www.fercit.org/	Medical Professions Act (2009), Articles 47-50: http://www.fercit.org/SIDCER-FERCAP/Handout_10/4.%20Accreditation-update_surveyor_aj.Sopit.pdf	NCRT: Regulation on the Permission of Foreign Researchers (1982): http://www.dnp.go.th/otec/eng_laws_regs/NRCT_Reg2525E.pdf MCT: Rule of the Medical Council on the Observance of Medical Ethics (1983): http://thailaws.com/law/t_laws/tlaw0510.pdf	MCT: National Guideline for Ethical Research on Human Subjects (2002) FERCIT: Ethical Guidelines for Research on Human Subject in Thailand (2007): http://www.fercit.org/file/Guideline_English_version.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Drugs and Devices</i>	<i>Drugs</i> 1. Food and Drug Administration, Drug Control Division: http://www.fda.moph.go.th/eng/index.stm 2. Medical Council of Thailand (MCT): http://www.tmc.or.th/en_home.php	Consumer Protection Act (2007)		MCT: Thailand Good Clinical Practice Guidelines (2002)
	<i>Devices</i> 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		
<i>Clinical Trials Registry</i>	Thai Clinical Trials Registry: http://www.clinicaltrials.in.th/			FAQs: http://www.clinicaltrials.in.th/index.php?meun=home&smenu=4&task=home&task1=openpage&task2=view&topid=4
<i>Privacy/Data Protection</i>	Office of the Information Commission: http://www.oic.go.th/content_eng/default_eng.asp	Official Information Act, B.E. 2540 (1997): http://www.oic.go.th/content_eng/act.htm		
Uzbekistan				
Note: All websites and documents are in Uzbek and Russian.				
<i>General</i>	1. Government of the Republic of Uzbekistan: http://www.gov.uz 2. Ministry of Health: http://www.minzdrav.uz	1. Constitution of Republic of Uzbekistan, Articles 24, 26, 40, 44 (1992): http://www.gov.uz 2. Law on Protection of Citizens' Health (1997): http://www.minzdrav.uz		
<i>Drugs and Devices</i>	1. Ministry of Health, Pharmacological Committee of the Central Department for Quality Control of Pharmaceuticals and Medical Equipment: http://www.minzdrav.uz 2. Ministry of Health, National Ethics Committee 3. Scientific Boards of Medical Institutes	1. Law on Protection of Citizens' Health (1997): http://www.minzdrav.uz 2. Law on Drugs and Pharmaceutical Activity (1997) 3. Law on Narcotic and Psychoactive Drugs (2000)	1. Guidelines on Conducting Clinical Trials and Determining Clinical Sites (2001) 2. National Standard of Uzbekistan: Good Clinical Practice (2013)	
<i>Human Biological Materials</i>	1. Ministry of Health, Pharmacological Committee of the Central Department for Quality Control of Pharmaceuticals and Medical Equipment: http://www.minzdrav.uz		1. Guidelines on Conducting Clinical Trials and Determining Clinical Sites (2001) 2. National Standard of Uzbekistan: Good Clinical Practice (2013)	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of Health, National Ethics Committee 3. Scientific Boards of Medical Institutes			
Vietnam				
For an overview of the clinical research regulations in Vietnam, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=233				
<i>General</i>	1. Ministry of Health (MOH): http://www.moh.gov.vn/homebyt/en/portall/index.jsp 2. Ministry of Health, Independent Ethics Committee (MOH) (Vietnamese): http://iecmoh.vn	MOH: Decision No. 111/QD-BYT – On Promulgation of Regulation on Organization and Operation of Council of Ethics in Biomedical Research at Grass-Roots Level, Chapter I (Articles 3 and 4), Chapter II, and Chapter III (2013): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo111-QD-BYT.pdf	MOH: Decision No. 460/QD-BYT – On the Promulgation of Regulations on Organization and Operation of Ethical Evaluation Committee in Biomedical Research of the Ministry of Health, Period 2012-2017, Chapters I-III (2012): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo460-QD-BYT.pdf	
<i>Drugs and Devices</i>	Ministry of Health: http://www.moh.gov.vn/homebyt/en/portall/index.jsp	1. Law on Pharmacy (No. 34/2005/QH11), Chapter II (Section III, Article 20), Chapter VIII (Articles 54 and 59) (2005): http://www.vertic.org/media/National%20Legislation/Vietnam/VN_Law_on_Pharmacy.pdf 2. Decision No. 799/QD-BYT on the Issuance of Guideline on Good Clinical Practice, Chapter III, Articles 1 and 2 (2008): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo799-QD-BYT.pdf	1. Decision No. 799/QD-BYT of the Minister of Health on the Promulgation of the Guidelines on Good Clinical Practice of Clinical Trials (2008): http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo799-QD-BYT.pdf 2. Circular – Guidelines for Clinical Trials on Drugs (C-ClinDrugTrial), Articles 2, 4, 5, 9, 17, 18, 31, and 39 (2012): http://clinregs.niaid.nih.gov/documents/vietnam/C-ClinDrugTrial.pdf	Guidelines for Clinical Trials of Drugs, Chapter III, Articles 10, 16, and 17 (2012): https://clinregs.niaid.nih.gov/documents/vietnam/C-ClinDrugTrial.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
MIDDLE EAST				
Egypt				
<i>General</i>	Medical Professionals Union	Constitution of the Arab Republic of Egypt, Article 43: http://www.sis.gov.eg/Newvr/Dustor-en001.pdf	Professional Ethics Regulations: Conducting Medical Research on Human Beings, Articles 52-61 (2003)	
<i>Drugs and Devices</i>	Egyptian Drug Authority: http://www.eda.mohp.gov.eg/			
Iran				
<i>General</i>	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)	
<i>Clinical Trials Registry</i>	Iranian Registry of Clinical Trials: http://www.irct.ir/			FAQs: http://www.irct.ir/faq.php
Israel				
<i>General</i>	Ministry of Health: http://www.health.gov.il/english/		Public Health Regulations (Medical Experiments Involving Human Subjects) (1999) (Hebrew)	
<i>Drugs and Devices</i>	Ministry of Health, Pharmaceutical Administration: http://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/Drugs/Pages/default.aspx	Public Health Order (1940)	1. Public Health Regulations (Clinical Studies in Human Subjects) – 1980 2. 1990 Amendment 3. 1992 Amendment 4. 2005 Amendment	Guidelines for Clinical Trials in Human Subjects (2006): https://firstclinical.com/regdocs/doc/?db=INT_Israel_Clinical_Trials
<i>Privacy/Data Protection</i>	Israeli Law, Information, and Technology Authority: http://www.justice.gov.il/MOJEng/ILITA/	1. Privacy Protection Act No. 5741 (1981): http://www.justice.gov.il/NR/rdonlyres/6A5EC09A-BDBC-419F-8007-5FD6A6B8E0A5/18334/ProtectionofPrivacyLaw57411981unofficialtranslationio.pdf 2. Protection of Privacy Law No. 5741, as Amended by Law No. 5745 (1985)		
<i>Genetic Research</i>	Ministry of Health: http://www.health.gov.il/english/	Genetic Information Law (2000) (Hebrew): http://www.moital.gov.il/NR/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)

Country	Key Organizations	Legislation	Regulations	Guidelines
				2. Amendment (2007)
<i>Embryos, Stem Cells, and Cloning</i>		Genetic Intervention Prohibition Law (Human Cloning and Genetic Changes in Reproduction Cells) (1999)		
Jordan				
<i>Drugs and Devices</i>	1. Ministry of Health: http://www.moh.gov.jo/en/Pages/default.aspx 2. Jordan Food and Drug Administration: http://www.jfda.jo/Default.aspx	1. Law of Clinical Studies, Law No. 2 (2011) 2. Drug and Pharmacy Law No. 12 (2013) 3. Narcotic and Psychotropic Law No. 23 (2016)		
<i>Research Injury</i>			Regulations for Insurance on Research-Related Injury (2013) (Arabic): http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/22_252.pdf	
<i>Embryos, Stem Cells, and Cloning</i>		Stem Cell By-law No. 10 (2014)		
Kuwait				
<i>General</i>	Ministry of Health, Kuwait Institute for Medical Specialization: http://www.kims.org.kw/			Ethical Guidelines for Biomedical Research: http://www.kims.org.kw/Ethical%202.doc
Qatar				
<i>General</i>	Supreme Council of Health: https://www.sch.gov.qa/home-en			Various: https://www.sch.gov.qa/about-sch/departments/research
Saudi Arabia				
<i>General</i>	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	
Turkey				
For an overview of human subject protections in Turkey, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPRPReportFiles/Turkey%20definitive%20Updated.pdf				
<i>General</i>	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	1. Regulation on Medical Deontology, Article 11 (1960) 2. Bylaw on Patient Rights No. 23420 (1998)	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Human Rights and Biomedicine (2004) 4. Update on the Law of the Support of Research and Development Activities (2016). Official Gazette (Turkish): http://www.resmigazete.gov.tr/eskiler/2016/02/20160226.htm		
<i>Drugs and Devices</i>	<i>Drugs</i>	Turkish Penal Law, Article 90 (2005)	1. Fundamental Law #3359 on Health Services, Supplemental Article 10 (2011) (Turkish): http://www.titck.gov.tr/Default.aspx?sayfa=klidik_mevzuat&lang=tr-TR&thelawtype=1&thelawId=347 2. Regulation on Clinical Trials with Drugs and Biological Products (2015): An Update of 2014 Clinical Trials Regulation (Turkish): http://www.klinikarastirmalar.org.tr/doc/file_345.docx 3. Regulation on Efficacy, Safety, and Clinical Trials of Cosmetic Products (2015) (Turkish): http://www.klinikarastirmalar.org.tr/doc/file_346.pdf 4. Update on the Regulation of the Management and Inspection of the Support of Research and Development Activities (2016). Official Gazette (Turkish): http://www.resmigazete.gov.tr/eskiler/2016/08/20160810-7.htm	CRA: Various: http://www.klinikarastirmalar.org.tr/en/documents.php?dok_cat=0
	<i>Devices</i>	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	
	<i>Research Injury</i>	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)	
<i>Human Biological</i>		1. Law on Procurement,	Regulation on Blood and Blood	1. Convention on Human Rights and

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Materials</i>		Preservation, Grafting, and Transplantation of Organs and Tissues, No. 2238 (1979) 2. Law on Blood and Blood Products, No. 2857 (1983)	Products, No. 7314 (1983)	Biomedicine (Convention of Oviedo), Articles 21-22 (1999) 2. Good Clinical Practice Guidelines for Advanced Therapy Medicinal Products (2011)
<i>Genetic Research</i>			Regulation on Centers for Diagnosis and Genetic Diseases, No. 23368 (1998)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14 (1999)
<i>Embryos, Stem Cells, and Cloning</i>			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)
United Arab Emirates				
<i>General</i>	Health Authority - Abu Dhabi: http://www.haad.ae/haad/			Standard Operating Procedures for Research Ethics Committees (2012): http://www.haad.ae/HAAD/LinkClick.aspx?fileticket=UL7o8f5muke%3D&tabid=820

Country	Key Organizations	Legislation	Regulations	Guidelines
LATIN AMERICA and the CARIBBEAN				
Regionwide				
<i>General</i>	Caribbean Public Health Agency: http://carpha.org/What-We-Do/Research-Training-and-Policy-Development			
<i>Drugs and Devices</i>	<i>Drugs</i>			Good Clinical Practices: Document for the Americas (2004): http://www.paho.org/english/ad/ths/ev/GCP-Eng-doct.pdf
	Pan American Health Organization: http://www.paho.org/			
<i>Drugs and Devices</i>	<i>Devices</i>			A Model Regulatory Program for Medical Devices: An International Guide (2001): http://www.paho.org/English/HSP/HSE/medical_devices.pdf
	Pan American Health Organization: http://www.paho.org/			
Argentina				
Notes: Several provinces have their own regulations pertaining to human subjects research. All websites and documents are in Spanish.				
<i>General</i>	Ministry of Health: http://www.msal.gov.ar	Civil and Commercial Code, Articles 26, 58, and 59 (2015): http://servicios.infoleg.gob.ar/infolegInternet/anexos/235000-239999/235975/norma.htm	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
<i>Drugs and Devices</i>	<i>Drugs</i>			
	National Administration of Medications, Foods, and Medical Technology (ANMAT): http://www.anmat.gov.ar/index.asp		1. Provision 2247/09: Guide for the Study of Clinical Trials of Type II Diabetes (2009): 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): http://www.anmat.gov.ar/Comunicados/Dispo_6677-10.pdf	
<i>Drugs and Devices</i>	<i>Devices</i>			
	National Administration of Medications, Foods, and Medical Technology (ANMAT): http://www.anmat.gov.ar/index.asp		1. Provision 969/97 on the Regulation of Good Clinical Practice with Medical Technology Products (1997)	

Country	Key Organizations	Legislation	Regulations	Guidelines
			2. Disposition N° 969/97(Including Modifications of Disposition ANMAT N° 6550/2008)	
<i>Privacy/Data Protection</i>	National Directorate for the Protection of Personal Data (Spanish): http://www.jus.gob.ar/datos-personales.aspx	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
Bermuda				
<i>General</i>	Department of Health: https://www.gov.bm/department/health			Research Governance Framework (2008): http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.592.8671&rep=rep1&type=pdf
Bolivia				
<i>General</i>	1. Ministry of Health and Sport (MHS): http://www.sns.gob.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): https://www.constituteproject.org/constitution/Bolivia_2009.pdf	1. Regulations on Public Health Research, Chapter V (1978) 2. Rules and Regulations of the National Bioethics Committee	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
<i>Drugs and Devices</i>	1. Ministry of Health and Sport, National Pharmacological Commission (MHS): http://www.sns.gob.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 an overview of clinical research regulations in Brazil, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=30				
<i>General</i>	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	CNS/CONEP: 1. Resolution CNS No. 240/97 - Defining "Participating User" According to IRB (Portuguese): http://conselho.saude.gov.br/resolucoes/1997/reso240.doc 2. Regulation of Resolution CNS No. 292/99 on Research with	CNS/CONEP: Operational Standard N° 001/2013: http://conselho.saude.gov.br/arquivos/NO_01-12_english.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			<p>Foreign Cooperation: http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/regulation_res_292_english.doc</p> <p>3. Resolution CNS No. 304/2000: http://conselho.saude.gov.br/resolucoes/2000/Res304_en.pdf</p> <p>4. Internal CONEP Regulation (2001) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/aquivos/conep/regimento.doc</p> <p>5. Resolution CNS No. 301, 16th March 2002: http://conselho.saude.gov.br/resolucoes/2000/Res301_en.pdf</p> <p>6. Resolution CNS No. 346/2005 on Multicenter Research: http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf</p> <p>7. Resolution CNS No. 370/07 on Registration and Accreditation or Renewal of Registration and Accreditation of CEP (Portuguese): http://conselho.saude.gov.br/resolucoes/2007/Reso370.doc</p> <p>8. Resolution CNS No. 421/09 (Portuguese): http://conselho.saude.gov.br/resolucoes/2009/Reso421.doc</p> <p>9. Resolution CNS No. 446/2011 on Composition of the National Commission on Research Ethics: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf</p> <p>10. Resolution CNS No. 466/2012 on Guidelines and Rules for Research Involving humans Subjects: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf</p>	
<i>Drugs and Devices</i>	<p>1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/</p>	<p>Law N° 9782/99 Defining the National Health Surveillance System (Portuguese):</p>	<p>CNS: 1. Resolution CNS No. 251/1997: On Complimentary Rules for</p>	

Country	Key Organizations	Legislation	Regulations	Guidelines
	<p>2. Brazilian Health Surveillance Agency: http://portal.anvisa.gov.br/wps/portal/anvisa-ingles</p> <p>3. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html</p> <p>4. National Secretary on Science, Technology and Innovation (Portuguese): http://www.saude.gov.br/sctie/</p>	<p>http://www.planalto.gov.br/ccivil_03/leis/L9782.htm</p>	<p>Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests: http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf</p> <p>2. Resolution CFM N° 1.885, 2008 (Portuguese): http://www.portalmédico.org.br/resolucoes/cfm/2008/1885_2008.htm</p> <p>3. Resolution ANVISA 09/15 - Regulations for Clinical Trials with Drugs (Portuguese): http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=03/03/2015&jornal=1&pagina=69&totalArquivos=140</p> <p>4. Resolution ANVISA 10/15 - Regulations for Clinical Trials with Drugs (Portuguese): http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=03/03/2015&jornal=1&pagina=73&totalArquivos=140</p> <p>5. Resolution RDC No. 9 of 20 February 2015: https://clinregs.niaid.nih.gov/documents/brazil/ResolutionNo9-English.pdf</p>	
<i>Clinical Trials Registry</i>	<p>Brazilian Clinical Trials Registry: http://www.ensaiosclinicos.gov.br/</p>			<p>FAQs: http://www.ensaiosclinicos.gov.br/assistance/faq/</p>
<i>Research Injury</i>	<p>1. Brazilian Health Surveillance Agency: http://portal.anvisa.gov.br/wps/portal/anvisa-ingles</p> <p>2. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/</p> <p>3. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html</p>	<p>ANVISA: Law N° 6360/76 (Portuguese): http://www.planalto.gov.br/ccivil_03/leis/l6360.htm</p>	<p>CNS/CONEP: 1. Standards Survey of New Drugs, Medicines, Vaccines, and Diagnostic Tests Involving Human Beings - Resolution CNS No. 251/97 (Portuguese): http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf</p> <p>2. Resolution CNS No. 346/2005 on Multicenter Research (Portuguese): http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf</p> <p>3. Resolution MS/CNS No. 466/2012 - Guidelines and Rules</p>	<p>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</p>

Country	Key Organizations	Legislation	Regulations	Guidelines
			for Research Involving Human Subjects: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf	
<i>Privacy/Data Protection</i>	<ol style="list-style-type: none"> 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 3. Federal Council of Medicine: http://portal.cfm.org.br 		Resolution CFM N° 1.821, 23 November 2007 (Portuguese): http://www.portalmedico.org.br/resolucoes/cfm/2007/1821_2007.htm	
<i>Human Biological Materials</i>	<ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 1. Resolution No. 347, 13th January 2005 (Portuguese): http://conselho.saude.gov.br/resolucoes/2005/Res347_en.pdf 2. Resolution CNS No. 441 of 12 May 2011: http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/Resolucao441_English_contribuicao_pesquisadora.doc 3. Resolution – RDC No. 20 of 10 April 2014 (Portuguese): http://www.saude.pr.gov.br/arquivos/File/RDC_20_de_10_de_abril_2014_Transporte_de_material_Biologico.pdf 	
<i>Genetic Research</i>	<ol style="list-style-type: none"> 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/ 	<ol style="list-style-type: none"> 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 	CTNBio: <ol style="list-style-type: none"> 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 3. Resolution CNS No. 340/2004: On Research on Human Genetics (2004): http://conselho.saude.gov.br/resolucoes/2004/Res340_en.pdf 	<ol style="list-style-type: none"> 1. Guidance to Researchers and Ethics Committees about the Item V.1.a of CNS Resolution 340 2004 (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/aquivos/documentos/Carta_Circular_041_Orientacoes_pesquisadores_comites.pdf 2. Statement on Pharmacogenetic Studies in Brazil N° 011/2012/CONEP, 12 January 2012: http://www.fcm.unicamp.br/fcm/sites/default/files/11_-_Comunicado_sobre_estudos_farmacogeneticos_no_Brasil.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Embryos, Stem Cells, and Cloning</i>	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	Resolution RDC No. 9, 14 March 2011 (Portuguese): http://portal.anvisa.gov.br/wps/wcm/connect/623ecb0047458efe9836dc3fbc4c6735/RDC_09_2011.pdf?MOD=AJPERES	
Chile Note: All websites and documents are in Spanish.				
<i>General</i>	1. Ministry of Health: http://www.minsal.cl 2. Institute of Public Health: http://www.ispch.cl	1. Law No. 20.120 Regarding Scientific Research in Human Beings, their Genome, and the Prohibition of Human Cloning (2006): 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): 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): 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: http://www.leychile.cl/Navegar?idNorma=1032919 2. Supreme Decree N° 30/2013 Regulation on Law N°20.120 Modifying Supreme decree N°114/2010, Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning Official Diary January 14, 2013: http://www.leychile.cl/Navegar?idNorma=1048008&	
<i>Drugs and Devices</i>	1. Ministry of Health : http://www.minsal.cl 2. Institute of Public Health: http://www.ispch.cl	Law No. 20.724 Modifying the Health Code in the Area of the Regulation of Pharmacies and Medications (2014): 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: 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
			<p>Diary of June 25, 2011: http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/ds_minsal_3_2010.pdf</p> <p>3. Exempt Resolution 2263, July 30th 2015 Modifying Resolution N° 403 Ex. February 5, 2015 that Approves the Guidelines for Use Control of Pharmaceuticals Products in Scientific Research: http://www.leychile.cl/Navegar?idNorma=1080011</p>	
<i>Research Injury</i>	<p>1. Ministry of Health: http://www.minsal.cl 2. Institute of Public Health: http://www.ispch.cl</p>	<p>Law No. 20.120 Regarding Scientific Research in Human Beings, their Genome, and the Prohibition of Human Cloning (2006): http://www.leychile.cl/Navegar?idNorma=253478</p>	<p>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: http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/ds_minsal_3_2010.pdf</p> <p>2. General Technical Rule No. 140 Regarding the National System of Pharmacovigilance of Pharmaceutical Products for Human Use. June 20, 2012: http://web.minsal.cl/portal/url/item/c4a31ad6db50e085e040010165017a39.pdf</p> <p>3. Resolution No. 441, Notification of Adverse events in Clinical Research in Chile, February 13, 2012: http://www.ispch.cl/sites/default/files/res_441.pdf</p>	
<i>Privacy/Data Protection</i>	<p>1. Ministry of Health: http://www.minsal.cl 2. Ministry of the Secretary General of the Government: http://www.msgg.gob.cl</p>	<p>1. Law for the Protection of Private Life No. 19.628 (1999): http://www.bcn.cl/leves/141599 2. Law No. 20584. Regulating the Rights and Duties Incumbent upon Persons in Connection with Actions Linked to their Health Care (2012): http://www.leychile.cl/Navegar?idNorma=1039348</p>	<p>Supreme Decree No. 41 of 2012: Regulation Regarding Clinical Records of December 15, 2012: http://www.leychile.cl/Navegar?idNorma=1046753</p>	

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Genetic Research</i>	Ministry of Health: http://www.minsal.cl	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: http://www.leychile.cl/Navegar?idNorma=1032919	
<i>Embryos, Stem Cells, and Cloning</i>	Ministry of Health: http://www.minsal.cl	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: http://www.leychile.cl/Navegar?idNorma=1032919	
Colombia				
Note: All websites and documents are in Spanish.				
<i>General</i>	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 8430 (1993): https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF	1. Guide for Research Ethics Committees. Code: ASS-RSA-GU040 Version: 00 (2015): https://www.invima.gov.co/images/stories/for/matotramite/ASS-RSA-GU040.pdf 2. Guide for Assessing and Monitoring of Research Protocols. Code: ASS-RSA-GU039 Version: 00 (2016): https://www.invima.gov.co/images/stories/for/matotramite/ASS-RSA-GU039.pdf
<i>Drugs and Devices</i>	<i>Drugs</i> National Institute of Drug and Food Surveillance: http://www.invima.gov.co/		1. Resolution No. 2378 of 2008, Adapting Good Clinical Practices for Institutions that Conduct Research with Medicines in Human Beings: http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=31169 2. Resolution No. 2011020764 of June 10th, 2011: Regulation Related to the Content and Frequency of Adverse Event Reports in Clinical Investigation in Humans: https://www.invima.gov.co/index.php	1. ABC Good Clinical Practice (2009) https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/ABCBCPultima_version.pdf 2. Circular No 600-5776-14: Processes of Good Clinical Practice (2014): https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/normatividad/CIRCULAR_600-5776-14-2.pdf 3. Guide of Medications and Supplies for Clinical Research (2015): https://www.invima.gov.co/images/stories/for/matotramite/ASS-RSA-GU045.pdf 4. Guide for the Evaluation and Follow-up

Country	Key Organizations	Legislation	Regulations	Guidelines
			?option=com_content&view=article&id=725:resolucion-no-2011020764-del-10-de-junio-de-2011&catid=58:2011&Itemid=105	of Research Protocols (2016): https://www.invima.gov.co/images/stories/for_matotramite/ASS-RSA-GU039.pdf 5. External Circular No. 600-2006-16: National Reporting Serious Adverse Events (2016): https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/normatividad/Circular-600-1081-16-Reporte-de-Eventos-adversos-serios-Nacionales-Febrero2016.pdf 6. External Circular No. 600-1414-16: Notification of Deviations (2016): https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/normatividad/Circular_600-2006-16_Alcance-Circular-600-1081-16_Abril2016.pdf
	<i>Devices</i>			
	National Institute of Drug and Food Surveillance: http://www.invima.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapters I and III (1993): https://www.unisabana.edu.co/fileadmin/Documentos/Investigacion/comite_de_etica/Res_8430_1993_-_Salud.pdf	
<i>Research Injury</i>	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Art. 13 (1993): https://www.unisabana.edu.co/fileadmin/Documentos/Investigacion/comite_de_etica/Res_8430_1993_-_Salud.pdf	
<i>Privacy/Data Protection</i>	Ministry of Health and Social Protection: http://www.minsalud.gov.co	Constitution of Colombia, Article 15 (2003): http://www.corteconstitucional.gov.co/inicio/Constitucion%20politica%20de%20Colombia%20-%202015.pdf	Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Article 8 (1993)	
<i>Human Biological Materials</i>	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter VI (1993):	

Country	Key Organizations	Legislation	Regulations	Guidelines
			https://www.unisabana.edu.co/fileadmin/Documentos/Investigacion/comite_de_etica/Res_8430_1993_-_Salud.pdf	
<i>Genetic Research</i>	Ministry of Health and Social Protection: http://www.minsalud.gov.co		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapter II (1993): https://www.unisabana.edu.co/fileadmin/Documentos/Investigacion/comite_de_etica/Res_8430_1993_-_Salud.pdf	
Costa Rica				
Note: All websites and documents are in Spanish.				
<i>Drugs and Devices</i>	National Health Research Council: http://www.ministeriodesalud.go.cr/index.php/consejos/conis	Regulatory Law of Biomedical Research No. 9234 (2014): http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=77070&nValor3=96424&strTipM=TC	1. Regulatory Decree N° 39061-S (2016) on the Regulatory Law of Biomedical Research N° 39533-S: http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC 2. Reforms to the Regulatory Decree No. 39533-S (2016) Regulatory Law of Biomedical Research No. 9234: http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC	Various: http://www.ministeriodesalud.go.cr/index.php/consejos/conis
<i>Clinical Trials Registry</i>	National Health Research Council (Spanish): http://www.ministeriodesalud.go.cr/index.php/consejos/conis (scroll to bottom of page to Investigaciones Registradas)			
Cuba				
Note: All websites and documents are in Spanish.				
<i>Drugs and Devices</i>	Center for State Control of Medications: http://www.cecmecd.cu/			Various: http://www.cecmecd.cu/ensayos-clinicos/autorizos
<i>Clinical Trials Registry</i>	Public Cuban Registry of Clinical Trials: http://registroclinico.sld.cu/en/home			

Country	Key Organizations	Legislation	Regulations	Guidelines
Dominica				
<i>General</i>	Ministry of Health: http://www.dominica.gov.dm/cms/index.php?q=node/21			Guidelines for the Conduct of Research on Human Subjects (2005)
Dominican Republic				
<i>General</i>	National Council on Health Bioethics: http://conabios.gob.do/	National Health Law 42-01, Chapter VI: https://www.dol.gov/ilab/submissions/pdf/20100408-10.pdf	Regulation for Evaluation Request for a Clinical Investigation Project: http://conabios.gob.do/index.php/reglamentos	
<i>Biological Materials</i>		National Health Law 42-01, Book Five: https://www.dol.gov/ilab/submissions/pdf/20100408-10.pdf		
Ecuador				
Note: All websites and documents are in Spanish.				
<i>General</i>	Ministry of Public Health : http://www.salud.gob.ec/	1. National Constitution of the Republic: http://www.asambleanacional.gob.ec/sites/default/files/documents/old/constitucion_de_bolsillo.pdf 2. 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
<i>Drugs and Devices</i>	1. Ministry of Public Health: http://www.salud.gob.ec/ 2. National Health Agency for Regulation, Control, and Oversight: http://www.controlsanitario.gob.ec/ensayos-clinicos/		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	
<i>Biological Materials</i>	National Institute on Donation and Transplantation of Organs, Tissues, and Cells: http://www.donaciontrasplante.gob.ec/indot/	1. Organic Health Law of December 22, 2006, Articles 81-86 (2006): http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf 2. Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells (2011):	Regulation for the Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells. Executive Order 1205, July 13, 2012: http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_de_donacion_y_trasplantes.pdf	de donacion y trasplantes.pdf	
<i>Genetic Research</i>	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		
<i>Embryos, Stem Cells, and Cloning</i>	1. Ministry of Public Health: http://www.salud.gob.ec/ 2. National Institute of Donation and Transplantation of Organs, Tissues, and Cells: http://www.donaciontrasplante.gob.ec/indot/	Organic Health Law of 22 December 2006, Article 214 (2011): 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: http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_de_donacion_y_trasplantes.pdf	
Grenada				
<i>General</i>	St. George's University/Windward Islands Research and Education Foundation: http://www.sgu.edu/school-of-medicine/institutional-review-board.html			45 CFR 46: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
Guyana				
			Medical Research Involving Human Subjects Regulations (2007)	
Guatemala				
Note: All websites and documents are in Spanish.				
<i>Drugs and Devices</i>	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				
<i>General</i>	Ministry of Public Health and Population (French): http://mspp.gouv.ht/newsite/			Internal Regulations (2010) (French)

Country	Key Organizations	Legislation	Regulations	Guidelines
Honduras				
Note: All websites and documents are in Spanish.				
<i>General</i>	Secretariat of Health: http://www.salud.gob.hn/		Health Code, Decree No. 65-91, Articles 175 and 176	
Jamaica				
<i>General</i>	Ministry of Health, Ethics and Medico-Legal Affairs Panel: http://moh.gov.jm/			Ministry of Health Guidelines for the Conduct of Research on Human Subjects (2010): http://moh.gov.jm/guidelines/guidelines-for-the-conduct-of-research-on-human-subjects/
<i>Drugs and Devices</i>	Ministry of Health, Standards and Regulation Division: http://moh.gov.jm/divisions-agencies/divisions/standards-and-regulation-division/	Food and Drugs Act (1975): http://www.moj.gov.jm/sites/default/files/laws/Food%20and%20Drugs%20Act%20LN%2065%20of%2075.pdf	Food and Drugs Regulations (1975): http://www.moj.gov.jm/sites/default/files/laws/Food%20and%20Drugs%20Act%20LN%2065%20of%2075.pdf	
México				
Note: All websites and documents are in Spanish.				
<i>General</i>	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)	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 (2016): http://www.dof.gob.mx/nota_detalle.php?codigo=5422410&fecha=11/01/2016 2. National Guidelines for the Integration and Operation of Research Ethics Committees (2016): http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/registrocomites/Guia_CEI_paginada_con_forros.pdf
<i>Drugs and Devices</i>	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)	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 2. Technical Rule No. 314 for Registration and Follow-up in the Area of Health Research 3. Technical Rule 315 for the Operation of Research Commissions in Healthcare Institutions: http://www.cofepris.gob.mx/AS/Documents/M

Country	Key Organizations	Legislation	Regulations	Guidelines
				olécular%20Nuevas/Formatos/CONFIDENCIALIDAD%20CMN%20CAS-CAS-P-02-F-02.pdf
<i>Privacy/Data Protection</i>	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		
<i>Human Biological Materials</i>	Secretariat of Health: http://www.salud.gob.mx/	General Health Law, Title XIV, Articles 313-342 (2005): http://www.diputados.gob.mx/LeyesBiblio/pdf/142_040615.pdf	Regulation of the General Law of Health in Matter of Transplants (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MT.pdf	
<i>Genetic Research</i>	National Institute of Genomic Medicine: http://www.inmegen.gob.mx/es/	1. Biosafety Law on Genetically Modified Organisms (2005): http://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM.pdf 2. Regulation of the Biosafety Law on Genetically Modified Organisms (2008) http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LBOGM.pdf 3. Modifications to the General Health Law to Protect Genomic Sovereignty (2008) 4. 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				
<i>General</i>	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) 2. Executive Decree N°1843 on the National Research Ethics Committee of Panama (2014) (Spanish):	CBI : Various (Spanish): http://www.gorgas.gob.pa/index.php?option=com_content&view=article&id=54&Itemid=103&lang=es

Country	Key Organizations	Legislation	Regulations	Guidelines
			https://www.gacetaoficial.gob.pa/.../GacetaNo_27716_20150206.pdf 3. Executive Decree N° 6 on the National Research Ethics Committee of Panama (2015) (Spanish): https://www.gacetaoficial.gob.pa/pdfTemp/27716/GacetaNo_27716_20150206.pdf	
<i>Drugs and Devices</i>		Law 1 of 2001, Official Gazette 24,218 (Spanish): http://www.perezcarrera.com/leyes/ley-registro-sanitario-panama.pdf		
<i>Privacy/Data Protection</i>		Law 68 of 2003, Official Gazette 24,935		
<i>Human Biological Materials</i>		Law 3 of 2010, Official Gazette 26,468-B on Transplant of Organs and Tissues: https://www.gacetaoficial.gob.pa/pdfTemp/26468_B/GacetaNo_26468b_20100210.pdf		
<i>Embryos, Stem Cells, and Cloning</i>			Executive Decree No. 2 on Stem Cells (2013) (Spanish): http://www.gacetaoficial.gob.pa/pdfTemp/27207/40367.pdf	
Perú				
For an overview of clinical research regulations in Peru, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=170				
<i>General</i>	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.wipo.int/wipolex/en/text.jsp?file_id=203140		
<i>Drugs and Devices</i>	1. National Institute of Health (Spanish): http://www.ins.gob.pe/portal/jerarquia/1/251/drug-quality-control/jer.251 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): http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990	
<i>Clinical Trials Registry</i>	Peruvian Registry of Clinical Trials: http://www.ins.gob.pe/ensayosclinicos/			
<i>Research Injury</i>	National Institute of Health (Spanish): http://www.ins.gob.pe/portal/jerarquia/1/2		Regulation on Clinical Trials in Peru: Articles 26, 27 and 28	

Country	Key Organizations	Legislation	Regulations	Guidelines
	51/drug-quality-control/jer.251		(Spanish): http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990	
<i>Privacy/Data Protection</i>	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		
Trinidad and Tobago				
	1. Ministry of Health http://www.health.gov.tt/ 2. University of the West Indies (UWI), St. Augustine: http://sta.uwi.edu/fms/research/ethics.asp			UWI: 1. UWI Policy on Research Ethics 2. Application Guidelines 3. Ethics Committee Protocols Access: http://sta.uwi.edu/fms/research/ethics.asp
Uruguay				
Note: All websites and documents are in Spanish.				
<i>General</i>	Ministry of Public Health: http://www.msp.gub.uy/	1. Decree 189/998 http://www.mercosur.int/msweb/Normalas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF 2. Decree 379/008: http://www.elderechodigital.com.uy/smu/legisla/D0800379.html	Decree No. 370/2008: Regulation Concerning Research with Humans	
<i>Drugs and Devices</i>	Ministry of Public Health: http://www.msp.gub.uy/	Decree 189/998: http://www.mercosur.int/msweb/Normalas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF		
<i>Research Injury</i>	Ministry of Public Health: http://www.msp.gub.uy/	1. Decree 189/998 http://www.mercosur.int/msweb/Normalas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF 2. Decree 379/008:		

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.elderechodigital.com.uy/smu/legisla/D0800379.html		
<i>Privacy/Data Protection</i>	Ministry of Public Health: http://www.msp.gub.uy/	1. Law 18.331: http://www0.parlamento.gub.uy/leyes/AccesoTextoLey.asp?Ley=18331 2. Decree 379/008: http://www.elderechodigital.com.uy/smu/legisla/D0800379.html		
<i>Human Biological Materials</i>	1. Ministry of Public Health: http://www.msp.gub.uy/ 2. National Institute on Donation and Transplantation: www.indt.edu.uy	Decree 160/006: http://www.indt.edu.uy/documentos/documentacion_legal/decreto_160-006.pdf		
Venezuela				
Note: All websites and documents are in Spanish.				
<i>General</i>	1. National Fund on Science and Technology, Commission on Bioethics and Biosecurity (FONACIT): www.fonacit.gov.ve/ 2. Venezuelan Institute of Scientific Research, Bioethics Commission (IVIC): http://www.ivic.gob.ve/bioetica/?mod=home.php	Constitution, Article 46 (3): http://www.venezuelaemb.or.kr/english/ConstitutionoftheBolivarianingles.pdf	Resolution No. 48 (1998): http://www.ivic.gob.ve/bioetica/?mod=bioeticahome.php	FONACIT: Code on Bioethics and Biosecurity (2002) IVIC: 1. Annex 1: General Ethical Issues in Research Involving Living Persons: http://www.ivic.gob.ve/bioetica/?mod=Anexo.php 2. Annex 2: Necessity of Establishing a Clear and Precise Study Protocol Before Starting Research: http://www.ivic.gob.ve/bioetica/?mod=Anexo.php 3. Informed Consent: http://www.ivic.gob.ve/bioetica/?mod=manual.php
<i>Drugs and Devices</i>	National Institute of Hygiene “Rafael Rangel”: http://www.inhrr.gob.ve/	Medicines Act, Title III, Chapter II: http://www.ginecweb.com/PDF/Ley-del-Ejercicio-de-la-Medicina.pdf		
<i>Genetic Research</i>	Venezuelan Institute of Scientific Research, Bioethics Commission: http://www.ivic.gob.ve/bioetica/?mod=home.php			1. Contract for Accessing Genetic Resources (2003): http://www.ivic.gob.ve/bioetica/contrato.pdf 2. Revised Outline of the International Declaration of Human Genetic Data (2003): http://www.ivic.gob.ve/bioetica/chapter3.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
AFRICA				
Regionwide				
<i>Clinical Trials Registry</i>	Pan African Clinical Trials Registry: http://www.pactr.org/			FAQs: http://www.pactr.org/ATMWeb/appmanager/atm/atmregistry?_nfpb=true&_pageLabel=atmportal_page_FAQ
Benin				
<i>General</i>		Law No. 2010-40 of 8 December, 2010 Regarding the Ethical Code and Duties in Health Research in the Republic of Benin (French): http://ethique-sante.org/pdf/loi-portant-code-ethique.pdf		
Botswana				
<i>General</i>	Ministry of Health, Research and Development Committee: http://www.moh.gov.bw/	Anthropological Research Act 45 (1967): http://www.elaws.gov.bw/docs/statutes/Botswana%20Statute%20Law%201967.pdf		1. Guidelines for Application for Research Permit (2004): http://www.gov.bw/Global/OP%20Ministry/RESEARCH%20PERMIT%20GUIDELINES.pdf 2. Guidelines for the Review of Research Proposals (2005)
<i>Drugs and Devices</i>	Ministry of Health, Drug Regulatory Unit: http://www.moh.gov.bw/		Drugs and Related Substances Regulations (1993)	SADC Guidelines for Regulating Clinical Trials in Human Subjects (2006)
Burkina Faso				
Note: All websites and documents are in French.				
<i>General</i>	Ethics Committee for Health Research		Joint Order 2004-147 / MS / MESSE of 11 May 2004 on the Organization and Functioning of the Ethics Committee for Health Research in Burkina Faso	
<i>Drugs and Devices</i>			Order No. 2010-292 / MS / CAB of 1 October 2010 on the Conditions for Granting Authorizations for Clinical Trials: http://elearning.trree.org/pluginfile.php/34806/mod_folder/content/0/19_Arrete_autorisations_essais_cliniques.pdf?forcedownload=1	

Country	Key Organizations	Legislation	Regulations	Guidelines
Cameroon				
For an overview of human subject protections in Cameroon, see: http://elearning.trree.org/mod/nationalsupplement/view.php?id=227				
<i>General</i>	Cameroon Bioethics Initiative: www.cambin.org		Ministerial Order No. 079/A/MSP/DS of MINSANTE (1987) (French): http://elearning.trree.org/pluginfile.php/34735/mod_folder/content/0/cm-arrete-079-MSP-CreationComiteEthique-1987.pdf?forcedownload=1	Operational Guidelines for Ethics Committees in Charge of the Evaluation of Biomedical Research
Congo, Democratic Republic of				
<i>General</i>		National Policy on Health Systems Research (2004) (French)		
Côte-d'Ivoire				
For an overview of human subject protections in Côte-d'Ivoire, see: http://elearning.trree.org/course/view.php?id=19 Note: All websites and documents are in French.				
<i>Drugs and Devices</i>	National Committee on Ethics and Research		Decree No 317 / SP / DSPH of 14 July 1987 on the Regulation of Drugs Before and After Marketing in Ivory Coast: http://elearning.trree.org/pluginfile.php/34816/mod_folder/content/0/20_Arrete_Regl_exp_clinique_des_substances_med.pdf?forcedownload=1	
Ethiopia				
<i>General</i>	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 (2014): http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf
<i>Drugs and Devices</i>	Food, Medicine, and Health Administration and Control Authority: www.fmhaca.gov.et		Drug Administration and Control Proclamation No. 176/1999, Article 21	
<i>Human Biological Materials</i>	Ethiopian Science and Technology Commission, Health Department: http://www.most.gov.et/			National Health Research Ethics Review Guideline, Fourth Edition, Chapter 9 (2005): http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf
Gambia				
<i>Genetic Research</i>	MRC: Gambia Unit: http://www.mrc.gm/			Guidelines of the National DNA Bank (2001)

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Ghana				
<i>Drugs and Devices</i>	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 2. Good Clinical Practice Document No. FDA/SMC/CTD/GL-GCP/2013/02, Version No. 01
Guinea				
For an overview of the clinical research regulations in Guinea, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=90 Note: All websites and documents are in French.				
<i>General</i>	National Ethics Committee on Health Research (CNERs): http://cners-guinee.org/	Public Health Code, Articles 237-316 (1997): http://www.vertic.org/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf	Decree No. D/218/PRG/SGG: On the Establishment, Functions and Organization of the National Ethics Committee for Research in Health (CNERs), Chapters I and II (1998): http://cners-guinee.org/wp-content/uploads/2014/02/Decret-.pdf	CNERs: Frequently Asked Questions: http://cners-guinee.org/faq/
<i>Research Injury</i>	National Ethics Committee on Health Research: http://cners-guinee.org/	Public Health Code, Articles 301-302 (1997): http://www.vertic.org/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf		
Kenya				
For an overview of the clinical research regulations in Kenya, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=111				
<i>General</i>	1. National Council for Science and Technology (NCST): http://www.nacosti.go.ke/ 2. Ministry of Health (MOH): www.health.go.ke/	1. Science and Technology Act (2001) 2. HIV and AIDS Prevention and Control Act, Chapter 14 (2006)		MOH: National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): https://healthresearchweb.org/?action=download&file=Final%20national%20ethical%20guidelines-last%20draft.pdf
<i>Drugs and Devices</i>	Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/	Pharmacy and Poisons Act, Chapter 244 (2009): http://apps.who.int/medicinedocs/documents/s18245en/s18245en.pdf	MOH: Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005)	Guidelines for Applications to Conduct Clinical Trials in Kenya (2014): http://pharmacyboardkenya.org/downloads/?file=Clinical%20Trial%20Guidelines%202014.pdf
<i>Human Biological Materials</i>	Ministry of Health (MOH): www.health.go.ke/		Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, page 44 (2005)	

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Liberia				
For an overview of the clinical research regulations in Liberia, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=122				
<i>General</i>	Ministry of Health and Social Welfare: http://www.mohsw.gov.lr/		1. Institutional Review Board (IRB) Policies and Procedures Handbook (2008): http://www.ul-acre.org/wp-content/uploads/2013/03/UL-IRB-Policy-Handbook.pdf 2. Ethics Committee Guidelines: Procedures for Researchers, Section 1 (2011): http://clinregs.niaid.nih.gov/documents/liberia/G-LIBR-NHSREC.pdf	
<i>Drugs and Devices</i>	Liberia Medicines and Health Products Regulatory Authority			Guideline for Application to Conduct Clinical Trials in Liberia (2014): https://clinregs.niaid.nih.gov/documents/liberia/G-LibClinTrial.pdf
Malawi				
For an overview of the clinical research regulations in Malawi, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=129				
<i>General</i>	1. National Commission for Science and Technology (NCST): http://www.ncst.mw/ 2. National Health Sciences Research Committee (NHSRC): http://www.ncst.mw/national-health-science-research-committee-nhsrc/ 3. College of Medicine Research and Ethics Committee (COMREC): http://www.medcol.mw/ 4. Ministry of Health: www.malawi.gov.mw	1. Presidential Decree on 30 th March 1974 2. Malawi Government Gazette, June 11, 1976, General Notice No. 398 3. Constitution of Malawi, Article 19(5) (1994)		NCST: 1. The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011) 2. Policy Requirements, Procedures and 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: General Guidelines on Health Research (2014): http://www.medcol.mw/comrec/wp-content/uploads/2014/07/comrec_guidelines.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Drugs and Devices</i>	Pharmacy, Medicines, and Poisons Board of Malawi	1. Pharmacy, Medicines, and Poisons Act, Act 15 of 1988: http://www.google.com/url?sa=t&rc=t=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CB0QFjAAahUKEwi3qf2P2vLIAhUEqh4KHfyNBvw&url=http%3A%2F%2Fwww.malawilii.org%2Ffiles%2Fmw%2Flegislation%2Fconsolidated-act%2F35%3A01%2Fpharmacy_medicines_poisons_act_pdf_19885.pdf&usg=AFQjCNFJR-Y4F7y3eoC6DV0H7Jr77s5MMsg 2. Section 42(1) of PMPB Act, 2003 Supplement		
<i>Genetic Research</i>	National Research Council of Malawi (NRCM): www.sdn.org.mw/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/course/view.php?id=14&lang=en				
<i>General</i>				Science and Technology Ethics Code (2007) (Portuguese): http://elearning.trree.org/pluginfile.php/34764/mod_folder/content/0/02-CodigoDeEtica.pdf?forcedownload=1
Nigeria				
For an overview of human subject protections in Nigeria, see: http://elearning.trree.org/mod/page/view.php?id=142				
<i>General</i>	National Health Research Ethics Committee: http://nhrec.net/	National Health Act 2014		Nigerian Code of Health Research Ethics (2007): http://www.nhrec.net/nhrec/NCHRE_10.pdf Various: http://nhrec.net/download-guides-and-forms/
<i>Drugs and Devices</i>	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	
<i>Clinical Trial Registries</i>	National Health Research Ethics Committee: http://nhrec.net/			Frequently Asked Questions: http://nhrec.net/nctr/FAQ.php
<i>Human Biological Materials</i>	National Health Research Ethics Committee: http://nhrec.net/			Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria (2013): http://nhrec.net/nhrec/NHREC_Policy_Statement_on_Biobanks_FINAL.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Rwanda				
<i>General</i>	Ministry of Health, National Ethics Committee: http://www.moh.gov.rw/index.php?id=2			Standard Operating Procedures (2009): http://www.moh.gov.rw/index.php?option=com_docman&task=doc_download&gid=126&Itemid=81
Senegal				
<i>General</i>	National Committee on Health Research Ethics	Law Supporting the Code of Ethics for Health Research (2009) (French): http://www.sante.gouv.sn/document/1432205899.pdf		
Sierra Leone				
For an overview of the clinical research regulations in Sierra Leone, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=193				
<i>General</i>	Sierra Leone Ethics and Scientific Review Committee			1. Application Guidelines http://health.gov.sl/wp-content/uploads/2015/01/Guidelines-and-Checklist-for-Ethical-Clearance-2016.pdf 2. Application Form: https://www.healthresearchweb.org/?action=download&file=SierraLeoneEthicsandScientificReviewCommittee.docx
<i>Drugs and Devices</i>	1. Ministry of Health (French): http://www.sante.gov.bf/ 2. Pharmacy Board of Sierra Leone: http://pharmacyboard.gov.sl/		1. Guidelines for Conducting Clinical Trials of Medicines, Food Supplements, Vaccines, and Medical Devices in Sierra Leone, Sections: 3.1.7 and 3.2 (2014): http://pharmacyboard.gov.sl/site/LinkClick.aspx?fileticket=9jeTGC2WIZ8%3d&tabid=316&portalid=1&mid=934 2. Guideline for Good Clinical Practice (GCP) in Sierra Leone, Sections 3.2 and 3.3 (2014): http://pharmacyboard.gov.sl/site/LinkClick.aspx?fileticket=9jeTGC2WIZ8%3d&tabid=316&portalid=1&mid=934 3. Guideline for Conducting Clinical Trials: http://pharmacyboard.gov.sl/site/LinkClick.aspx?fileticket=YrGQkXzfLP8%3d&tabid=316&portalid=1&mid=934&forcedownload=true	Forms: http://pharmacyboard.gov.sl/site/Downloads/Forms.aspx

Country	Key Organizations	Legislation	Regulations	Guidelines
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 an overview of the clinical research regulations, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=199				
<i>General</i>	1. Department of Health (DH): http://www.doh.gov.za 2. National Health Research Ethics Council: http://www.nhrec.org.za/ 3. Medical Research Council of South Africa (MRC): http://www.mrc.ac.za 4. Human Sciences Research Council (HSRC): http://www.hsrc.ac.za/index.phtml	1. Constitution of South Africa, Section 12 (2) (1996) 2. National Health Act No. 61, Chapter 9 (2003): http://www.saflii.org/za/legis/consolidated/nha2003147.pdf	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-notice/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=AFQjCNFpKA9W0jNveWhk0n0l0Q-WxazBtg	DH: Ethics in Health Research: Principles, Structures, and Processes (2015): http://www.nhrec.org.za/docs/Documents/EthicsHealthResearchFinalAused.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)
<i>Drugs and Devices</i>	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.hpcsa.co.za/Uploads/Editor/UserFiles/downloads/legislations/acts/medicines_and_related_sub_act_101_of_1965.pdf	General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (2003): http://www.hpcsa.co.za/Uploads/Editor/UserFiles/downloads/legislations/acts/medicines_and_related_sub_act_101_of_1965.pdf	DH: Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006): http://www.nhrec.org.za/docs/trainingrequirements/gcp.pdf
<i>Clinical Trials Registry</i>	South African National Clinical Trials Register: http://www.sanctr.gov.za/			FAQs: http://www.sanctr.gov.za/InvestigatorbrnbspInformation/FAQ/tabid/200/Default.aspx
<i>Human Biological Materials</i>	Department of Health (DH): http://www.doh.gov.za	National Health Act No. 61, Chapter 8, Sections 53-68 (2003): http://www0.sun.ac.za/ruralhealth/ukwandahome/rudasaresources2009/DOH/ethics/app5.pdf	1. Regulations Relating to the Use of Human Biological Material, 2 March 2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf 2. Regulations Regarding General Control of Human Bodies, Tissues, Blood Products and Gametes, 2 March 2012 3. Regulations Relating to Blood and Blood Products, 2 March 2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf 4. Regulations Relating to Artificial Insemination of Persons, 2 March 2012:	

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.sashg.org/documents/GovGazette2Mar2012.pdf	
<i>Genetic Research</i>	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
<i>Embryos, Stem Cells, and Cloning</i>	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za	National Health Act No. 61, Chapter 8, Section 57 (2003): http://www0.sun.ac.za/ruralhealth/ukwandahome/rudasaresources2009/DOH/ethics/app5.pdf	Regulations relating to Stem Cell Banks, 2 March 2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf	Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.kznhealth.gov.za/research/ethics2.pdf
Sudan				
<i>General</i>	Federal Ministry of Health: http://www.fmoh.gov.sd/			National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): http://sites.google.com/site/healthresearchlibrary/national-guidelines
<i>Drugs and Devices</i>	National Medicines and Poisons Board: http://www.nmpb.gov.sd/en/	Act on Pharmaceuticals and Poisons (2009) (Arabic): http://www.nmpb.gov.sd/index.php/2015-08-05-11-05-04/regulations/113-laws2009		
<i>Human Biological Materials</i>	Federal Ministry of Health: http://www.fmoh.gov.sd/	Human Organs and Tissues Transplant Legislation, Chapter 2, Articles 3 and 4 (1978)		
<i>Genetic Research</i>	University of Khartoum, Institute of Endemic Diseases: http://iend.uofk.edu/index.php?lang=en			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 an overview of the clinical research regulations in Tanzania, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=212				
<i>General</i>	1. Ministry of Health (MOH) 2. National Institute for Medical Research (NIMR), National Health Research Ethics Committee (NHREC): http://www.nimr.or.tz/ 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. Brochure for Health Researchers in Tanzania (2006) 2. Guidelines on Ethics for Health Research in Tanzania (2009): https://clinregs.niaid.nih.gov/documents/tanzania/G-EthicsHR.pdf COSTECH: COSTECH Guidelines on Research Permits and Clearance (2006)

Country	Key Organizations	Legislation	Regulations	Guidelines
<i>Drugs and Devices</i>	<i>Drugs</i>	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003): http://www.tfda.or.tz/index.php?option=com_phocadownload&view=category&download=44:tfdc-acts-2003&id=52:tfdc-acts-2003&Itemid=417	
	<i>Devices</i>	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Medical Device Act (1988)	
	Tunisia			
<i>Drugs and Devices</i>	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
<i>Clinical Trials Registry</i>	Tanzania Clinical Trial Registry: http://www.tzctr.or.tz/			FAQs: http://www.tzctr.or.tz/faq.php
Uganda	For an overview of the clinical research regulations in Uganda, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=223			
<i>General</i>	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
<i>Drugs and Devices</i>	National Drug Authority: http://www.nda.or.ug/	National Drug Policy and Authority Act (CAP 206) (1993)		
Zambia				
<i>General</i>	Ministry of Health: http://www.moh.gov.zm/	National Health Research Act (2013)		
Zimbabwe				
<i>General</i>	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw	1. Medical Research Government Notice Act (1974) 2. Research Act (1986)		Various: http://www.mrcz.org.zw/faqs/
<i>Drugs and Devices</i>	<i>Drugs</i>			
	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	1. Guidelines for Good Clinical Practice (2012): http://www.medbox.org/guidelines-for-good-clinical-trial-practice-in-zimbabwe-2012/download.pdf 2. Pharmacy Guidelines for Investigational Drugs (2016):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.mcaz.co.zw/index.php/downloads/file/114-pharmacy-guidelines-for-investigational-drugs-draft-1
	<i>Devices</i>			
	Medicines Control Authority of Zimbabwe: http://www.mcaz.co.zw/devices.html	Medicines and Allied Substances Control Act, Chapter 15:03 (1997): https://www.unodc.org/res/cld/document/zwe/medicines-and-allied-substances-control-act_html/Zimbabwe_Medicines_and_Allied_Substances_Control_Act.pdf	Medicines and Allied Substances Control (Condom) Regulations (2005): http://www.mcaz.co.zw/index.php/downloads/category/15-regulations-and-guidelines?download=29:condom-regulations	
<i>Human Biological Materials</i>	Research Council of Zimbabwe: www.rcz.ac.zw	Research Act (2001): http://faolex.fao.org/docs/pdf/zim93551.pdf		Various: http://www.rcz.ac.zw/research-registration/
<i>Genetic Research</i>	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-biotechnology-authority-act		

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