International Compilation of Human Research Standards

2018 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 (collectively referred to as standards) that govern human subjects research in 130 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. Four new countries are featured in the 2018 Edition: Algeria, Madagascar, Mali, and Saint Lucia. For the first time, this year's Compilation includes a section on Social-Behavioral Research.

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. Social-Behavioral Research
6. Privacy/Data Protection (also see Privacy International reports: https://www.privacyinternational.org/reports)
7. Human Biological Materials
8. Genetic (also see the HumGen International database: http://www.humgen.umontreal.ca/int/)
9. Embryos, Stem Cells, and Cloning

These nine 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.

TABLE OF CONTENTS

Country	Key Organizations	Legislation	Regulations	Guidelines
INTERNATIONAL				
General	Council for International Organizations of Medical Sciences (CIOMS): http://www.cioms.ch/			International Ethical Guidelines for Health-related Involving Humans (2016): https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/
	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 4. Guidelines on Ethical Issues in Public Health Surveillance (2017): http://www.who.int/ethics/publications/public-health-surveillance/en/
	United Nations Educational, Scientific, and Cultural Organization, Bioethics Program (UNESCO): https://en.unesco.org/			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/jc1

Country	Key Organizations	Legislation	Regulations	Guidelines
				399_ethical_considerations_en.pdf
	Office of the United Nations High Commissioner for Human Rights (OHCHR): http://www.ohchr.org/english/	International Covenant on Civil and Political Rights, Article 7 (1976): 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		
Drugs, Biologics, and Devices	*Drugs*			
	International Conference on Harmonization (ICH): http://www.ich.org/			Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice (2016): https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf
	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)
	Devices			
	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

Country	Key Organizations	Legislation	Regulations	Guidelines
				Archived Documents from the Global Harmonization Task Force (GHTF), replaced by the IMDRF in 2012: 1. Clinical Evaluation (2007) 2. Clinical Evidence – Key Definitions and Concepts (2007) 3. Post-Market Clinical Follow-Up Studies (2010) 4. Clinical Investigations (2010) 5. Reportable Events During Pre-Market Clinical Investigations (2012) 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/ghtf/ghtf-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/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=45557
Clinical Trials Registry	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
Research Injury	World Medical Association: http://www.wma.net/e/			Declaration of Helsinki, Paragraph 15 (2013): http://www.wma.net/en/30publications/10policies/b3/index.html
	International Conference on Harmonization (ICH): http://www.ich.org/			Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ,

Country	Key Organizations	Legislation	Regulations	Guidelines
				Section 5.8 (2016): https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf
	Council for International Organizations of Medical Sciences: http://www.cioms.ch/			International Ethical Guidelines for Biomedical Research Involving Human Subjects, Guideline 19 (2002): https://cioms.ch/shop/product/international-ethical-guidelines-for-biomedical-research-involving-human-subjects-2/
Social-Behavioral Research	UNESCO: http://www.unesco.org/			Code of Conduct and Ethical Guidelines for Social Science Research: http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/SHS/pdf/Soc_Sci_Code.pdf
Privacy/Data Protection	World Medical Association: http://www.wma.net/e/index.htm			1. Declaration on Ethical Considerations Regarding Health Databases (2002): http://www.wma.net/en/30publications/10policies/d1/index.html 2. Declaration of Helsinki, Paragraph 24 (2013): http://www.wma.net/en/30publications/10policies/b3/index.html
Human Biological Materials	World Health Organization: http://www.who.int/en/			1. Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens (1997): www.who.int/csr/emc97_3.pdf 2. Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research (2003): http://www.who.int/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
Genetic Research	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-

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				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
	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
Embryos, Stem Cells, and Cloning	International Society for Stem Cell Research: http://www.isscr.org/			Guidelines for the Conduct of Human Embryonic Stem Cell Research (2006): http://www.isscr.org/docs/default-source/hesc-guidelines/isscrhescguidelines2006.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
NORTH AMERICA				
Canada Note: Several Canadian provinces and territories also have human subject research standards.				
General	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, 2nd 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
Drugs, Biologics, and Devices	*Drugs*			
	1. Health Canada, Therapeutic Products Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index		1. 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 2. Good Clinical Practice Consolidated Guideline (2004): http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/e6-eng.pdf	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 11: Clinical Trials (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/
	Devices			
	Health Canada, Medical Devices: http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php		Medical Devices Regulations (SOR/98-282) (1998): http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/FullText.html	
Clinical Trials Registry	1. Health Canada Clinical Trial Database: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdonclin/index-eng.php 2. Interagency Advisory Panel on			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 11.3 (2014): http://www.pre.ethics.gc.ca/eng/policy-

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	Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			politique/initiatives/tcps2-eptc2/chapter11-chapitre11/
Research Injury	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Article 3.2(j) (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/
Social-Behavioral Research	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. Exemptions (Chapter 2) and Qualitative Research (Chapter 10) (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/
Privacy/Data Protection Note: Each of the Canadian provinces and territories also has enacted privacy legislation.	1. Office of the Privacy Commissioner of Canada (OPC): 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, 2nd 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
Human Biological Materials	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 12: Human Biological Materials Including Materials Related to Human Reproduction (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/
Genetic Research	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 2. Canadian Biotechnology Advisory Committee (CBAC): http://www.hc-sc.gc.ca/sr-sr/biotech/role/strateg-eng.php 3. Biologics and Genetic Therapies			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 13: Human Genetic Research (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter13-

Country	Key Organizations	Legislation	Regulations	Guidelines
	Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php			chapitre13/
Embryos, Stem Cells, and Cloning	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 (2007): http://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-137/index.html	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 12, Sections E and F (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/
United States All of the following departments and agencies subscribe to subpart A, often referred to as the Common Rule (last updated in 2009), and 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: • Subpart B: Additional Protections for Pregnant Women, Human Fetuses, and Neonates (2001) • Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (1978) • Subpart D: Additional Protections for Children Involved as Subjects in Research (1991) • Subpart E: Institutional Review Board Registration Requirements (2009)				
General	Agency for International Development: www.usaid.gov/		22 CFR 225, Subpart A	Protection of Human Subjects in Research Supported by USAID: A Mandatory Reference for ADS Chapter 200 (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): https://www.afm.ars.usda.gov/media/10444/pp605-1.pdf
	Department of Commerce, National Institute of Standards and Technology: www.commerce.gov/		15 CFR 27, Subpart A	
	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	1. 34 CFR 97 subparts A (1991) and D (1997) 2. 34 CFR 98 (1984)	

Country	Key Organizations	Legislation	Regulations	Guidelines
		and Privacy Act (1974)	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	
	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 Health and Human Services, Food and Drug Administration: https://www.fda.gov/		*For studies funded by FDA:* 45 CFR 46, Subparts A, D, and E: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html	
	Department of Homeland Security: www.dhs.gov/	Public Law 108-458, Section 8306	1. 45 CFR 46, Subparts A-D 2. DHS Directive 026-04, Human Subjects Research (2007): https://www.dhs.gov/xlibrary/assets/foia/mgmt-directive-026-04-protection-of-human-subjects.pdf	
	Department of Housing and Urban Development: www.hud.gov/		24 CFR 60.101, which cites 45 CFR part 46, subpart A.	
	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/USCODE-2010-title42/html/USCODE-2010-title42-chap46-subchapVIII-sec3789g.htm 3. 28 CFR 46 (1991), Subpart A: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr46_main_02.tpl	
	Department of Transportation: www.dot.gov/		49 CFR 11, Subpart A	
	Department of Veterans Affairs: 1. Office of Research Oversight (ORO): http://www1.va.gov/oro/ 2. Office of Research and		1. 38 FR 16 (1991), Subpart A 2. 38 CFR 17.85 (1998)	Various: https://www.research.va.gov/resources/policies/human_research.cfm

Country	Key Organizations	Legislation	Regulations	Guidelines
	Development: www.research.va.gov			
	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 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)	Scientific and Ethical Approaches for Observational Exposure Studies (2008): http://www.epa.gov/nerl/sots/SEAOES_doc20080707.pdf
	National Aeronautics and Space Administration: www.nasa.gov/		14 CFR 1230, Subpart A	
	National Science Foundation: www.nsf.gov/		45 CFR 690, Subpart A	
	Social Security Administration: http://www.ssa.gov/		45 CFR 46, Subpart A: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html	
Drugs, Biologics, and Devices	*Drugs and Biologics*			
	Food and Drug Administration: http://www.fda.gov/Drugs/default.htm	1. Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (2012): https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/default.htm#Part_A 2. Public Health Service Act, 42	1. 21 CFR 50 (Informed Consent) 2. 21 CFR 312 (Investigational New Drug Application) 3. 21 CFR 56 (Institutional Review Boards) 4. 21 CFR 314 (Applications for Approval to Market a New Drug) 5. 21 CFR 54 (Financial	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/GuidanceComplianc

Country	Key Organizations	Legislation	Regulations	Guidelines
		USC Section 262 (1998): https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/ucm149278.htm 3. 21st Century Cures Act, Section 3024 (2016): https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf	Disclosure by Clinical Investigators) 6. 21 CFR 320 (Bioavailability and Bioequivalence Requirements)	eRegulatoryInformation/Guidances/default.htm
	Devices			
	Food and Drug Administration, Center for Devices and Radiological Health: http://www.fda.gov/MedicalDevices/default.htm	1. Food, Drug, and Cosmetic Act, 21 USC Section 360 (2012): https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/default.htm#Part_A 2. 21st Century Cures Act, Section 3024 (2016): https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf	1. 21 CFR 50 (Informed Consent) 2. 21 CFR 56 (Institutional Review Boards) 3. 21 CFR 807, Subpart E 4. 21 CFR 812 (Investigational Device Exemptions) 5. 21 CFR 814 (Premarket Approval of Medical Devices) 6. 21 CFR 54 (Financial Disclosure by Clinical Investigators)	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
Clinical Trials Registry	Food and Drug Administration: http://www.fda.gov/Drugs/default.htm	1. Food and Drug Administration Modernization Act, Section 113 (1997): https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/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		
	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):	FAQs on ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/manage-recs/faq

Country	Key Organizations	Legislation	Regulations	Guidelines
			https://www.federalregister.gov/documents/2016/09/21/2016-22379/dissemination-of-nih-funded-clinical-trial-information	
	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
Research Injury	Same as *General*, 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)	
Social-Behavioral Research	All Common Rule agencies		Exempt research (categories 1, 2, 3, and 4) and Expedited research (categories 6 and 7)	
	National Science Foundation: https://www.nsf.gov/			Frequently Asked Questions and Vignettes: https://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp
Privacy/Data Protection	1. DHHS National Institutes of Health (NIH): http://privacyruleandresearch.nih.gov/ 2. DHHS Office for Civil Rights (OCR): http://www.hhs.gov/ocr/hipaa/	1. Privacy Act, 5 U.S.C. § 552a (1974): http://www.justice.gov/opcl/privacyact1974.htm 2. Health Insurance Portability and Accountability Act (1996): 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): https://www.gpo.gov/fdsys/pkg/PL	1. HIPAA Privacy Rule, 45 CFR parts 160 and 164, Subparts A and C (2002): http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html 2. HIPAA Security Rule, 45 CFR parts 160, 162, and 164 (2009): 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/ OCR: Various: https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html and https://www.hhs.gov/hipaa/for-professionals/faq/research-uses-and-disclosures

Country	Key Organizations	Legislation	Regulations	Guidelines
		AW-111publ5/pdf/PLAW-111publ5.pdf		
	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		
Human Biological Materials	Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/			1. Issues to Consider in the Research Use of Stored Data or Tissues (1997) 2. Guidance on Research Involving Coded Private Information or Biological Specimens (2008)
	Food and Drug Administration: a. Office of In Vitro Diagnostic Device Evaluation and Safety: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm b. Center for Biologics Research and Evaluation (CBER): - Office of Cellular, Tissue and Gene Therapies - Office of Blood Research and Review: http://www.fda.gov/BiologicsBloodVaccines/default.htm			1. Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable (2006): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078384.htm 2. In Vitro Diagnostic (IVD) Device Studies - Frequently Asked Questions (2010) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071230.pdf 3. CBER-Specific: Various: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/ucm094338.htm
Genetic Research	1. DHHS Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/ 2. DHHS National Institutes of Health, Office of Science Policy, Biosafety, Biosecurity, and Emerging Biotechnology Policy Division: https://osp.od.nih.gov/biosafety-biosecurity-and-emerging-biotechnology/	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 or Synthetic Nucleic Acid Molecules (2016): https://osp.od.nih.gov/wp-

Country	Key Organizations	Legislation	Regulations	Guidelines
				content/uploads/2013/06/NIH_Guidelines.pdf
Embryos, Stem Cells, and Cloning	Food and Drug Administration, Center for Biologics Evaluation and Research: http://www.fda.gov/BiologicsBloodVaccines/default.htm			Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products. October 14, 1993. 58 FR 53248: 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
	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		1. Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Executive Order 13505 (2009): https://www.gpo.gov/fdsys/pkg/DCPD-200900136/pdf/DCPD-200900136.pdf 2. NIH Guidelines on Human Stem Cell Research (2009): http://stemcells.nih.gov/policy/2009-guidelines.htm 3. NIH Human Embryonic Stem Cell Registry (2016): https://grants.nih.gov/stem_cells/registry/current.htm Access: http://stemcells.nih.gov/

Country	Key Organizations	Legislation	Regulations	Guidelines
EUROPE				
Regionwide				
General	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			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
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG		
Drugs, Biologics, and Devices	*Drugs*			
	European Commission: DG SANTE: Directorate-General for Health and Food Safety: http://ec.europa.eu/health/index_en.htm	1. Directive 2001/20/EC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf 2. Directive 2005/28/EC Laying		EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/health/documents/eudralex/vol-10/

Country	Key Organizations	Legislation	Regulations	Guidelines
		Down Principles and Detailed Guidelines for Good Clinical Practice as Regards Investigational Medicinal Products for Human Use, as Well as the Requirements for Authorization of the Manufacturing or Importation of Such Products: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2005_28/dir_2005_28_en.pdf 3. Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: http://ec.europa.eu/health/files/eudralex/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): https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/3cc1aen_en.pdf 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 (2015): http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/10/WC500174378.pdf 4. Guideline for Good Clinical Practice E6(R2) (2016): http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
				5. Q&A: Good Clinical Practice (GCP): http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000016.jsp&mid=WC0b01ac05800296c5 6. Inspections Procedure - Recommendations and Guidance Related to the Implementation of GCP: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000140.jsp&mid=WC0b01ac05800296c6 7. GCP Inspectors Working Group: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000136.jsp&mid=WC0b01ac05800296c4
	Devices			
	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 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		Various: http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm
Clinical Trials Registry	EU Clinical Trials Register: https://www.clinicaltrialsregister.eu/			FAQs: https://www.clinicaltrialsregister.eu/doc/EU_CTR_FAQ.pdf
Research Injury	European Commission: DG SANTE: Directorate-General for	1. Clinical Trials Directive 2001/20/EC:		

Country	Key Organizations	Legislation	Regulations	Guidelines
	Health and Food Safety: http://ec.europa.eu/health/index_en.htm	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=10/24/2007&CL=ENG		
Privacy/Data Protection	1. European Commission: Directorate-General for Justice and Consumers: http://ec.europa.eu/justice/mission/index_en.htm 2. European Medicines Agency (EMA): http://www.ema.europa.eu/	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		EMA: External Guidance on the Implementation of the European Medicines Agency Policy on the Publication of Clinical Data for Medicinal Products for Human Use (2016): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/12/WC500218567.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
		Protection Regulation): http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN		
	Council of Europe: Data Protection and Cybercrime Division: http://www.coe.int/t/dghl/standardsetting/dataprotection/default_EN.asp	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		1. 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 2. Article 29 Working Party Documentation: http://ec.europa.eu/justice/data-protection/article-29/index_en.htm
Human Biological Samples	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		
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics	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		Recommendation Rec (2016) 6 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff
Genetic Research	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	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Co		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&BackCo

Country	Key Organizations	Legislation	Regulations	Guidelines
		mmun/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		lorIntranet=FFBB55&BackColorLogged=FFAC75 2. Recommendation Rec (2006)4 of the Committee of Ministers to Members States on Research on Biological Materials of Human Origin (2016): https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff 5. Recommendation Rec(2016)8 of the Committee of Ministers to Member States on the Processing of Personal Health-Related Data for Insurance Purposes, Including Data Resulting from Genetic Tests (2016): https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016806b2c5f
Embryos, Stem Cells, and Cloning	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/sec2003-441report_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/KAAJ07022ENC_002.pdf;pgid=y8dIS7GUWMdSR0EAlMEUUsWb0000dz-kvfzb;sid=Iexx3tq0IOFxyokBvtfvebiRJj93DZfXP54=?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		Statement on Genome Editing Technologies by the Committee on Bioethics (2015): https://rm.coe.int/168049034a

Country	Key Organizations	Legislation	Regulations	Guidelines
Armenia 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 Note: All websites and documents are in Armenian.				
Drugs, Biologics, and Devices	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 New Medications in Armenia: http://www.arlis.am/DocumentView.aspx?docID=9154		
Human Biological Materials	Ethical Committee of the National Center for AIDS Prevention: http://www.armaids.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/EFGCPReportFiles/Austria%20definitive.pdf				
General	1. Ministry of Health (German): http://www.bmg.gv.at 2. Forum of Austrian Ethics Committees (German): http://www.ethikkommissionen.at 3. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	1. University Act (2011): http://www.ris.bka.gv.at/Dokumente/Erv/ERV_2002_1_120/ERV_2002_1_120.pdf 2. Hospitals Act (2014) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010285&ShowPrintPreview=True	Regulation on Leading Ethics Committees (2004) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20003352&ShowPrintPreview=True	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
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Health (German): http://www.bmg.gv.at 2. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/en/ages-austrian-agency-for-health-and-food-safety/ 3. Austrian Federal Office for Safety in Health Care: http://www.basg.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/
	Devices			
	1. Ministry of Health (German):	Medical Devices Act (2014)		Various (German):

Country	Key Organizations	Legislation	Regulations	Guidelines
	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/	(German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003		http://www.basg.at/medizinprodukte/formulare/klinische-pruefung/
Research Injury	1. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/en/ages-austrian-agency-for-health-and-food-safety/ 2. Austrian Federal Office for Safety in Health Care: http://www.basg.at/en/austrian-federal-office-for-safety-in-health-care/	1. Austrian Drug Law, Article 32 (2013) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True 2. Austrian Medical Devices Law, Article 47 (2017) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003&ShowPrintPreview=True		
Privacy/Data Protection Note: The Austrian states also have privacy/data protection laws	Austrian Data Protection Authority: https://www.dsb.gv.at/DesktopDefault.aspx?alias=dsken	Federal Act Concerning the Protection of Personal Data (2014): http://www.ris.bka.gv.at/Dokumente/Erv/ERV_1999_1_165/ERV_1999_1_165.pdf		
Human Biological Materials	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	1. Law on Safety of Blood (2009) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011145&ShowPrintPreview=True 2. Law on Quality and Safety of Human Tissue and Cells (2013) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005698&ShowPrintPreview=True	Regulation on Tissue Banks (2014) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005848&ShowPrintPreview=True	Bioethics Commission: 1. Opinion of the Bioethics Commission at the Federal Chancellery: Biobanks for Medical Research (2007) 2. Biobanks for Medical Research - Amendments to the Bioethics Commission Report of May 2007 (2011) Access*:* http://www.bundeskanzleramt.at/site/4070/default.aspx
Genetic Research	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575	Gene Technology Act (2012) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen		

Country	Key Organizations	Legislation	Regulations	Guidelines
	/default.aspx	&Gesetzesnummer=10010826&ShowPrintPreview=True		
Embryos, Stem Cells, and Cloning	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	Reproductive Medicine Act (2010) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10003046&ShowPrintPreview=True		Bioethics Commission: 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				
General	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. National Bioethics Committee	1. Constitution of the Republic of Belarus, Article 25 (2004) (Russian): http://www.pravo.by/WEBNPA/text.asp?RN=v19402875 2. Law on Health Care System, Articles 40, 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: 1. Ordinance No. 274 on Establishing the National Bioethics Committee (2006) 2. Decree No. No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html	MOH: 1. Code of Medical Ethics (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37726.html 2. Guidelines for Ethics Committees on Standard Operational Proceedings (No. 55-0004, 2000) (Russian): http://www.levonevski.net/pravo/norm2009/num35/d35896/index.html 3. Methodological Guidelines of Health Ministry (2000)
Drugs, Biologics, and Devices	*Drugs* 1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. State Pharmacological Committee 3. Centre for Expertise and Testing in Health Care (Russian): http://rceth.by/	1. Law on Drugs, Articles 15,16 (2009) (Russian): http://pravo.by/webnpa/text.asp?RN=h10600161 2. Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: 1. Ordinance No. 254 on Clinical Drug Trials and Good Clinical Practice (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num36/d36922/index.html 2. Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37336.html 3. Decree No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html	MOH: Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004) (Russian): http://www.levonevski.net/pravo/norm2009/num24/d24926.html

Country	Key Organizations	Legislation	Regulations	Guidelines
			4. Decree No. 50 on Certain Aspects of Clinical Drug Trials (2009)	
	Devices			
	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. Centre for Expertise and Testing in Health Care (Russian): http://rceth.by/	Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: 1. Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37336.html 2. Decree No. 216 on Certain Aspects of Clinical Trials of Medical Devices (2008) (Russian): http://86.57.250.247/data/pravo/ipb_prikazmz/N216_2008.htm	MOH: Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004) (Russian): http://www.levonevski.net/pravo/norm2009/num24/d24926.html
Privacy/Data Protection	1. Ministry of Health: http://minzdrav.by/en/ 2. National Bioethics Committee	1. Constitution of the Republic of Belarus, Article 28 (2004) (Russian): http://www.pravo.by/WEBNPA/text.asp?RN=v19402875 2. Law on Health Care System, Article 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435		
Human Biological Materials	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. National Bioethics Committee 3. State Service of Forensic Medicine (SSFM)	Law on Health Care System, Articles 40 and 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	MOH: Ordinance No. 111 on Further Development of National Pathology Service (1993) (Russian): http://86.57.250.247/data/pravo/ipb_prikaznew/N111_1993(1994).doc SSFM: Ordinance No. 38-c on Rules for Conducting Morphological Examinations (1999)	
Belgium For an overview of human subject protections in Belgium, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Belgium%20definitive.pdf				
General	Belgium Advisory Committee on Bioethics (BACB):	Law Relating to Experimentation on Humans		BACB: 1. Opinion No. 13: Regarding

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.health.belgium.be/en	(2004): http://www.erasme.ulb.ac.be/page.asp?id=11365&langue=EN		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
Drugs, Biologics, and Devices	Medicines Directorate-General: http://www.health.belgium.be/eportal		1. Royal Decree of September 27, 1994 2. Royal Decree of June 30, 2004 Determining the Implementation Measures of the Law 3. Royal Decree of June 30, 2004 Modifying the Royal Decree of June 6, 1960 4. Royal Decree of July 15, 2004 Determining Payments for Ethical Opinions or Authorization for the Conduct of a Clinical Trial or Experiment 5. Application of the Law of May 7, 2004 Relating to Experiments on Human Volunteers who Participate in Phase I Trials (2004) 6. Explanations Concerning the Submission of a Request for an Ethical Opinion or Authorization for the Conduct of a Clinical Trial (2004)	
Research Injury		Law Relating to Experimentation on Humans, Chapter XVII (Responsibility and Insurance) Article 29 (2004)		

Country	Key Organizations	Legislation	Regulations	Guidelines
Privacy/Data Protection	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	
Human Biological Materials	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	1. Royal Decree (1987) Regarding the Expression of Consent for the Removal of Organs and Tissues on Living Donors 2. Royal Decree (1997) Regarding the Removal and Allocation of Organs of Human Origin 3. Act on the Removal and Transplantation of Organs (2006) 4. 2007 Amendment		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 CSS: Various: http://www.health.belgium.be/eportal/Aboutus/relatedinstitutions/SuperiorHealthCouncil/domains/cellstissuesorgans/index.htm#.Viovr88XQ0U
Embryos, Stem Cells, and Cloning	1. Belgian Advisory Committee on Bioethics: https://www.health.belgium.be/en/belgian-advisory-committee-bioethics 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

Country	Key Organizations	Legislation	Regulations	Guidelines
Bosnia and Herzegovina Note: All websites and documents are in Bosnian.				
General		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (2007): 2. Additional Protocol Concerning Biomedical Research, CETS No. 195 (2007) 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%20izmjenama%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/zakoni-i-strategije/zakoni/zakon-o-zdravstvenoj-zastiti		
Drugs, Biologics, and Devices	*Federation of Bosnia and Herzegovina*			
	1. Ministry of Health: http://www.fmoh.gov.ba/ 2. Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Law on Drugs No. 58/08: http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf 2. Law on Changes and Amendments of the Law on Drugs No. 29/05: http://www.almbih.gov.ba/_doc/regulative/fbih/Zakon_o_lijekovima-sluzbene_novine_FBiH_broj_29-05.pdf 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 4. Instructions on Manner of Reporting on Safety in the Framework of Clinical Trials (2016): http://www.almbih.gov.ba/_doc/upustva-vodici/uputstvo_o_nacinu_izvjestavanja_o_sigurnosti.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Republic of Srpska			
	1. Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx 2. Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Law on Drugs No. 58/08: http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf 2. Law on Changes and Amendments of Law on Drugs No. 34/08: http://www.almbih.gov.ba/_doc/regulative/rs/ID_Zakona_o_lijekovima_34_08.pdf	1. Regulation about Clinical testing of IMP and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf 2. Regulation about Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_ms_bos.pdf 3. Standards of GCP in Conducting CTs (2012): http://www.almbih.gov.ba/_doc/regulative/Smjernice_dobre_klinicke_prakse-bo.pdf 4. Instructions on Manner of Reporting on Safety in the Framework of Clinical Trials (2016): http://www.almbih.gov.ba/_doc/upustva-vodici/uputstvo_o_nacinu_izvjestavanja_o_sigurnosti.pdf	
Research Injury	*Federation of Bosnia and Herzegovina*			
	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 (2008): http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf 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	
	Republic of Srpska			
	Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx	1. Medicinal Products and Medicinal Devices Act, Article 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	Regulation about Clinical Testing of IMP and Medical Devices, 4/10: http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf	
Privacy/Data	Personal Data Protection Agency of	1. Law on the Protection of	Regulation on the Manner of	

Country	Key Organizations	Legislation	Regulations	Guidelines
Protection	Bosnia and Herzegovina: http://www.azlp.gov.ba/Default.aspx?langTag=en-US&template_id=147&pageIndex=1	Personal Data in Bosnia and Herzegovina (2005): http://www.azlp.gov.ba/propisi/Default.aspx?id=5&langTag=en-US&pageIndex=1 2. Law on Amendments to the Law on the Protection of Personal Data in Bosnia and Herzegovina, Official Gazette of Bosnia and Herzegovina No. 76/11 (2011): http://www.azlp.gov.ba/Default.aspx?langTag=en-US&template_id=147&pageIndex=1	Keeping the Records of Personal Data Filing Systems and the Pertinent Records Form (2009): http://www.azlp.gov.ba/propisi/default.aspx?id=1321&langTag=bs-BA	
Embryos, Stem Cells and Cloning	*Federation of Bosnia and Herzegovina*			
	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		
	Republic of Srpska			
	Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx	1. Law on Transplantation of Organs (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20transplantaciji%20ljudskih%20organa.pdf 2. Law on Transplantation of human tissues and cells (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20transplantaciji%20ljudskih%20tkiva%20i%20celija.pdf		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%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

Country	Key Organizations	Legislation	Regulations	Guidelines
				%81%d0%ba%d0%b8%d1%85_%d0%be%d1%80%d0%b3%d0%b0%d0%bd%d0%b0_64_10.pdf
Bulgaria				
General	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.parliament.bg/bg/const 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-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf 4. Medicinal Products in Human Medicine Act (2016): http://www.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf 5. Healthcare Act, Articles 197-206 (2017) (Bulgarian): http://www.lex.bg/laws/ldoc%20/2135489147		
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Healthcare (MOH) (Bulgarian): http://www.mh.government.bg/ 2. Bulgarian Drug Agency (BDA): http://www.bda.bg/en/	Medicinal Products in Human Medicine Act, Chapter 4 (2016): http://www.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	
	Devices			
	Bulgarian Drug Agency (BDA): http://www.bda.bg/en/	Medical Devices Act (2016): http://www.bda.bg/images/stories/documents/legal_acts/ZMI_en_20160308.pdf	Ordinance No. 10 of 2008 on the Documents Required from the Principal/Coordinating Investigator or Sponsor for Obtaining an Ethics Committee Statement and on the Procedure	Various: http://www.bda.bg/en/114-information-for-companies-section/medical-devices-category

Country	Key Organizations	Legislation	Regulations	Guidelines
			for Safety Monitoring of Medical Devices During Clinical Investigations and Assessment of the Clinical Data Collected During such Investigations (2010): http://www.bda.bg/images/stories/documents/legal_acts/Ordinance_Clinical_investigations_MD_EN.pdf	
Research Injury	Bulgarian Drug Agency (BDA): http://www.bda.bg/en/	Medicinal Products in Human Medicine Act, Chapter 4, Articles 91 and 92 (2016): http://www.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	
Privacy/Data Protection	1. Bulgarian Commission for Personal Data Protection: https://www.cpdp.bg/en/index.php?p=rubric&aid=2 2. Ombudsman: www.ombudsman.bg	Law for Protection of Personal Data (2016): https://www.cpdp.bg/en/index.php?p=element&aid=373		
Human Biological Materials:	1. Executive Agency for Transplantation (Bulgarian): http://www2.bgtransplant.bg/bg 2. Council of Ministers, Ethics Committee for Transplantation	1. 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-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf 2. Law on Transplantation of Organs, Tissues, and Cells (2013) (Bulgarian): http://bgtransplant.bg/iat/docs/Zakoni_ZTOTK.doc	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 (Bulgarian): http://www2.bgtransplant.bg/sites/default/files/docs/naredbi/Naredba_no13_ot_04_april_2007_g.rtf	
Embryos, Stem Cells, and Cloning	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	1. 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/me		

Country	Key Organizations	Legislation	Regulations	Guidelines
		dia/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf 2. Law on Transplantation of Organs, Tissues, and Cells (2013) (Bulgarian): http://bgtransplant.bg/iat/docs/Zakoni_ZTOTK.doc		
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/EFGCPReportFiles/Croatia%20definitive%20Updated.pdf				
General		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		
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Health: https://zdravlje.gov.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.halmed.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	Ordinance on Clinical Trials and Good Clinical Practice (2015): http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html	
	Devices			
	1. Ministry of Health: https://zdravlje.gov.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.halmed.hr/	Medical Devices Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1521.html		
Research Injury	1. Agency for Medicinal Products and Medical Devices of Croatia: http://www.halmed.hr/	1. Law on Mandatory Health Insurance (2013): http://www.hzzo.hr/wp-	Ordnance on Clinical Trials and Good Clinical Practice, Articles 11 and 16, Act 5.8., 6.8. and	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of Health: https://zdravlje.gov.hr/ 3. Croatian Health Insurance Fund: http://www.hzzo.hr/en/	content/uploads/2013/10/ZOZO_PROCISCENI_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	8.2.5 (2015): http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html	
Privacy/Data Protection	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		
Human Biological Materials	Ministry of Health: https://zdravlje.gov.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 (2012): 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	
Embryos, Stem Cells, and Cloning	Ministry of Health: https://zdravlje.gov.hr/	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and	Ordinance on the Conditions of Space, Professional Workers, Medical-Technical Equipment and Quality Assurance for Collection, Retrieval, Testing,	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Medicine, on the Prohibition of Cloning Human Beings (2003): http://zakon.poslovna.hr/public/Konvencija-o-zastiti-ljudskih-prava-i-dostojanstva-ljudskog-bica-u-pogledu-primjene-biologije-i-medicine-u-vezi-presadivanja-organa-i-tkiva-ljudskog-porijekla/243337/zakoni.aspx 2. Medical Fertilization Act, Article 32: (2012): http://www.hzzo-net.hr/dload/zakoni/20_01.pdf 3. Law on the Implementation of Human Tissues and Cells (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3070.html	Processing, Preservation, Storage and Allocation of Human Tissues and Cells (2013): http://www.propisi.hr/print.php?id=9354	
Cyprus For an overview of human subject protections in Cyprus, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Cyprus%20definitive%20Updated.pdf				
General		1. Law No. 31 (III)/2001: Oviedo Convention on Human Rights and Biomedicine 2. The Safeguarding and Protection of Patients' Rights Law (2004): http://www.bioethics.gov.cy/Moh/cnbc/cnbc.nsf/All/745717D26F068582C2257CCA003B350F/$file/Patients%20Rights%20Law-English%20translation.pdf		
Drugs, Biologics, and Devices	1. Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/Moh/phs/phs.nsf/dmlindex_en/dmlindex_en?opendocument 2. Ministry of Health, National Bioethics Committee: http://www.bioethics.gov.cy/moh/cnbc/cnbc.nsf/index_en/index_en?OpenDocument	Law for Good Clinical Practice (2004) (Greek): http://www.moh.gov.cy/Moh/phs/phs.nsf/All/9C064264122B82BEC22572FA003433A5/$file/%CE%9A.%CE%94.%CE%A0.%20452%20%CF%84%CE%BF%CF%85%202004.pdf?OpenElement		
Research Injury	Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/moh/moh.nsf/index_en/index_en?OpenDocument	Legislation Concerning Medicinal Products of Human Use (Good Clinical Practice) No. 452/2004 Article 11 (8) (Greek): http://www.moh.gov.cy/Moh/phs/ph		

Country	Key Organizations	Legislation	Regulations	Guidelines
		s.nsf/All/9C064264122B82BEC22572FA003433A5/$file/%CE%9A.%CE%94.%CE%A0.%20452%20%CF%84%CE%BF%CF%85%202004.pdf?OpenElement		
Privacy/Data Protection	Commissioner's Office for the Protection of Personal Data: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/index_en/index_en?opendocument	1. Processing of Personal Data (Protection of Individuals) Law of 2001: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/138(I)-2001_en.pdf 2. 2003 Amendments: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/37(I)-2003_en.pdf		
Embryos, Stem Cells, and Cloning		Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002)		
Czech Republic For an overview of human subject protections in the Czech Republic, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Czech%20definitive%20Updated.pdf				
General	Ministry of Health, Central Ethics Committee (Czech): http://www.mzcr.cz	1. Oviedo Convention on Human Rights and Biomedicine (2001) 2. Act No. 130/2002 Collection on Research and Development Support, as Amended 3. Act No. 372/2011 on Healthcare Services 4. Act. No. 373/2011 on Specific Healthcare Services		
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Health (MOH) (Czech): http://www.mzcr.cz 2. State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lr	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

Country	Key Organizations	Legislation	Regulations	Guidelines
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	Devices			
	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
Research Injury		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001) 2. Law No. 89/2012 Coll. Civil Code: http://www.czechlegislation.com/en/89-2012-sb		
Privacy/Data Protection	Office for Personal Data Protection: https://www.uoou.cz/en/	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	
Embryos, Stem Cells, and Cloning	1. Ministry of Education, Youth, and Sport: http://www.msmt.cz/index.php?lchan=1&lred=1 2. Research and Development Council, Bioethical Commission: http://www.vyzkum.cz/FrontClanek.aspx?idsekce=15908	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/EFGCPReportFiles/Denmark%20definitive.pdf				
General	National Committee on Health Research Ethics (NVK): http://www.nvk.dk/english	Act No. 1083 on Research Ethics Review of Health Research Projects (2017) (Danish): https://www.retsinformation.dk/Forms/R0710.aspx?id=192671 2013 version (English): http://www.nvk.dk/english/act-on-research	Executive Order No. 1464 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects (2016) (Danish): https://www.retsinformation.dk/Forms/R0710.aspx?id=185233	Guidelines about Notification (Checklist) (2017): http://www.nvk.dk/forsker/forskervejledning
Drugs, Biologics, and Devices	Danish Medicines Agency: https://laegemiddelstyrelsen.dk/en/	1. Act No. 506 on Medicinal Products (2013) (Danish):	1. Executive Order No. 295 on Clinical Trials of Medicinal	Guidelines for Applications for Authorisation of Clinical Trials of Medical

Country	Key Organizations	Legislation	Regulations	Guidelines
		https://www.retsinformation.dk/forms/r0710.aspx?id=146586 2. Act No. 620 on Clinical trials on Medical Products No. 620 (2016) (Danish): https://www.retsinformation.dk/Forms/r0710.aspx?id=180117	Products on Humans (2006): https://www.retsinformation.dk/Forms/R0710.aspx?id=9891 2. Executive Order No. 1464 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects (2016) (Danish): https://www.retsinformation.dk/Forms/R0710.aspx?id=185233	Products in Humans (2017): https://laegemiddelstyrelsen.dk/en/licensing/clinical-trials/trials-in-humans/guideline-for-applications-for-authorisation-of-clinical-trials-of-medicinal-products-in-humans/
Research Injury	Patient Compensation Association: http://pebl.dk/en.aspx	1. Liability for Damages Act (2007): http://pebl.dk/Patientskader/Love-og-regler/Lov-om-klage-og-erstatningsadgang/Behandlingsskader 2. Act No. 1022 on the Right to Complain and Receive Compensation within the Health Service (2017): https://www.retsinformation.dk/Forms/R0710.aspx?id=192623		
Privacy/Data Protection	Danish Data Protection Agency (DPA): https://www.datatilsynet.dk/english/the-danish-data-protection-agency/introduction-to-the-danish-data-protection-agency/	Act No. 429 on Processing of Personal Data (2007): https://www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/read-the-act-on-processing-of-personal-data/compiled-version-of-the-act-on-processing-of-personal-data/	Executive Order No. 1188 on Health Law, Chapter 9 (2016) (Danish): https://www.retsinformation.dk/forms/r0710.aspx?id=183932#idc101cee1-c9c0-4880-ac97-586a56134f56	
Human Biological Materials	National Committee on Health Research Ethics (NVK): http://www.nvk.dk/english	1. Executive Order No. 1188 on Health Law (2016) (Danish): https://www.retsinformation.dk/forms/r0710.aspx?id=183932 2. Act No. 1083 on Research Ethics Review of Health Research Projects (2017) (Danish): https://www.retsinformation.dk/Forms/R0710.aspx?id=192671		1. Biobanks are Covered by the Act on Processing of Personal Data (2010): https://www.datatilsynet.dk/english/health-research-and-statistics-projects/biobanks-are-covered-by-the-act-on-prcessing-of-personal-data/ 2. Guidelines on the Use of Biological Material in Health Research Projects (2017) (Danish): http://www.nvk.dk/emner/biobanker/vejledning-om-bio-mat
Genetic Research	National Committee on Health Research Ethics (NVK): http://www.nvk.dk/english	Act No. 1083 on Research Ethics Review of Health Research Projects (2017) (Danish):		Guidelines on Health Research Projects Involving Genome Research (2017) (Danish): http://www.nvk.dk/emner/genomer/vejledning-om-genomer

Country	Key Organizations	Legislation	Regulations	Guidelines
		https://www.retsinformation.dk/Forms/R0710.aspx?id=192671 2013 version (English): http://www.nvk.dk/english/act-on-research		
Embryos, Stem Cells, and Cloning	Danish Council of Ethics: http://www.etiskraad.dk/english	Act No. 440 on Danish Council of Ethics (2004) (Danish): https://www.retsinformation.dk/forms/r0710.aspx?id=9909	Executive Order No. 93 on Medically Assisted Procreation (2015) (Danish): https://www.retsinformation.dk/forms/r0710.aspx?id=167647	
Estonia For an overview of human subject protections in Estonia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Estonia%20definitive.pdf				
General	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
Drugs, Biologics, and Devices	*Drugs:* 1. State Agency of Medicines: http://www.sam.ee/en/clinical-trials-medicinal-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: Rules of Procedure of Medical Ethics Committee for Clinical Trials, a List of Data to be Submitted for Obtaining Approval, Procedure for Adoption of Resolutions and Format of Application for Obtaining Approval (2005): https://www.riigiteataja.ee/en/eli/502052017001/consolide 2. Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 (2005): https://www.riigiteataja.ee/en/eli/502052017002/consolide	
	Devices: Estonian Health Board: http://www.terviseamet.ee/en/medical-devices.html	Medical Devices Act (2004): https://www.riigiteataja.ee/en/eli/ee/509012015001/consolide/current	Regulation No 86: 2010 of the Minister of Social Affairs on the Conditions and Procedures for the Clinical Investigation of Medical Devices	
Research Injury	1. Minister of Social Affairs (MSA): https://www.sm.ee/en 2. Estonian Health Insurance Fund:	Medicinal Products Act, Section 90: https://www.riigiteataja.ee/en/eli/ee/	Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation	

Country	Key Organizations	Legislation	Regulations	Guidelines
	https://www.haigekassa.ee/en	525112013005/consolide/current	No. 23 of the Minister of Social Affairs of (2005): http://www.sam.ee/en/clinical-trials-medicinal-products-estonia	
Privacy/Data Protection	Estonian Data Protection Inspectorate: http://www.aki.ee/en/inspectorate	Personal Data Protection Act (2016): https://www.riigiteataja.ee/en/eli/ee/512112013011/consolide/current		
Genetic Research		Human Genes Research Act (RT I 2000, 104, 685) (2014): https://www.riigiteataja.ee/en/eli/ee/518062014005/consolide		
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002) (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				
General	1. Ministry of Social Affairs and Health (MSAH): http://www.stm.fi/en/frontpage 2. National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en 3. Finnish Advisory Board on Research Integrity (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	Decree on Medical Research Nos. 986/1999, 313/2004, and 65/2016: http://www.finlex.fi/en/laki/kaannokset/1999/en19990986.pdf	TUKIJA: 1. Report on Children in Medical Research (2003) 2. Operating Procedures of the National Committee on Medical Research Ethics (2017) Access*:* http://tukija.fi/en/publications1
Drugs, Biologics, and Devices	*Drugs*			
	1. Finnish Medicines Agency (FIMEA): http://www.fimea.fi/frontpage 2. Ministry of Social Affairs and Health (MSAH): http://stm.fi/en/frontpage 3. National Committee on Medical	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:	TUKIJA: Templates for Clinical Trial Information Leaflet and Consent Form (2016) Access*:* http://tukija.fi/en/publications1

Country	Key Organizations	Legislation	Regulations	Guidelines
	Research Ethics (TUKIJA): http://www.tukija.fi/en		Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2012 (Finnish): http://www.fimea.fi/download/22302_Maarays_2-2012_kliiniset_laaketutkimukset.pdf	
	Devices			
	National Supervisory Authority for Welfare and Health (VALVIRA): http://www.valvira.fi/en/licensing/medical_devices	Medical Devices Act No. 629/2010 (Finnish): http://www.finlex.fi/fi/laki/kokoelma/2010/20100085.pdf EU Regulations: Medical Device Regulation 2017/745: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN In Vitro Diagnostic Medical Devices Regulation 2017/746: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746&from=EN	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	
Research Injury	1. Finnish Patient Insurance Centre (Finnish): http://www.potilasvakuutuskeskus.fi/www/page/pvk_www_2181 2. Pharmaceutical Injuries Insurance http://www.laakevahinko.fi/in-english/	Patient Injuries Act No. 585/1986 (Finnish): http://www.finlex.fi/fi/laki/ajantasa/1986/19860585		Pharmaceutical Injuries Insurance: General Terms and Conditions (2017): http://www.laakevahinko.fi/in-english/terms-and-conditions/
Social-Behavioral Research	Finnish Advisory Board on Research Integrity (TENK): http://www.tenk.fi/en/index.html			Ethical Principles of Research in the Humanities and Social and Behavioural Sciences and Proposals for Ethical Review (2009): http://www.tenk.fi/sites/tenk.fi/files/ethicalprinciples.pdf
Privacy/Data Protection	Office of the Data Protection Ombudsman: http://www.tietosuoja.fi/1560.htm	Personal Data Act No. 523/1999 (Finnish): http://www.finlex.fi/fi/laki/ajantasa/1999/19990523		
Human Biological Materials	National Supervisory Authority for Welfare and Health (Valvira): http://www.valvira.fi/web/en	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	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 (Finish	

Country	Key Organizations	Legislation	Regulations	Guidelines
		688/2012 (Finnish and Swedish): http://www.finlex.fi/fi/laki/ajantasa/2012/20120688	and Swedish): http://www.finlex.fi/fi/laki/alkup/2013/20130649	
Genetic Research	1. National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en 2. Board for Gene Technology http://www.geenitekniikanlautakunta.fi/en	1. Medical Research Act No. 488/1999 (Amended 295/2004, 794/2010, and 143/2015): 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		
Embryos, Stem Cells, and Cloning	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 3. Finnish Advisory Board on Research Integrity (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	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002) 2. Medical Research Act No. 488/1999 (amended 295/2004, 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 4. Criminal Code of Finland (39/1889), Chapter 22, Section 4: https://www.finlex.fi/en/laki/kaannokset/1889/en18890039.pdf		TUKIJA: Report on Stem Cells, Cloning, and Research (2005): http://tukija.fi/documents/1481661/1546647/2005cells.pdf/c14b7dd0-11b4-428d-bdae-539566ade614
France For an overview of human subject protections in France, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/France%20definitive%20Updated.pdf				
General	1. Ministry of Social affairs and Health (French): http://www.sante.gouv.fr/ 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr/en 3. National Commission for Informatics and Freedoms (CNIL): http://www.cnil.fr/english/the-cnil/	1. Law No. 2012-300 of 5 March 2012 on Research Involving Human Persons: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025441587 2. Law No. 2011-814 of 7 July 2011 on Bioethics	Public Health Code Articles R1121-1 and subsequent sections: http://legifrance.gouv.fr/	CCNE: Various: http://www.ccne-ethique.fr/en/type_publication/avis

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs, Biologics, and Devices	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr 2. National Health Products Safety Agency (ANSM): http://ansm.sante.fr/	Medications for Human Use, Articles L5121-11, L5124-1, and L5126-1) (2004): http://www.legifrance.gouv.fr/	Decision on Good Clinical Practices: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000819256	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)
Social-Behavioral Research	National Consultative Ethics Committee			Opinion on the Ethics of Research in the Sciences of Human Behavior No. 38 (1993): http://www.ccne-ethique.fr/en/publications/opinion-ethics-research-sciences-human-behaviour#.WNkybNfytEY
Privacy/Data Protection	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	1. 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 2. Law No. 2016-1321 of 7 October 2016 for a Numeric Republic: https://www.legifrance.gouv.fr/affichLoiPubliee.do?idDocument=JORFDOLE000031589829&type=general&legislature=14	CNIL: Decree No. 2005-1309 of 20 October 2005 Enacted for the Application of Act No. 78-17 of 6 January 1978 on Data Processing, Files and Individual Liberties (Amended by Decree 2007-451 of 25 March 2007): http://www.cnil.fr/fileadmin/documents/en/Decree%202005-1309.pdf	CCNE: 1. Ethical Questions Arising from the Transmission of Scientific Information Concerning Research in Biology and Medicine (1995) 2. Biometrics, Identifying Data and Human Rights (2007)
Human Biological Materials	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr 2. Ministry of Higher Education, Research, and Innovation: http://www.enseignementsup-recherche.gouv.fr/	1. Donation and Use of the Components and Products of the Human Body, Articles L1211-1 to L1274-3 (2004) (French): http://www.legifrance.gouv.fr/ 2. Public Health Code Articles L1241-1 and following sections: (2010) (French): http://www.legifrance.gouv.fr/initRechCodeArticle.do		CCNE: 1. Umbilical Cord Blood Banks for Autologous Use for Research (2002) 2. Ethical Issues Raised by Collections of Biological Material and Associated Information Data: "Biobanks," "Biolibraries" (2003)
Genetic Research	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr 2. Biomedicine Agency (French): http://www.enseignementsup-recherche.gouv.fr/	Civil Code Articles 16-10 to 16-13 (French): http://www.legifrance.gouv.fr/affichCode.do;jsessionid=D2DE023194483D3384DE19DE8959BDDA.tpdjo17v_3?idSectionTA=LEGISCTA000006136513&cidTexte=LEGITEXT000006070721&dateTexte=20131006		1. Ethical Issues in Connection with the Development of Foetal Genetic Testing on Maternal Blood (2013) 2. Ethical Reflection on Developments in Genetic Testing in Connection with Very High Throughput Human DNA Sequencing (2016): http://www.ccne-ethique.fr/en/type_publication/avis

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr 2. Biomedicine Agency (French): http://www.enseignementsup-recherche.gouv.fr/	Law No. 2013-715 of 6th August 2013: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000027811435&dateTexte=&categorieLien=id	Decree No. 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				
General	Bioethics and Health Law Studies Society: http://www.patientsrights.ge/index.php?page=385&lang=geo	1. Oviedo Convention on Human Rights and Biomedicine ETS No.164 (2001) 2. Additional Protocol to the Convention's on Human Rights and Biomedicine, concerning Biomedical Research, ETS No. 195 (2010) 3. Law on Health Care, Chapter XIX (2017): https://matsne.gov.ge/en/document/view/29980?publication=37		
Drugs, Biologics, and Devices	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	Law on Medicines and Pharmaceutical Activities No. 659 and 1586 (2015): https://matsne.gov.ge/en/document/view/29836?impose=translateEn	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/20160809105943176.pdf	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
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
Privacy/Data Protection	Office of the Personal Data Protection Inspector: https://personaldata.ge/en/data-protection-day-event-2014/177	Law on Data Protection (2017): https://matsne.gov.ge/en/document/view/1561437?publication=9		
Embryos, Stem Cells, and Cloning		1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning ETS No. 168 (2001)		

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Law on Health Care, Article 142 (2017): https://matsne.gov.ge/en/document/view/29980?publication=37		
Germany For an overview of human subject protections in Germany, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Germany%20definitive%20Updated.pdf				
General	1. German Medical Association (BÄK): http://www.bundesaerztekammer.de/weitere-sprachen/english/german-medical-association/ 2. Central Ethics Committee of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/ 3. Permanent Working Party of Research 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 (BMG): http://www.bundesgesundheitsministerium.de/en/en.html 6. German Research Foundation (DFG), Permanent Senate Commission on Key Questions in Clinical Research (SCCR): http://www.dfg.de/en/dfg_profile/statutory_bodies/senate/clinical_research/index.html			BÄK: (Model) Professional Code for Physicians in Germany, Article 15 (2011) (German): http://www.bundesaerztekammer.de/downloads/MBOen2012.pdf
Drugs, Biologics, and Devices	*Drugs*			
	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html 2. Paul-Ehrlich-Institut (PEI): http://www.pei.de/EN/home/node.html4 3. Federal Ministry of Health (BMG): http://www.bmg.bund.de/ministerium/english-version.html	Medicinal Products Act (2017) (German): http://www.gesetze-im-internet.de/amg_1976/ *2016 English version, without amendments:* Medicinal Products Act, Sixth Chapter (2016): http://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p0925	1. Promulgation on the Principles of the Conduct of Clinical Trials of Drugs According to the Rules (1987) 2. Second Promulgation on the Clinical Trial of Drugs in Human (1997) 3. Regulation on the Application of Good Clinical Practice in the Conduct of Clinical Trials of Medicinal Products for Human Use (2012) (German): http://www.gesetze-im-	BfArM and PEI: Third Notification on the 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
			internet.de/gcp-v/	
	Devices			
	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html 2. Paul-Ehrlich-Institut (PEI): http://www.pei.de/EN/home/node.html4	Act on Medical Devices, Fourth Chapter (2017) (German): http://www.gesetze-im-internet.de/mpg/	Regulation on Clinical Trials of Medical Devices (2014) http://www.gesetze-im-internet.de/mpkpv/	
Clinical Trials Registry	German Clinical Trials Register (DRKS): https://www.drks.de/drks_web/setLocale_EN.do			FAQs: https://www.drks.de/drks_web/navigate.do?navigationId=faq&messageEN=FAQ
Research Injury		1. Medicinal Products Act, Section 40(3) (2016): http://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p0926 2. Act on Medical Devices, Section 20(3) (2017) (German): http://www.gesetze-im-internet.de/mpg/__20.html		
Privacy/Data Protection Note: The 16 German states also have data protection laws (German): http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html	Federal Commissioner for Data Protection and Freedom of Information (German): https://www.bfdi.bund.de/	Federal Data Protection Act (2017) (German): https://www.gesetze-im-internet.de/bdsg_1990/ *2009 English version:* Federal Data Protection Act: http://www.gesetze-im-internet.de/englisch_bdsg/		
Human Biological Materials		1. Act of Quality and Security of Human Tissue and Cells (2007) (German): http://www.gesetze-im-internet.de/gewebeg/ 2. Transfusion Law (2017) (German): http://www.gesetze-im-internet.de/tfg/ 3. Transplantation Law (2017) (German): http://www.gesetze-im-internet.de/tpg/		
	German Ethics Council: http://www.ethikrat.org/?set_language=en			Opinion on Human Biobanks for Research (2010): http://www.ethikrat.org/files/der_opinion_hum

Country	Key Organizations	Legislation	Regulations	Guidelines
				an-biobanks.pdf
	Central Ethics Committee of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/			Opinion on the (Re)Use of Human Body Material for Medical Research Purposes (2003) (German): http://www.zentrale-ethikkommission.de/downloads/Koerpermat.pdf
	German Society of Surgery (DGCH): 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/serviceemeldungen/069_Gewebegesetz_GFP-Leitfaden_der_DGCH_fuer_die_Gewinnung_menschlicher_Gewebe.pdf
Genetic Research		1. Embryo Protection Act (2011) (German): http://www.gesetze-im-internet.de/eschg/ 2. Genetic Engineering Act (2017): http://www.gesetze-im-internet.de/gentg/		
	German Society of Human Genetics (GfH): 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): http://www.medgenetik.de/sonderdruck/2007_gfh_positionspapier.pdf
	German Research Foundation (DFG), Permanent Senate Commission on Genetic Research: http://www.dfg.de/en/dfg_profile/statutory_bodies/senate/genetic_research/index.html			Statements: http://www.dfg.de/en/dfg_profile/statutory_bodies/senate/genetic_research/publications/index.html
Embryos, Stem Cells, and Cloning	Federal Ministry of Education and Research (BMBF): http://www.bmbf.de/en/index.php	1. Embryo Protection Act (2011) (German): http://www.gesetze-im-internet.de/eschg/ 2. Stem Cell Act (2017) (German): http://www.gesetze-im-internet.de/stzg/	Regulation on the Central Ethics Committee for Stem Cell Research and the Competent Authority Pursuant to the Stem Cell Act (2017) (German): http://www.gesetze-im-internet.de/zesv/	

Country	Key Organizations	Legislation	Regulations	Guidelines
	German Ethics Council: http://www.ethikrat.org/?set_language=en *Previously:* National Ethics Council (2001-2008): http://www.ethikrat.org/archive/national-ethics-council			1. The Import of Human Embryonic Stem Cells (2001): http://www.ethikrat.org/files/Opinion_Import-HESC.pdf 2. Cloning for Reproductive Purposes and Cloning for the Purposes of Biomedical Research (2004): http://www.ethikrat.org/files/Opinion_Cloning.pdf 3. Should the Stem Cell Law be Amended? (2007): http://www.ethikrat.org/files/Opinion_Should_the_Stem_Cell_Law_be_amended.pdf 4. Human-Animal Mixtures in Research (2011): http://www.ethikrat.org/files/opinion-human-animal-mixtures-in-research.pdf 5. Stem Cell Research - New Challenges for the Ban on Cloning and Treatment of Artificially Created Germ Cells? (2014): http://www.ethikrat.org/files/recommendation-stem-cell-research.pdf 6. Germline Intervention in the Human Embryo (2017): http://www.ethikrat.org/publications/ad-hoc-recommendations/files/recommendation-germline-intervention-in-the-human-embryo.pdf
	Central Ethics Committee of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/			Opinion 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/Committees/StemCell/StemCell_content.html			
Greece				
General	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-incidental-findings-in-research-and-clinical-practice
Drugs, Biologics, and Devices	1. National Organization for Medicines (NOM): http://www.eof.gr/web/guest/home, then click on "EN" in upper left hand section for English 2. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 2. Act 3418/2005 Code on Medical Ethics	1. Ministerial Decision ΔΥΓ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC 2. Ministerial Decision ΔΥΓ 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
Research Injury	National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 2. Act 3418/2005 Code on Medical Ethics	1. Ministerial Decision ΔΥΓ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC 2. Ministerial Decision ΔΥΓ 3 α/79602/2007 Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2005/28/EC:	
Privacy/Data Protection	Hellenic Data Protection Authority (Greek): http://www.dpa.gr/	1. Greek Constitution 1975/1986/2001 Article 9.1 2. Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998) 3. Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Laws 2819/2000 and 2915/2000) (Greek): http://www.dpa.gr/portal/page?_pageid=33,19052&_dad=portal&_schema=PORTAL 4. Act 3418/2005 Code on Medical Ethics		
Genetic Research	National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3	1. Greek Constitution 1975/1986/2001, Article 5.5 2. Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998) 3. Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by Laws 2819/2000 and 2915/2000): 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		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_pgd_opin_eng2.pdf 4. Opinion on Direct-To-Consumer Genetic Testing (2012): http://www.bioethics.gr/index.php/en/gnomes/91-direct-to-consumer-dtc-genetic-testing 5. Opinion on Incidental Findings in Research and Clinical Practice (2015): http://www.bioethics.gr/images/pdf/GNOMES/OPINION_Incidental_Findings_FINAL_.pdf 6. Opinion on Advances in Human Genome Editing (2016): http://www.bioethics.gr/images/pdf/GNOMES/OPINION__gene%20editing_Final_EN.pdf
Embryos, Stem Cells, and Cloning	1. National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3 2. National Authority for Medically Assisted Reproduction (Greek)	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		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

Country	Key Organizations	Legislation	Regulations	Guidelines
		of Medically Assisted Reproduction		Access: http://www.bioethics.gr/index.php/gnomes
Hungary For an overview of human subject protections in Hungary, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Hungary%20definitve.pdf Note: All webpages and documents are in Hungarian.				
General	1. Ministry of Human Capacities (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Research Ethics Committees (KFEB, TUKEB, HRB): https://ett.aeek.hu/en/secretariat/	1. Fundamental Law of Hungary, Updated with the Fifth Amendment (2016), Articles II-III: http://njt.hu/cgi_bin/njt_doc.cgi?docid=140968.322953 2. Act CLIV of 1997 on Health Care, Chapters VIII and IX: http://njt.hu/cgi_bin/njt_doc.cgi?docid=30903.339193 3. Act VI. of 2002 on the Promulgation of the Oviedo Convention on Human Rights and Biomedicine: http://njt.hu/cgi_bin/njt_doc.cgi?docid=64201.264663 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: 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: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM 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: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900235.KOR&celpara=#xcelparam	
Drugs, Biologics, and Devices	*Drugs*			
	1. National Institute of Pharmacy and Nutrition: http://www.ogyei.gov.hu 2. Medical Research Council, Ethics Clinical Pharmacology Ethics Committee (KFEB): https://ett.aeek.hu/kfeb/	*Clinical Trials:* Act XCV of 2005 on Medicinal Products for Human Use, Section 3: http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=a0500095.tv&dbnum=62 *Non-Interventional Trials:* Act CLIV of 1997 on Health Care, Chapter VIII, Section 164/A:	*Clinical Trials:* Decree 35/2005 (VIII. 26) of the Minister of Health on the Clinical Trial and Application of Correct Clinical Practices of Investigational Medicinal Products Intended for Use in Humans: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM&celpara=#xcelparam	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV	*Non-Interventional Trials:* Decree 23/2002. (V. 9) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam	
	Devices			
	1. Authority for Medical Devices, National Healthcare Service System: http://www.enkk.hu/index.php/hun/ 2. Medical Research Council, Ethics Committee for Clinical Pharmacology: https://ett.aeek.hu/kfeb/	Act CLIV of 1997 on Health Care, Chapter VIII, Section 159: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV	*Clinical Trials:* Decree 4/2009. (III. 17.) of the Minister of Health on Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900004.EUM&celpara=#xcelparam *Non-Interventional Trials:* 1. 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 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 3. Government Decree 27/2015 (II.25.) About the National Health Care Service System: http://njt.hu/cgi_bin/njt_doc.cgi?docid=174246.343548	
Research Injury	National Institute of Pharmacy and Nutrition: http://www.ogyei.gov.hu	Act XCV of 2005 on Medicinal Products for Human Use, Section 3, Paragraph 5: http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=a0500095.tv&dbnum=62		
Privacy/Data	Hungarian National Authority for	1. Act XLVII of 1997 on the		

Country	Key Organizations	Legislation	Regulations	Guidelines
Protection	Data Protection and Freedom of Information: http://www.naih.hu/general-information.html	Handling of Medical and Other Related Data: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700047.TV&celpara=#xcelparam 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&celpara=#xcelparam		
Human Biological Materials	Ministry of Human Capacities (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma	Act LXXX of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Transplantation of Organs and Tissues of Human Origin: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0600080.TV&celpara=#xcelparam	Decree 18/1998 (XII 27) EüM on Implementing Act CLIV of 1997 on Health Care as Regards Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam	
Genetic Research	1. Ministry of Human Capacities (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Committee for Human Reproduction (HRB): https://ett.aeek.hu/hrb/	Act XXI of 2008 on the Rules of Protection of Human Genetic Data, of Human Genetic Examinations and Research and of the Operation of Biobanks: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0800021.TV&celpara=#xcelparam		Decree 60/2003. (X. 20.) of the Minister of Health, Social and Family Affairs on the Minimum Professional Requirements Necessary for Providing Health Services: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0300060.ESC&celpara=#xcelparam
Embryos, Stem Cells, and Cloning	1. Ministry of Human Capacities (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Research Ethics Committees (KFEB, TUKEB, HRB): https://ett.aeek.hu/hrb/	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				
General	1. Ministry of Welfare (MOW): http://eng.velferdarraduneyti.is/ 2. National Bioethics Committee	1. Act on the Rights of Patients No. 74/1997, Article 10 (2009): http://eng.velferdarraduneyti.is/medi		NBC: 1. Vulnerable Groups Including Children: http://www.vsn.is/en/content/vulnerable-

Country	Key Organizations	Legislation	Regulations	Guidelines
	(NBC): http://www.vsn.is/en	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/media/acrobat-enskar_sidur/Health-Sector-Research-Act-No-44-2014.pdf 3. Oviedo Convention on Human Rights and Biomedicine (2004)		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
Drugs, Biologics, and Devices	*Drugs*			
	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
	Devices			
	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-ad946f3deeaa 3. Regulation on In Vitro Diagnostic Medical Devices No. 936/2011 (Icelandic): http://stjornartidindi.is/Advert.aspx?ID=f20b3e4e-ab25-44d3-8e32-e5f42a7b02f0	
Research Injury	Icelandic 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.	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-	

Country	Key Organizations	Legislation	Regulations	Guidelines
		112/2008 (2012): https://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act-on-Health-Insurance-No-112-2008-16.pdf	in-humans-no-443-2004-as-amended.pdf	
Privacy/Data Protection	Data Protection Authority: http://www.personuvernd.is/information-in-english/	Act on the Protection of Privacy as Regards the Processing of Personal Data, No. 77/2000 (2011): http://www.personuvernd.is/information-in-english/		
Human Biological Materials	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
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2004) 2. Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No. 55/1996 (2010): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act_No_55_1996_on_Artificial_Fertilisation_etc_as_amended.pdf	Regulation on Artificial Fertilization No. 144/2009 (Icelandic): http://stjornartidindi.is/Advert.aspx?ID=9442c80d-2b63-4a43-9526-41d03d9b2495	
Ireland For an overview of human subject protections in Ireland, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Ireland%20definitive.pdf; and see this summary on Clinical Trials Involving Medical Products: http://health.gov.ie/blog/policy/clinical-trials-involving-medicinal-products/				
General	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/

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs, Biologics, and Devices	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/878/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
Research Injury	Health Products and Regulatory Authority: https://www.hpra.ie/		European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, Section 13(6)(k) and Schedule 1, Part 2, Paragraph 4 (S.I. No. 190 of 2004): http://www.irishstatutebook.ie/eli/2004/si/190/made/en/html	
Privacy/Data Protection	Data Protection Commissioner: http://www.dataprotection.ie/docs/Home/4.htm	Data Protection Act (1988), as Amended (2003): http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html		
Human Biological Materials	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
Genetic Research	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				
General	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
Drugs, Biologics, and Devices	*Drugs*			
	1. National Monitoring Center for Clinical Trials: http://www.agenziafarmaco.com/en/content/national-monitoring-centre-clinical-trials 2. Italian Medicines Agency (Italian):	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)	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	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.agenziafarmaco.it/ 3. Ministry of Health (MOH) (Italian): http://www.ministerosalute.it	(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 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	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 Work within Clinical Trials on Medicinal Products	
	Devices			
	Ministry of Health, Directorate General for Medicines and Medical Devices (Italian): http://www.ministerosalute.it		Ministerial Decree 2 of August 2005: Procedures for the Presentation of Documentation to Notify about Clinical Investigations with Medical Devices	Administrative Procedures Concerning the Conduction of Clinical Investigations with CE-Marked Medical Devices (2007)
Research Injury	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	
Privacy/Data Protection	Italian Data Protection Independent Authority (Italian): http://www.garanteprivacy.it/garante/navig/jsp/index.jsp?solotesto=N	Italian Personal Data Protection Code, Legislative Decree No. 196 of June 30, 2003: http://www.garanteprivacy.it/garante/navig/jsp/index.jsp?folderpath=Normativa%2FItaliana%2FIl+Codice+in+materia+di+protezione+dei+dati+personali	1. Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000) 2. Regulation for the Implementation of Articles No. 20 and 21 of the Legislative Decree No. 196 of June 30, 2003 3. Ministerial Decree No. 277 (2007)	

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research	1. Instituto Superiore di Sanita (ISS): http://www.iss.it/chis/?lang=2 2. Italian Society of Human Genetics (SIGU): http://www.sigu.net/			ISS: Guidelines for Phase I Clinical Trials with Investigational Medicinal Products Employed in Gene Somatic Therapy (2004) (Italian): http://www.iss.it/binary/publ/publi/0478.1106653420.pdf SIGU: Various: http://www.sigu.net/show/documenti/5/1/linee%20guida
Embryos, Stem Cells, and Cloning		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				
General	Central Medical Ethics Committee		Statutes of Central Medical Ethics Committees (1998) (Latvian): http://likumi.lv/doc.php?id=46597	
Drugs, Biologics, and Devices	*Drugs*			
	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_Productsx.doc	
	Devices			
	State Agency of Medicines: http://www.zva.gov.lv/?setlang=en&large=	Medical Treatment Law, Section 34 (2014): http://www.vvc.gov.lv/export/sites/	Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for	

Country	Key Organizations	Legislation	Regulations	Guidelines
		default/docs/LRTA/Likumi/Medical_Treatment_Law.pdf	Human Use (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._891_-_Procedures_for_the_Clinical_Trial_of_Medical_Devices.doc	
Research Injury	State Agency of Medicines: http://www.zva.gov.lv/?setlang=en&large=		*Drugs:* 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, 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 *Devices:* Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for Human Use, Sections 42.7 and 62.5 (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._891_-_Procedures_for_the_Clinical_Trial_of_Medical_Devices.doc	
Privacy/Data Protection	1. Data State Inspectorate: http://www.dvi.gov.lv/en/ 2. Central Medical Ethics Committee	1. Personal Data Protection Law (2014): http://www.dvi.gov.lv/en/wp-content/uploads/legal-acts/Personal_Data_Protection_Law.doc	Cabinet Regulation No. 446: Procedures for Using Patient Data in a Specific Research (2015): http://likumi.lv/wwwraksti/VVC_TULKOJUMI/LRTA/MK_NOTEIKUMI/CAB_REG_NO_446_PROCEDUR	

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Law on the Rights of Patients, Section 10 (2013): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Law_On_the_Rights_of_Patients.doc	ES_FOR_USING_THE_PATIENT_DATA.DOC	
Human Biological Materials	Central Medical Ethics Committee	Law on the Protection of Dead Human Beings and Use of Human Organs and Tissue (2008): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/On_the_Protection_of_the_Body_of_Deceased_Human_Beings_and_the_Use_of_Human_Tissues_and_Organs_in_Medicine.doc	Cabinet Regulation No. 1176 (2013) Procedures for Use of Human Tissues and Cells (Latvian): http://likumi.lv/ta/id/261810-cilveka-audu-un-sunu-izmantosanas-kartiba	
Genetic Research	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	
Embryos, Stem Cells, and Cloning	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. 1176 (2013) Procedures for Use of Human Tissues and Cells (Latvian): http://likumi.lv/ta/id/261810-cilveka-audu-un-sunu-izmantosanas-kartiba	
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				
General	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Oviedo Convention on Human Rights and Biomedicine (2002): http://conventions.coe.int/treaty/en/treaties/html/164.htm 2. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL 3. Decree on Changes of Law on	1. V-405, Decree 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/dokpaieska.showdoc_l?p_id=372121&p_query=&p_tr2= 2. Government of the Republic of	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386	Lithuania: Decree No. 1458 on State Fees (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.E3A145C8DD49/adJtSaHbRM 3. V-15, 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-tar.lt/portal/lt/legalAct/2a0242a0b5fe11e5a6588fb85a3cc84b 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 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/dokpaieska.showdoc_l?p_id=1002481&p_tr2=2 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	
	Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?1608991497		1. V-28, Decree on the Procedure to Conduct Biomedical Research on Medical Documents, No. V-28 (2011): https://www.e-	Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical Research of the LBEC (2017): http://bioetika.sam.lt/index.php?3315136866

Country	Key Organizations	Legislation	Regulations	Guidelines
			tar.lt/portal/lt/legalAct/TAR.480CDD584ADB 2. V-7, Decree on the Sample Form of the Biomedical Research Protocol, Summary of the Protocol and the CV of Investigator (2017): https://www.e-tar.lt/portal/lt/legalAct/352d55b0c44111e583a295d9366c7ab3/Maiuzzfyns 3. 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 4. 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/hqOKwHTIBs	
Drugs, Biologics, and Devices	*Drugs*			
	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	1. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL 2. Law on Pharmacy (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.FF33B3BF23DD/gRoLvrgCbW 3. Decree on Changes of Law on Ethics of Biomedical Research (2017): https://www.e-	1. Decree No. 320 on the Rules of Good Clinical Practice (2004): https://www.e-tar.lt/portal/lt/legalAct/TAR.EF5F8A32B830/WkRbILGNxF 2. Corrections of GCP Terminology in Lithuanian (2006) https://www.e-tar.lt/portal/lt/legalAct/TAR.1C6613E02B96 3. Decree No. 435 on the Procedure for Issuing a Favorable	

Country	Key Organizations	Legislation	Regulations	Guidelines
		tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386	Opinion to Conduct Clinical Trials on Medicinal Product, Approval for Clinical Trials on Medicinal Product, and Conducting and Controlling Clinical Trials (2017): https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.277308/QPLLKpOUKw	
	Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?1608991497		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/qcrDrSCSCJ	Guidelines to Advertise Clinical Trials, Adopted by the Group of Experts on Biomedical Research of the LBEC (2007)
	Devices			
	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG		Decree No. V-2 on the Procedure to Issue Approvals to Conduct Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.47B235393D3A/zpczrvbOOR	
	State Health Care Accreditation Agency Under the Ministry of Health (SHCA): http://www.vaspvt.gov.lt/en	1. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL 2. Decree on Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386		
Research Injury	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL 2. Decree on Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386	MOH: Decree No. 745 on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor (2015): https://www.e-tar.lt/portal/lt/legalAct/c86cf490b3be11e598c4c7724bda031b/IaIhDiebov	
Privacy/Data Protection	State Data Protection Inspectorate: https://www.ada.lt/go.php/lit/English	Law on Legal Protection of Personal Data (2017):		

Country	Key Organizations	Legislation	Regulations	Guidelines
		https://www.e-tar.lt/portal/lt/legalAct/TAR.5368B592234C/XSpzxvEjIg		
Human Biological Materials	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	1. Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL 2. Decree on Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386		
Embryos, Stem Cells, and Cloning	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 3. Decree on Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/3a2e2c708d8911e7a3c4a5eb10f04386	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): https://www.e-tar.lt/portal/lt/legalAct/TAR.8A75E79827FD 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 (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.E2473B1958CA/gEtbNSRzzc	
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.				
General	National Ethics Consultative Commission:			Various: http://www.cne.public.lu/fr/publications/avis.ht

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.cne.public.lu/fr/commission/statut.html			ml
Drugs, Biologics, and Devices	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-sante/ministere-sante/direction-sante/div-pharmacie-medicaments/index.html	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	
Privacy/Data Protection	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/archives/1992/0074/a074.pdf#page=12	
Macedonia Note: All websites and documents are in Macedonian.				
Drugs and Devices	*Drugs*			
	1. Ministry of Health of Republic of Macedonia: http://moh.gov.mk/ 2. Drug and Devices Register: https://lekovi.zdravstvo.gov.mk/ 3. Drug Agency http://malmed.gov.mk/	1. Law on Medicinal Products and Medical Devices (Official Gazette No.106/2007) and Laws Amending and Supplementing the Law (2010-2016, according to year of amendment): Click on file folder 1., then open sub-folders: https://lekovi.zdravstvo.gov.mk/documents/2 2. Health Care Law (Official Gazette No. 43/2012) and Laws Amending and Supplementing the Law, Article 275: http://www.fzo.org.mk/default.asp?ItemID=37115BDC6DEF524D877A8C36F95A85F6	1. Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2009): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/817325622?t:ac=1/1 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	1. Guideline for the Clinical Trial Applicant (Annex 3) (2012): https://lekovi.zdravstvo.gov.mk/documents/1/1 (Sub-folder 23.2) 2.Guideline for Good Clinical Practice, Official Gazette No.62/2009, Document No. 19: https://lekovi.zdravstvo.gov.mk/documents/1/1

Country	Key Organizations	Legislation	Regulations	Guidelines
			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 Applicant) (Document No. 23.3) (2012): https://lekovi.zdravstvo.gov.mk/documents/1/1 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 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	
	Devices			
	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 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	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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): https://lekovi.zdravstvo.gov.mk/documents/1/2	
Research Injury	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	
Privacy/Data Protection	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	
Human Biological Materials	1. Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/ 2. Health Insurance Fund of Republic	1. Law on Health Protection: (Official Gazette No. 43/2012) and Laws Amending and	Regulations for Transplantation of Tissues and Organs: http://www.fzo.org.mk/default.asp?ItemID=6541AC10FFC3C5498F0887	Regulation on Criteria Relating to Space, Personnel and Equipment for Collection, Transplantation and Exchange of Organs

Country	Key Organizations	Legislation	Regulations	Guidelines
	of Macedonia: http://www.fzo.org.mk	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-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 (2009): http://www.pravo.org.mk/documentDetail.php?id=5543	C57131D996	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
Genetic Research	Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/	Law on Patient Rights Protections, Article 21: Action on Human Genome (2012): http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-za-zastita-na-pravata-na-pacientite-precisten.pdf		
Embryos, Stem Cells, and Cloning	Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/	Law on Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, With Additional Protocol on the Prohibition of		

Country	Key Organizations	Legislation	Regulations	Guidelines
		Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (2009): 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/EFGCPReportFiles/Malta%20definitive%20Updated.pdf				
General	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
Drugs, Biologics, and Devices	*Drugs*			
	Medicines Authority: http://medicinesauthority.gov.mt/	1. Medicines Act, 2003: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8924&l=1 2. Subsidiary Legislation, 458.43, Clinical Trials Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11281&l=1 3. Subsidiary Legislation, 458.47, Good Clinical Practice and Requirements for Manufacturing or Import Authorisation of Investigational Medicinal Products (Human Use) Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11285&l=1		Guidance Notes on Good Clinical Practice (2010): http://medicinesauthority.gov.mt/clinicaltrials.htm
	Devices			
	1. Medicines Authority: http://medicinesauthority.gov.mt/ 2. Malta Competition and Consumer Affairs Authority, Technical Regulations Division, Regulatory Affairs Directorate: http://www.mccaa.org.mt/en/regulatory-affairs-directorate	1. Product Safety Act, 2001: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8893&l=1 2. Subsidiary Legislation, 427.16, *In Vitro* Diagnostic Medical Devices Regulations, 2003 http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemi		

Country	Key Organizations	Legislation	Regulations	Guidelines
		d=10756&l=1 3. Subsidiary Legislation, 427.44, Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10781&l=1 4. Subsidiary Legislation, 427.10, Active Implantable Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10753&l=1		
Privacy/Data Protection	Office of the Information and Data Protection Commissioner: http://idpc.gov.mt/index.aspx	Data Protection Act, 2002: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8906&l=1		
Moldova For an overview of human subject protections in Moldova, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 7: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf Note: All websites and documents are in Moldovian.				
General	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)		
Drugs, Biologics, and Devices	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	
Research Injury	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	1. Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Expertise of Clinical Trials:	

Country	Key Organizations	Legislation	Regulations	Guidelines
		&lang=1	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	
Privacy/Data Protection	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): http://datepersonale.md/en/international003/ 2. Decision of Parliament No. 483-XIV Dated 02.07.1999 on Ratification of Convention No. 108: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=309121 3. Law No. 982 Dated 11.05.2000 on Access to Information: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311759 4. Law No.133 Dated 08.07.2011 on the Protection of Personal Data: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=340495	Decision of Government No. 1123 Dated 14.12.2010 on the Approval of the Requirements for the Assurance of Personal Data Security at their Processing within the Information Systems of Personal Data: http://www.datepersonale.md/file/hotariri/cerinte_securitate%20eng_101228.pdf	
Human Biological Materials	1. Ministry of Health (MOH): http://www.ms.gov.md/ 2. Transplant Agency http://lex.justice.md/md/334622	Law No. 42 Dated 06.03.2008 on Transplantation of Organs, Tissues and Human Cells: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=327709	MOH: Order No.648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf	
Embryos, Stem Cells, and Cloning	1. Ministry of Health (MOH): http://www.ms.gov.md/ 2. National Commission on	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of		

Country	Key Organizations	Legislation	Regulations	Guidelines
	Biological Security: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=303353	the Human Being, on the Prohibition of Cloning Human Beings (2002) 2. Law No. 42 Dated 06.03.2008 on Transplantation of Organs, Tissues and Human Cells: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=327709		
Montenegro				
Drugs, Biologics, and Devices	1. Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat 2. Agency for Medicines and Medical Devices: https://www.calims.me/Portal/faces/glavna?_adf.ctrl-state=rsbe35pln_83	1. Law on Medicines ("Official Gazette of Montenegro", No. 56/2011 and 06/13): https://www.calims.me/Portal/faces/servlet1?putanja=CG_Zakon_o_ljekovima.pdf&_afrWindowMode=0&_afrLoop=3654755254077715&_adf.ctrl-state=13nzchbscd_171 2. Law on Medical Devices ("Official Gazette of Montenegro" No. 79/2004, 53/09, and 40/11): https://www.calims.me/Portal/faces/servlet1?putanja=CG-Zakon%2520o%2520medicinskim%2520sredstvima.pdf&_afrWindowMode=0&_afrLoop=3654994298177994&_adf.ctrl-state=13nzchbscd_181	Rulebook on More Detailed Conditions and Documentation Required for Approval and Conduct of Clinical Trials of Medicines for Human Use (2013): https://www.calims.me/Portal/faces/servlet1?_afrLoop=26656243505641585&_afrWindowMode=0&putanja=Rulebook%2520on%2520Clinial%2520trials.pdf&_adf.ctrl-state=wdqo8wvwo_214	
Research Injury	1. Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat 2. Agency for Medicines and Medical Devices: https://www.calims.me/Portal/faces/glavna?_adf.ctrl-state=rsbe35pln_83	1. Law on Medicines ("Official Gazette of Montenegro", No. 56/2011 and 06/13): https://www.calims.me/Portal/faces/servlet1?putanja=CG_Zakon_o_ljekovima.pdf&_afrWindowMode=0&_afrLoop=3654755254077715&_adf.ctrl-state=13nzchbscd_171 2. Law on Medical Devices ("Official Gazette of Montenegro" No. 79/2004, 53/09, and 40/11): https://www.calims.me/Portal/faces/servlet1?putanja=CG-Zakon%2520o%2520medicinskim%2520sredstvima.pdf&_afrWindowMode=0&_afrLoop=365499429817		

Country	Key Organizations	Legislation	Regulations	Guidelines
		7994&_adf.ctrl-state=13nzchbscd_181		
Privacy/Data Protection	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): http://www.azlp.me/docs/zajednicka/zakoni/zakon-o-zastiti-podataka-o-licnosti.pdf		
Human Biological Materials	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): http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=57491&rType=2&file=ZAKON%20O%20UZIMANJU%20I%20KORI%C5%A0%C4%86ENJU%20BIOLO%C5%A0KIH%20UZORAKA.pdf		
Genetics	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): http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=57566&rType=2&file=ZAKON%20O%20ZA%C5%A0TITI%20GENETI%C4%8CKIH%20PODATAKA%20.pdf		
Embryos, Stem Cells, and Cloning	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): http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=222783&rType=2&file=Pravilnik%20o%20postupku%20prikupljanja,%20%C4%8Duvanja%20i%20upotrebe%20mati%C4%8Dnih%20%C4%87elija%2056-2012.pdf	
Netherlands For an overview of human subject protections in the Netherlands, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Netherlands%20definitive%20Updated.pdf				
General	Central Committee for Research	1. Population Screening Act	1. Concerning the Use of a	Various (Dutch): http://www.ccmo.nl/en/publications-of-the-

Country	Key Organizations	Legislation	Regulations	Guidelines
	Involving Human Subjects (CCMO): http://www.ccmo.nl/en/	(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	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)	ccmo
Drugs, Biologics, and Devices	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
Clinical Trials Registry	1. Netherlands Trial Register (Dutch): http://www.trialregister.nl/trialreg/index.asp 2. Central Committee Register (Dutch): https://www.toetsingonline.nl/to/ccmo_search.nsf/Searchform?OpenForm			
Research Injury	Ministry of Health, Welfare and Sport: http://www.government.nl/ministries/vws#ref-minvws	Medical Research Involving Human Subjects Act, Article 7 (2006): http://www.ccmo.nl/attachments/files/wmo-engelse-vertaling-29-7-2013-afkomstig-van-vws.pdf	Regulation on Mandatory Insurance Regarding Medical Research Involving Human Subjects (2003): https://zoek.officielebekendmakingen.nl/stb-2014-477.html	
Privacy/Data Protection	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/bijlagen/coreon/code_of_conduct_for_medical_research_1.pdf 2. Explanatory Report Accompanying the Code (2004): http://www.federa.org/sites/default/files/bijlagen/coreon/explanatory_report1.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	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/bijlagen/coreon/codeproperseconda ryuseofhumantissue1_0.pdf
Genetic Research	1. Ministry of Infrastructure and the Environment (IenM): http://www.government.nl/ministries/ienm 2. Dutch Health Care Inspectorate (IGZ): http://www.igz.nl/english/ 3. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/en/	Medical Research Involving Human Subjects Act (2006): http://www.ccmo.nl/attachments/files/wmo-engelse-vertaling-29-7-2013-afkomstig-van-vws.pdf		IenM, VWS, and CCMO: Guidelines for Researchers and Sponsors with Regard to the Assessment by Official Bodies of Clinical Research Involving Gene Therapeutics in the Netherlands (2012): http://www.ggo-vergunningverlening.nl/dsresource?type=pdf&objectid=rivmp:193539&versionid=&subobjectname=
Embryos, Stem Cells, and Cloning	Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/en/	1. Foetal Tissue Act (2001) (Dutch): http://wetten.overheid.nl/BWBR0012983/ 2. Embryos Act (2002): http://www.ccmo.nl/attachments/files/embryos-act.pdf		
Norway For an overview of human subject protections in Norway, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Norway%20definitive%20Updated.pdf				
General	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 3. Act on Health Care Research (2008) (Norwegian): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&		1. 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 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/

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs, Biologics, and Devices	*Drugs*			
	Norwegian Medicines Agency: http://www.legemiddelverket.no/English/Sider/default.aspx		Regulation Relating to Clinical Trials on Medicinal Products for Human Use (2009) (Norwegian): http://lovdata.no/dokument/SF/forskrift/2009-10-30-1321?q=forskrift+om+kliniske+utpr%C3%B8vning	Guidelines for the Regulations Concerning Clinical Trials of Human Drugs (1999) (Norwegian): http://www.legemiddelverket.no/Godkjenning_og_regelverk/Klinisk-utproving/Regelverk%20og%20veiledninger/Documents/Veiledning%20-%20revidert%20versjon%202.2%2006.11.2012.pdf
	Devices			
	1. Norwegian Directorate of Health: http://www.helsedirektoratet.no/kvalitet-planlegging/medisinsk-utstyr/klinisk-utprovning/Sider/default.aspx 2. Regional Committees for Medical and Health Research Ethics: https://helseforskning.etikkom.no/ikbViewer/page/forside	Act of 12 January 1995 No. 6 Relating to Medical Devices (1995) (Norwegian): http://lovdata.no/dokument/NL/lov/1995-01-12-6?q=lov+om+medisinsk+utstyr	Regulation of December 15th 2005 No. 1690 Relating to Medical Devices (2005) (Norwegian): http://lovdata.no/dokument/SF/forskrift/2005-12-15-1690?q=forskrift+medisinsk+utstyr	Guidelines on Notification for Clinical Investigation of Medical Devices in Norway (2010): https://helsedirektoratet.no/Documents/Medisinsk%20utstyr/Guidance%20for%20completing%20the%20Notification%20form.pdf
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2007)		
Social-Behavioral Research	National Committee for Research Ethics in the Social Sciences and the Humanities			Guidelines for Research Ethics in the Social Sciences, Law, and the Humanities (2016): https://www.etikkom.no/globalassets/documents/english-publications/60127_fek_guidelines_nesh_digital_corr.pdf
	Norwegian National Research Ethics Committees			Ethical Guidelines for Internet Research (2014): https://www.etikkom.no/en/ethical-guidelines-for-research/ethical-guidelines-for-internet-research/
Privacy/Data Protection	Data Inspectorate: http://www.datatilsynet.no/English	Personal Data Act No. 31 (2000): http://lovdata.no/dokument/NL/lov/2000-04-14-31	Regulations on the Processing of Personal Data (2003)	
Human Biological Materials	1. Ministry of Health and Care Services (MHCS): https://www.regjeringen.no/en/dep/hod/id421/ 2. Ministry of Education and Research (MER): http://www.regjeringen.no/en/dep/kd.html?id=586	1. Act on Biobanks (February 21, 2003, No. 12): http://lovdata.no/dokument/NL/lov/2003-02-21-12?q=biobank 2. Act Relating to the Application of Biotechnology in Human Medicine, etc. (December 5, 2003, No. 100)	MHCS: Guidelines for the Norwegian Act on Biobanks (2003)	

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Act on Health Care Research (2008) (Norwegian): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&		
Genetic Research	1. Ministry of Health and Care Services (MHCS): https://www.regjeringen.no/en/dep/hod/id421/ 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		
Embryos, Stem Cells, and Cloning	Directorate for Health and Social Affairs: http://www.helsedirektoratet.no/kvalitet-planlegging/bio-genteknologi/Sider/default.aspx	1. Revised Act Relating to the Application of Biotechnology in Human Medicine (June 15, 2007) Regarding Changes in the Act Related to Stem Cell Research and Pre-implantation Diagnostics (2007) 2. Norwegian Law on the Human-Medical Use of Biotechnology, Chapter 3		
Poland For an overview of human subject protections in Poland, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Poland%20definitive.pdf				
General	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/orodek-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
Drugs, Biologics, and Devices	*Drugs*			
	Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/en	1. Pharmaceutical Law (2016): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20160002142 2. Law of 20/04/2004 on Amendment of the	1. Decree of the Minister of Health on Clinical Trials on Minors (2004) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20041041108	

Country	Key Organizations	Legislation	Regulations	Guidelines
		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)	2. 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 3. May 9, 2012 Order of the Minister of Health Concerning the Application Forms of Documents Submitted Due to the Clinical Trial of Medicinal Products and about the Amount of Charges and the Way of their Payments for the Commencement of Clinical Trial: http://isap.sejm.gov.pl/DetailsServlet?id=WDU20120000491	
	Devices			
	Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products: http://en.urpl.gov.pl/general-information	1. Act on Medical Devices (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20101070679 2. Act Amending the Act on Medical Devices and Certain Other Acts: http://isap.sejm.gov.pl/DetailsServlet?id=WDU20170000211&min=1	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 Various (Polish): http://www.urpl.gov.pl/	
Research Injury		Pharmaceutical Law, Chapter 36b(2)(6) (2008)	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 2. Order of the Minister of Finance Amending the Regulation 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	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Mandatory Civil Liability Insurance of Researchers and Sponsors in Clinical Trials of Medicinal Products (2010) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20101941290	
Privacy/Data Protection	Inspector General for the Protection of Personal Data: http://www.giodo.gov.pl/168/j/en/	Act on the Protection of Personal Data (2006): http://www.giodo.gov.pl/data/filemanager_en/61.doc		
Human Biological Materials		1. Act of 22 August 1997 on the Public Blood Service: http://isap.sejm.gov.pl/DetailsServlet?id=WDU19971060681 2. July 1, 2005 Act Regarding Sampling, Storage, and Transplanting of Cells, Tissues, and Organs: http://isap.sejm.gov.pl/DetailsServlet?id=WDU20051691411&min=1		

Portugal For an overview of human subject protections in Portugal, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Portugal%20definitive%20Updated.pdf				
General	National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/	Oviedo Convention on Human Rights and Biomedicine (2001)		Various: http://www.cnecv.gov.pt/cnecv/en/opinions/
Drugs, Biologics, and Devices	*Drugs*			
	1. National Institute of Pharmacy and Medicines: http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH 2. Ethics Commission for Clinical Research (CEIC): http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/CEIC	1. Approval of the Applicable Legal Standards for the Conduct of Clinical Trials of Medicines for Human Use, Law No. 46/2004 2. Approval of the Composition, Operations, and Financing of the Ethics Commission for Clinical Research, Decree No. 57/2005 (Portuguese): http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/portaria_57-2005.pdf	Decree-Law No. 102/2007 of April 2	
	Devices			

Country	Key Organizations	Legislation	Regulations	Guidelines
	National Institute of Pharmacy and Medicines: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS	Various: http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_V/TITULO_V_CAPITULO_II		Various: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS/NOTAS_INFORMATIVAS
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
Privacy/Data Protection	National Data Protection Commission: http://www.cnpd.pt/english/index_en.htm	1. Constitution, Article 35 (1997) 2. Act on the Protection of Personal Data, No. 67/98 (1998): http://www.cnpd.pt/english/bin/legislation/Law6798EN.HTM		
Genetic Research	Ministry of Health: http://www.portugal.gov.pt/en/the-ministries/ministry-of-health.aspx	Law 12/2005		
Embryos, Stem Cells, and Cloning	National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/	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/EFGCPReportFiles/Romania%20definitive.pdf				
General	Ministry of Health (MOH) (Romanian): http://www.ms.ro/	Oviedo Convention on Human Rights and Biomedicine (2001)	Ordinance No. 57/16.08.2002 (2002): http://www.research.ro/ro/articol/1021/despre-ancs-legislatie	
Drugs, Biologics, and Devices	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		MOH: Order 904/25July 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 --	MOH: Guideline for Clinical Trials in Pediatric Populations (CPMP/ICH/2711/99) (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
	(Romanian): http://www.bioetica-medicala.ro/		Transposition of 2001/20/EC Directive Access*:* http://www.anm.ro/anmdm/en/med_legislatie_ordine.htm	
Research Injury	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)		
Privacy/Data Protection	National Supervisory Authority for Personal Data Processing: http://www.dataprotection.ro/index.jsp?page=documents&lang=en	Law No. 667/2001 On the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data: http://www.dataprotection.ro/servlet/ViewDocument?id=174		
Human Biological Materials	Ministry of Health (MOH) (Romanian): http://www.ms.ro/	Law No. 95/2006 Regarding the Reform in Health Field. Title VI. Performing of Sampling and Transplant of Organs, Tissues and Human Origin Cells with Therapeutic Purpose: http://www.transplant.ro/Lege/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	
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2001) 2. Law No. 301 from 2004 Penal Code – Chapter IV – Crimes and Felonies Regarding Genetic Manipulation: http://www.codpenal.ro/legislatie/document/lege-301-din-2004-codul-penal-capitol-4-crime-si-delicte-		

Country	Key Organizations	Legislation	Regulations	Guidelines
		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				
General	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
Drugs, Biologics, and Devices	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): http://www.gost.ru/wps/portal/pages.en.Main	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. 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 № 200н "On Approval of the Rules of Good	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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	
Research Injury		Federal Law #61FZ "On Circulation of Medicines" (2011), Art. 38-44: http://acto-russia.org/files/zakon_ob_obr_ls_en.docx		
Privacy/Data Protection		1. Federal Law of the Russian Federation on Information, Information Technologies, and Protection of Information (2006) (Russian): http://www.consultant.ru/document/cons_doc_LAW_165971/ 2. Federal Law of the Russian Federation No. 152-FZ on Personal Data (2006): http://base.garant.ru/12148567/		
Genetic	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	
Embryos, Stem Cells, and Cloning		Federal Law #30-FZ "On Introduction of Change in Art. 1 of the Federal Law "On Temporary Ban on Human Cloning" (2010) (Russian): http://base.garant.ru/184467/		
San Marino				
General	San Marino Bioethics Committee (Italian): http://www.sanita.sm/on-	Oviedo Convention on Human Rights and Biomedicine (1998)		

Country	Key Organizations	Legislation	Regulations	Guidelines
	line/home/comitato-bioetica/comitato-sammarinese-di-bioetica.html			
Research Injury		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/EFGCPReportFiles/Serbia%20definitive%20Updated.pdf				
Drugs, Biologics, and Devices	1. Ministry of Health (MOH): http://www.zdravlje.gov.rs/ 2. Serbian Drug Agency http://www.alims.gov.rs/eng/	Law on Medicines and Medical Devices, Official Gazette of RS No. 30/2010 and 107/2012: https://www.alims.gov.rs/eng/files/2013/04/Law-on-Medicines-and-Medical-Devices-2010.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`	
Research Injury	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.zdravlje.gov.rs/downloads/2013/Jun/Jul2013ZakonOPravimaPacijenata.pdf	
Privacy/Data Protection	Commissioner for Information of Public Importance and Personal Data Protection: http://www.poverenik.rs/en/the-commissioners-authority-di.html	Law on the Protection of Personal Data, Official Gazette 97/08, 104/09, 68/20 and 107/12 (Serbian): http://www.minrzs.gov.rs/files/doc/porodica/ostali/Zakon%20o%20zast		

Country	Key Organizations	Legislation	Regulations	Guidelines
		iti%20podataka%20o%20licnosti.pdf		
Genetics	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		
Embryos, Stem Cells, and Cloning	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 Transplantation of 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				
General	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.		
Drugs, Biologics, and Devices	State Institute for Drug Control: http://www.sukl.sk/en	Act No. 140/1998 Coll. on Drugs and Medical Devices, as amended by Acts No. 9/2004 and 542/2006, 489/2008, and 402/2009 Coll.	Ministerial Regulation No. 239/2004 Coll. on Requirements for Clinical Trials and Good Clinical Practice, as Amended by Ministerial Regulation No. 148/2009 Coll.	
Research Injury		Law 277/1994 on Health Care, Section 44		
Privacy/Data Protection	Office for Personal Data Protection: https://dataprotection.gov.sk/uoou/en	Act No. 428/2002 Coll. on Protection of Personal Data, as amended by Act No. 90/2005 Coll.		
Human Biological		1. Act No. 576/2004 Coll. on	Governmental Regulation No.	

Country	Key Organizations	Legislation	Regulations	Guidelines
Materials		Health Care, Sections 35-39. 2. Act No. 489/2008 Coll. on Drugs and Medical Devices, Section 18 (29b).	20/2007 Coll. on Tissue and Cell Collection	
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998) 2. Act No. 576/2004 Coll. on Health Care, Section 26.10.a.		
Slovenia Note: All websites and documents are in Slovenian.				
General	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)
Drugs, Biologics, and Devices	*Drugs*			
	1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/ 2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/	1. Medicinal Products Act, Official Gazette No. 17/2014: http://www.uradni-list.si/1/objava.jsp?sop=2014-01-0539 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	NMEC: 1. Statutory Notes (1998) 2. Rules on the Composition, Duties, Responsibilities, and Working Methods of the Commission for Medical Ethics, Official Gazette Nos. 30/1995, 69/2009, and 47/2017.	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Devices			
	1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/ 2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/	1. Act on Medical Devices, Official Gazette No. 98/2009: http://www.uradni-list.si/1/objava.jsp?sop=2009-01-4284 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		
Research Injury	Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1999) 2. Additional Protocol Concerning Biomedical Research, Article 13, CETS No. 195 (2007)		
Privacy/Data Protection	Information Commissioner of the Republic of Slovenia: http://www.ip-rs.si/	Personal Data Protection Act No. 94/2007: http://www.uradni-list.si/1/objava.jsp?sop=2007-01-4690		
Human Biological Materials	1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/ 2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/	1. Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin (2006) 2. Act on Quality and Safety of 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 3. Rules on Donation and Procurement of Human Tissues and Cells, Official Gazette Nos. 70/2008, 67/2014, and 79/2014 4. Act Regulating the Collection and Transplantation of Human Body Parts for the Purposes of Medical Treatment, Official Gazette No. 56/2015:	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-nmec.sazu.si/Docu/O_truplih_Isis.pdf	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.uradni-list.si/1/objava.jsp?sop=2015-01-2357		
Genetic	Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes (2009)		
Embryos, Stem Cells, and Cloning	1. Republic of Slovenia National Medical Ethics Committee (NMEC): http://www.kme-nmec.si/ 2. Agency for Medicinal Products and Medical Devices (JAZMP): http://www.jazmp.si/	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. 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 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 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/EFGCPReportFiles/Spain%20definitive%20Updated.pdf Note: Many of the 17 Spanish autonomous regions have their own laws and regulations on human subject protections.				
General	1. Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US 2. Coordinating Center for Ethical Committees on Clinical Research (Spanish): http://www.msc.es/profesionales/farmacia/	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		

Country	Key Organizations	Legislation	Regulations	Guidelines
	ceic/home.htm 3. Institute of Health Carlos III, Ministry of Science and Innovation http://www.isciii.es/htdocs/en/index.jsp	Research: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Drugs, Biologics, and Devices	*Drugs*			
	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-2015-8343 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	1. Order SCO/256/2007 That Establishes the Principles and Detailed Directives on Good Clinical Practice, and the Requirements to Approve the Manufacture and Import of Research Medications for Human Use (Spanish): http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rcl_2007_270.pdf 2. Order SCO/362/2008 that Modifies Order SCO/256/2007 (Spanish): http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rcl_2008_410.pdf 3. Order SAS/3470/2009 on Drugs Post Authorization Research (Spanish): http://www.aemps.gob.es/legislacion/espana/medicamentosUsoHumano/docs/farmacovigilancia/rcl_2009_2577.pdf	
	Devices			
	Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/investigacion	Royal Decree 1591/2009, Regulating Sanitary Devices: http://www.ont.es/infesp/Legislacin/	Various (Spanish): http://www.aemps.es/actividad/pschb/implantables1.htm#circulares	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Clinica/productosSanitarios/home.htm	RD_1591_2009.pdf		
Research Injury	Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/home.htm	1. Law 14/2007 on Biomedical Research, Article 18: http://www.catedraderechoygenomahumano.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		
Privacy/Data Protection	Spanish Data Protection Authority (Spanish): https://www.agpd.es/portalweb/index-ides-idphp.php	1. Organic Law 15/1999 of December 13 on the Protection of Personal Data: http://www.legislationline.org/documents/id/9044 2. Law 14/2007 on Biomedical Research, Title I, Article 5: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf	1. Royal Decree 1720/2007 (Spanish): http://www.davara.com/documentos/relacionados/proteccion/RD_1720-2007_english.pdf 2. Royal Decree of 19 January 2008	
Human Biological Materials	Ministry of Health and Consumption: http://www.msc.es/en/home.htm	1. Royal Decree 2070/1999 of December 30, Regarding Activities of Collection and Clinical Use of Human Organs for Organ Transplants and Tissues 2. Royal Decree 1301/2006 of November 10 Regarding the Use	Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples (2006) (Spanish): http://www.boe.es/boe/dias/2006/02/07/pdfs/A04626-04636.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
		of Cells and Human Tissue 3. Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf 4. Royal Decree 1716/2011 on Biobanks: http://www.comitedebioetica.es/normativa/docs/RD%201716_2011_de%20autorizacion%20y%20funcionamiento%20de%20los%20biobancos.pdf 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		
Genetic	Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US	Law 14/2007 of July 3 on Biomedical Research, Title I, Articles 6-9; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Embryos, Stem Cells, and Cloning	1. Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US 2. National Commission for the Donation and Use of Embryos, Cells, and Human Tissues for Biomedical Research: http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/organizacion.shtml 3. National Biobank Register: http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/organizacion.shtml	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2000) 2. Law 14/2006 on Methods of Assisted Human Reproduction, Chapters IV and V 3. Law 14/2007 of July 3 on Biomedical Research, Title III:		

Country	Key Organizations	Legislation	Regulations	Guidelines
	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	http://www.catedraderechoygenomahumano.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				
General	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 Board (2007): http://www.epn.se/media/1202/1068.pdf 3. Statute No. 2007:1069 Containing Instructions for Regional Ethical Review Boards (2007): http://www.epn.se/media/1203/1069.pdf	Information for Research Participants
	Swedish Research Council: http://www.vr.se/english		Regulations and General Counsel VRFS 2012:1 on Ethical Vetting of Human Subjects Research (Swedish): http://www.vr.se/download/18.7ef6967137344838702801340207447175/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 (2017): https://publikationer.vr.se/en/product/good-research-practice/
Drugs, Biologics, and Devices	*Drugs*			
	Medical Products Agency: https://lakemedelsverket.se/english/	1. Pharmaceuticals Act No. No 2015:315 (Swedish):	MPA Regulations on Clinical Trials in Humans -- LVFS	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.notisum.se/rnp/sls/lag/20150315.htm 2. Pharmaceuticals Ordinance 2015:458 (Swedish): http://www.notisum.se/rnp/sls/lag/20150458.htm	2011:19 (Swedish): http://www.lakemedelsverket.se/upload/lvfs/LVFS_2011_19.pdf	
	Devices			
	Medical Products Agency: http://www.lakemedelsverket.se/english/product/Medical-devices/Clinical-Investigations/	1. Swedish Medical Devices Act (SFS 1993:584): http://www.notisum.se/rnp/sls/lag/19930584.htm 2. Medical Devices Ordinance (SFS1993:876): http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-1993876-om-medicintekniska_sfs-1993-876	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	
Social-Behavioral Research	Swedish Research Council			Good Research Practice: Observational Studies Conducted Through Participating, Observing, and Recording (2011): https://publikationer.vr.se/en/product/good-research-practice/
Privacy/Data Protection	1. Swedish Data Protection Agency: 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 Protection Agency 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
Human Biological Materials	1. National Board of Health and Welfare (SOS): http://www.socialstyrelsen.se/english 2. Swedish Research Council (SRC): http://www.vr.se/english 3. BBMRI Sweden: http://bbmri.se/en/ 4. National Biobank Council: http://biobanksverige.se/info/basic-information-in-english/	1. Biobanks in Medical Care Act No. 297 (2002): http://vavnad.se/files/live/sites/Biobanken/files/biobanksverige/9.%20Documetns%20in%20English/Biobanks%20in%20medical%20care%20act%20(2002-297).pdf 2. Regulation No. 746 (2002): http://www.notisum.se/rnp/sls/lag/20020746.htm	SOS: Consolidated regulations (Swedish): http://www.socialstyrelsen.se/sosfs/2002-11	SRC: Research Ethics Guidelines for Using Biobanks (Swedish) (2003) http://www.vr.se/download/18.6b2f98a910b3e260ae28000350/Riktlinjer_Biobanker_11.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
Genetic Research	1. Medical Products Agency: https://lakemedelsverket.se/english/ 2. The Swedish Gene Technology Advisory Board (SGTAB): https://www.genteknik.se/	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	SGTAB: Advice for Ethical Assessments (Swedish): https://www.genteknik.se/wp-content/uploads/2017/09/072_2010-Etisk-v%C3%A4gledning.pdf
Embryos, Stem Cells, and Cloning	1. Swedish Research Council (SRC): http://www.vr.se/english 2. National Board of Health and Welfare (SOS): http://www.socialstyrelsen.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/				
General	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/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 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 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-	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 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	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
		compilation/20061313/index.html		
Drugs, Biologics, and Devices	*Drugs*			
	1. Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en 2. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en	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 2. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	1. Ordinance of 20 September 2013 on 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 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 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	
	Devices			
	Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en	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 2. Federal Act of 30 September 2011on Research involving Human Beings, (Human Research Act, HRA), RS. 810.30: https://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, Article 7: 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 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	Swissmedic Guide to the Regulation of Medical Devices: https://www.swissmedic.ch/medizinprodukte/00287/index.html?lang=en

Country	Key Organizations	Legislation	Regulations	Guidelines
			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	
Clinical Trials Registry	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 (2014): https://www.admin.ch/opc/en/classified-compilation/20061313/index.html		
Research Injury	1. Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en 2. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en	Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 19-20: 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	
Privacy/Data Protection Note: Most Swiss cantons have enacted laws regarding data collection in the public sector that are similar to the Federal Act on Data Protection.	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 810.30, Articles 2, 3, 8, 16-18, 31-35, 41-45, 47, 49, 58-60, and 63: http://www.admin.ch/opc/en/classifi	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 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305	

Country	Key Organizations	Legislation	Regulations	Guidelines
		ed-compilation/20061313/index.html	Articles 5, 7, 9, 12, 16-18, and 25, and Annexes 2-3: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html	
Human Biological Materials	1. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en 2. Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/en/News/News.html	Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 2, 3, 17, 18, 31, 32 - 35, 41-43, 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
Genetic Research	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 Human Beings (Human Research Act, HRA), RS 810.30, Articles 3, 32 - 35, 42, and 49: http://www.admin.ch/opc/en/classifi	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 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	

Country	Key Organizations	Legislation	Regulations	Guidelines
		ed-compilation/20061313/index.html	3 and 4: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html	
Embryos, Stem Cells, and Cloning	Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE): http://www.nek-cne.ch/en/homepage/	*Embryos in Vivo:* Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30 Articles 2, 25 - 27, 39, 40, 44, and 62: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html *Others:* Federal Act of 19 December 2003 on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), RS 810.31: http://www.admin.ch/opc/en/classified-compilation/20022165/index.html	*Embryos in Vivo:* 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				
General	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	1. Constitution of Ukraine Art. 28 (1996) 2. Health Care Law, Article 45 (1992) 3. Criminal Code of Ukraine 2001, Article 141 and 142		
Drugs, Biologics, and Devices	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-en/bioethics-committee	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/z1010-09 2. On Medicines, Articles 7 and 8 No. 123/96BP (2014): http://zakon4.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80	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/v0095282-09 2. Ministry of Health Act 14.12.2009 N 944 on Approval of the Clinical Trial and Expertise of Clinical Trials	Bioethics Committee: 1. Information Letters on Ethics Questions of Clinical Trials and Implementation of Medicines (2006) 2. Ethics Expertise of Clinical Trials Medicines (2007) 3. Methodological Aspects of Central EC Activity of Ukrainian Ministry of Health (2007) 4. Ethical Aspects of Placebo Controlled Clinical Trials in Patients with MS (2008)

Country	Key Organizations	Legislation	Regulations	Guidelines
			(Ukrainian): http://zakon4.rada.gov.ua/laws/show/z0053-10	5. Optimization of Local Ethics Committee Activities (2009) Guidelines for Pre-Clinical and Clinical Trials (Ukrainian): http://www.dec.gov.ua/index.php/ekspertiza-materialiv-doklinichnikh-ta-klinichnikh-viprobuvan/metodichni-rekomendatsiji-shchodo-provedennya-doklinichnikh-ta-klinichnikh-viprobuvan
Research Injury	Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	On Medicines, Article 8 No. 123/96BP (2014): http://zakon4.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80		
Privacy/Data Protection	1. State Service of Ukraine on Personal Data Protection 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/2297-17		
Human Biological Materials	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/286-2016-%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): http://zakon3.rada.gov.ua/laws/show/z1124-12	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	
Genetic Research	Academy of Medical Sciences of the Ukraine			Medical and Ethical Guidelines for Genetic Investigations in Humans
Embryos, Stem Cells, and Cloning	1. National Academy of Sciences Bioethics Committee: http://biomed.nas.gov.ua/index-	1. Act on the Banning of Human Reproductive Cloning (2004) (Ukrainian):	1. Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for	

Country	Key Organizations	Legislation	Regulations	Guidelines
	en/bioethics-committee 2. Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	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	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				
General	*England:*			
	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/organisations/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): https://www.mrc.ac.uk/			1. Research Involving Human Participants in Developing Societies (2004): https://www.mrc.ac.uk/publications/browse/research-involving-human-participants-in-developing-societies/ 2. Medical Research Involving Children (2004): https://www.mrc.ac.uk/documents/pdf/medical-research-involving-children/

Country	Key Organizations	Legislation	Regulations	Guidelines
				3. Medical Research Involving Adults Who Cannot Consent (2007): http://www.mrc.ac.uk/documents/pdf/medical-research-involving-adults-who-cannot-consent/ 4. Good Research Practice: Principles and Guidelines (2012): https://www.mrc.ac.uk/publications/browse/good-research-practice-principles-and-guidelines/
	Scotland:			
	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.hmso.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
	Wales:			
	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
	Northern Ireland:			
	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
Drugs, Biologics, and Devices	*Drugs*			
	1. Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency 2. Administration of Radioactive Substances Advisory Committee (ARSAC) (UK): https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee 3. Department of Environment, Food & Rural affairs (DEFRA) https://www.gov.uk/government/organisations/department-for-environment-food-	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 *Amended by:* IR(ME)R (Amendment) Regulations (2006) http://www.legislation.gov.uk/uksi/2006/2523/contents/made IR(ME)R (Amendment) Regulations (2011) http://www.legislation.gov.uk/uksi/2011/1567/made 2. Medicines for Human Use	Consultation Letter on the Medicines for Human Use (Clinical Trials) Regulations (2003): http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con007629.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
	rural-affairs 4. Health and Safety Executive (HSE) http://www.hse.gov.uk/		(Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004): http://www.legislation.gov.uk/uksi/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/uksi/2006/2984/pdfs/uksi_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/uksi/2008/941/contents/made 6. Genetically Modified Organisms (Deliberate Release) Regulations 2002: http://www.legislation.gov.uk/uksi/2002/2443/contents/made 7. Genetically Modified Organisms (Contained Use) Regulations 2014 *(*England, Scotland and Wales*):* http://www.legislation.gov.uk/uksi/2014/1663/part/1/made 8. The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015: http://www.legislation.gov.uk/nisr/2015/339/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-

Country	Key Organizations	Legislation	Regulations	Guidelines
				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/
	Devices			
	Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/collections/regulatory-guidance-for-medical-devices		1. Medical Devices Regulations (2002): http://www.opsi.gov.uk/si/si2002/20020618.htm 2. Medical Devices (Amendment) Regulations 2008 No 2936: http://www.legislation.gov.uk/uksi/2008/2936/contents/made	1. Clinical Trials for Medical Devices: https://www.gov.uk/government/collections/regulatory-guidance-for-medical-devices 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
	Health Research Authority (HRA): http://www.hra.nhs.uk/			Medical Devices Guidance: http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/medical-devices-research-2/
Clinical Trials Registry	1. ISRCTN: http://www.isrctn.com/ 2. Health Research Authority (HRA): http://www.hra.nhs.uk/			ISRCTN: FAQs: http://www.isrctn.com/page/faqs HRA: Transparency, Registration, and Publication: http://www.hra.nhs.uk/resources/during-and-after-your-study/transparency-registration-and-publication/
Research Injury	Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency		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	
	Department of Health (DH): https://www.gov.uk/government/organisations/department-of-health			NHS Indemnity Arrangements for Clinical Negligence Claims in the NHS: www.nhsla.com/claims/Documents/NHS%20Indemnity.pdf
	Association of the British Pharmaceutical Industry (ABPI):			1. Insurance and Compensation in the Event of Injury in Phase I Clinical Trials

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.abpi.org.uk			(2012): http://www.abpi.org.uk/our-work/library/guidelines/Pages/clinical-trials-insurance.aspx 2. Clinical Trial Compensation Guidelines (2014): http://www.abpi.org.uk/our-work/library/guidelines/Pages/ct-compensation.aspx
	Association of the British Healthcare Industry (ABHI): http://www.abhi.org.uk/			Clinical Investigations Compensation Guidelines (2014): http://www.abhi.org.uk/multimedia/groups/clinical-investigations/ci_compensationguidelines.doc
Social-Behavioral Research	Economic and Social Research Council			ESRC Framework for Research Ethics (2015): http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/
	UK Research Integrity Office			Good Practice in Research: Internet-Mediated Research (2016): http://ukrio.org/wp-content/uploads/UKRIO-Guidance-Note-Internet-Mediated-Research-v1.0.pdf
Privacy/Data Protection	*United Kingdom:*			
	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
	England and Wales:			
	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-	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):

Country	Key Organizations	Legislation	Regulations	Guidelines
	committees/section-251			http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/
Human Biological Materials	*United Kingdom:*			
	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.)* 3. Statutory Instrument 2006 No. 1659: The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 *(Different provisions apply to England, Wales, Northern Ireland, and/or Scotland.):* http://www.legislation.gov.uk/uksi/2006/1659/contents/made		Guidance for Professionals: https://www.hta.gov.uk/guidance-professionals
	Medical Research Council (MRC): https://www.mrc.ac.uk/			Human Tissue and Biological Samples for Use in Research (2014)
	Scotland:			
	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
Genetics Research	1. Public Health Genetics Foundation: http://www.phgfoundation.org/			

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Gene Therapy Advisory Committee: http://www.hra.nhs.uk/resources/applying-to-recs/gene-therapy-advisory-committee-gtac/ 3. Genomics England: https://www.genomicsengland.co.uk/			
Embryos, Stem Cells, and Cloning	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.legislation.gov.uk/ukpga/2008/22/contents	Human Fertilisation and Embryology Regulation and Chronology: https://www.hfea.gov.uk/about-us/how-we-regulate/	HFEA Code of Practice 8th Edition (2016): https://www.hfea.gov.uk/code-of-practice/

Country	Key Organizations	Legislation	Regulations	Guidelines
ASIA/PACIFIC				
Australia				
General	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Australian Research Council (ARC): http://www.arc.gov.au	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
Drugs, Biologics, and Devices	*Drugs*			
	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: National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2015): http://www.nhmrc.gov.au/guidelines/publicatio

Country	Key Organizations	Legislation	Regulations	Guidelines
				ns/e72 Australian States and Territories: National Mutual Acceptance of Scientific and Ethical Review of Multi-Centre Human Research (2017): http://www.health.nsw.gov.au/ethics/Pages/nma.aspx
	Devices			
	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
Clinical Trials Registry	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
Research Injury	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 (2012): https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/ NHMRC, ARC, and UA: National Statement on Ethical Conduct in Human Research. Paragraphs 3.3.24 and 3.3.25 (2015): http://www.nhmrc.gov.au/guidelines/publications/e72
Social-Behavioral Research	National Health and Medical Research Council			National Statement on Ethical Conduct in Human Research, Chapter 3.1 (2015): https://www.nhmrc.gov.au/book/chapter-3-1-qualitative-methods
Privacy/Data Protection	Office of the Australian Information Commissioner: http://www.oaic.gov.au/	Privacy Act 1988 (2016): https://www.legislation.gov.au/Deta	1. Australian Privacy Principles Guidelines (2014):	1. Australian Privacy Principles Guidelines (2015):

Country	Key Organizations	Legislation	Regulations	Guidelines
Note: All Australian states and territories have privacy/data protection laws: http://www.oaic.gov.au/privacy/other-privacy-jurisdictions/state-and-territory-privacy-law		ils/C2016C00838	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 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	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 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
Human Biological Materials Note: All Australian states and territories have laws on human biological materials.	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Therapeutic Goods Administration (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 (2017): http://www.tga.gov.au/industry/biologicals-argb.htm
Genetic Research	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. Office of the Gene Technology Regulator: http://www.ogtr.gov.au/	Gene Technology Act 2000 (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
Embryos, Stem Cells, and Cloning	1. National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/ 2. National Health and Medical Research Council: Embryo Research Licensing Committee 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 (2017): 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

Country	Key Organizations	Legislation	Regulations	Guidelines
				Practice and Research (2017): https://www.nhmrc.gov.au/guidelines-publications/e79
Bangladesh				
General	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			
Drugs, Biologics, and Devices	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_part.php?id=623		
Human Biological Materials	Bangladesh Medical Research Council, Ethics Review Committee: http://www.bmrcbd.org			Guidelines for Transfer of Human Biological Materials Abroad for Research Purposes (2004)
Burma (Myanmar)				
General	1. 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)
Drugs, Biologics, and Devices	Ministry of Health, Food and Drug Administration: http://www.fdamyanmar.gov.mm/index.php/en/	National Drug Law (1992)		
Human Biological Materials		1. Blood and Blood Products Law (2003) (Burmese): http://www.moh.gov.mm/file/Law/Blood%20and%20Blood%20Product%20Law%20(2003).pdf 2. Body Organ Donation Law (2004)		
China, People's Republic of For an overview of clinical research regulations in China, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=44				
General	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://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: Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2016) (Mandarin): http://www.moh.gov.cn/fzs/s3576/201610/84b33b81d8e747eaaf048f68b174f829.shtml NHFPC, CFDA, and State Administration of TCM: Management Guidelines for Conducting Clinical Research at Medical/Health

Country	Key Organizations	Legislation	Regulations	Guidelines
				Institutions (Mandarin) (2014): http://www.nhfpc.gov.cn/yzygj/s3593g/201410/9bd03858c3aa41ed8aed17467645fb68.shtml
Drugs, Biologics, and Devices	*Drugs*			
	Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/	Drug Administration Law of the People's Republic of China (2001): http://eng.sfda.gov.cn/WS03/CL0766/61638.html	1. Regulations for Implementation of the Drug Administration Law of the People's Republic of China (2002): http://eng.sfda.gov.cn/WS03/CL0767/61640.html 2. Chinese Good Clinical Practice (2003) (Mandarin): http://www.sfda.gov.cn/WS01/CL0053/24473.html 3. Special Review and Approval Procedure for Drug Registration of the State Food and Drug Administration (2005): 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	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 4. Interim Guidelines on International Multi-Regional Drug Clinical Trials (2015) (Mandarin): http://www.sda.gov.cn/WS01/CL0087/114002.html
	Devices			
	Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/		CFDA and NHFPC: Good Clinical Practice on Medical Device Clinical Trials (2016) (Mandarin): http://www.sda.gov.cn/WS01/CL0053/148101.html	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 Templates for Medical Device Clinical Trials (Mandarin):

Country	Key Organizations	Legislation	Regulations	Guidelines
				1. Ethical Review Application And 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
Clinical Trials Registry	Chinese Clinical Trial Registry: http://www.chictr.org.cn/index.aspx			FAQs: http://www.chictr.org.cn/question.aspx
Privacy/Data Protection	*Hong Kong:*			
	1. Office of the Privacy Commissioner for Personal Data: http://www.pcpd.org.hk 2. eHealth Record Office: http://www.ehealth.gov.hk/en/home/index.html	Personal Data (Privacy) Ordinance (2013): http://www.blis.gov.hk/blis_pdf.nsf/CurAllEngDoc/B4DF8B4125C4214D482575EF000EC5FF/$FILE/CAP_486_e_b5.pdf		1. Electronic Health Record Sharing System and Your Personal Data Privacy (10 Privacy Protection Tips): https://www.pcpd.org.hk/english/data_privacy_law/electronic_health_record_sharing_system/files/eHRSS_10_Tips_ENG.pdf 2. Personal Data (Privacy) Ordinance and Electronic Health Record Sharing System (Points to Note for Healthcare Providers and Healthcare Professionals): https://www.pcpd.org.hk/english/data_privacy_law/electronic_health_record_sharing_system/files/eHRSS_Points_to_Notes_ENG.pdf
Research Injury	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. Regulations on Recall of Medical Devices (Interim), Article 37 (2011) (Mandarin): http://www.gov.cn/flfg/2011-06/13/content_1882686.htm 2. Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2016), Articles 18.5, 20.8, 36.6, 37. (Mandarin): http://www.moh.gov.cn/fzs/s3576/201610/84b33b81d8e747eaaf048f68b174f829.shtml CFDA and NHFPC: Good Clinical Practice on Medical Device Clinical Trials (2016), Articles 10, 22, 33, and 48; (Mandarin):	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

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.sda.gov.cn/WS01/CL0053/148101.html	
Genetic Research	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Ministry of Science and Technology of the People's Republic of China (MOST): http://www.most.cn/eng/		NHFPC and MOST: 1. Interim Measures for the Administration of Human Genetic Resources (1998) (Mandarin): http://www.most.gov.cn/bszn/new/rlyc/wjxz/200512/t20051226_55327.htm 2. Regulations for the Administration of Human Genetic Resources (2012, public comment version) (Mandarin): http://www.gov.cn/gzdt/2012-10/31/content_2254379.htm	MOST: Service Guidelines for the Collection, Selling, Export and Admission Application of Human Genetic Resources (2015) (Mandarin): http://www.most.gov.cn/tztg/201507/t20150703_120547.htm
Embryos, Stem Cells, and Cloning	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.nhfpc.gov.cn/ 2. Ministry of Science and Technology of the People's Republic of China (MOST): http://www.most.cn/eng/		NHFPC: 1. Ethical Principles and Conduct Norms for Human Assisted Reproductive Technologies. (2003) (Mandarin): http://www.moh.gov.cn/qjjys/s3581/200805/f69a925d55b44be2a9b4ada7fcdec835.shtml 2. Regulation on the Clinical Application of Medical Technique (2009) http://www.moh.gov.cn/yzygj/s3589/201308/0c579ba3babf47dc8f0e811810d438a2.shtml NHFPC and 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
	Hong Kong:			
	Legislative Council of the Hong Kong Special Administrative Region of the People's Republic of China: http://www.legco.gov.hk/index.html		Human Reproductive Technology (Amendment) Ordinance 2016: http://www.legco.gov.hk/yr15-16/english/ord/ord020-2016-e.pdf	

Country	Key Organizations	Legislation	Regulations	Guidelines
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				
General	Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			1. National Ethical Guidelines For Biomedical and Health Research Involving Human Participants (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf 2. National Ethical Guidelines for Biomedical Research Involving Children (2017): http://icmr.nic.in/guidelines/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf
Drugs, Biologics, and Devices	*Drugs*			
	1. Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): http://cdsco.nic.in 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	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: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 7 (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
	Devices			
	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: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 7.7 (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
Clinical Trials Registry	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:

Country	Key Organizations	Legislation	Regulations	Guidelines
				Registration of Clinical Trial in ICMR Clinical Trial Registry: http://www.cdsco.nic.in/writereaddata/CTRegistration.doc
Research Injury	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 CDSCO: 1. Compensation and Reporting of SAE timelines GSR 889 (E) 2014 (scroll down to see English version): http://www.cdsco.nic.in/writereaddata/Notificatiohn%20on%20Compensation%20on%20clincial%20trial%20(1).pdf 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 3. Compensation Formula for Clinical Trial Injury Other than Death (2014) : http://www.cdsco.nic.in/writereaddata/ORDER%20and%20Formula%20to%20Determine%20the%20quantum%20of%20compensation%20in%20the%20cases%20of%20Clinical%20Trial%20related%20serious%20Adverse%20Events(SAEs)%20of%20Injury%20other%20than%20Death.pdf	ICMR: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 2.6 (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
Social-Behavioral Research				ICMR: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 9 (2017):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
Human Biological Materials	Ministry of Health and Family Welfare: http://mohfw.nic.in/		Govt. of India Office Memorandum (O.M. No.19015/53/1997 - IH Pt.) 19th November, 1997 on Exchange of Human Biological Material for Biomedical Research Purposes	ICMR: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 11 (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
Genetic Research	1. Department of Biotechnology (DBT): http://dbtindia.nic.in/ 2. Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm	Environmental Protection Act (1986)		DBT: 1. Recombinant DNA Safety Guidelines (1990) 2. Ethical Policies on the Human Genome, Genetic Research, and Services (2002) ICMR: National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 10 (2017): http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
Embryos, Stem Cells, and Cloning	Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/human_ethics.htm			National Guidelines for Stem Cell Research (2017): http://icmr.nic.in/guidelines/Guidelines_for_stem_cell_research_2017.pdf
Indonesia				
General	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)
Drugs, Biologics, and Devices	National Agency of Drug and Food Control: http://www.pom.go.id/index.php/home/en		Guidelines on Good Clinical Practice (2001)	
Human Biological Materials			National Guidelines on Use of Stored Biological Materials (2005)	
Japan				
General	1. Ministry of Education, Culture, Sports, Science, and Technology (MEXT): http://www.mext.go.jp/english/ 2. Ministry of Health, Labor, and Welfare (MHLW):	Clinical Research Act (2017) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000163413.pdf		MEXT and MHLW: Ethics Guidelines for Medical and Health Research Involving Human Subjects (2017) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n18

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.mhlw.go.jp/english/index.html			59_01.pdf 2015 version (English): http://www.lifescience.mext.go.jp/files/pdf/n1500_01.pdf
Drugs, Biologics, and Devices	*Drugs*			
	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	1. Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (2016) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html 2. Clinical Research Act (2017) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000163413.pdf	MHLW: Ministerial Ordinance on Good Clinical Practice for Drugs (2016) (Japanese): http://elaws.e-gov.go.jp/search/elawsSearch/elaws_search/lsg0500/detail?lawId=409M50000100028&openerCode=1	
	Devices			
	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	1. Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (2016) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html 2. Clinical Research Act (2017) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000163413.pdf	MHLW: Ministerial Ordinance on Good Clinical Practice for Medical Devices (2016) (Japanese): http://law.e-gov.go.jp/htmldata/H17/H17F19001000036.html 2009 version (English): https://www.pmda.go.jp/files/000153732.pdf	
Clinical Trials Registry	National Institute of Public Health: https://www.niph.go.jp/index_en.html			NIPH Clinical Trials Search: http://rctportal.niph.go.jp/en/
Privacy/Data Protection	1. Personal Information Protection Commission: http://www.ppc.go.jp/en/ 2. Office of Healthcare Policy of the Cabinet Secretariat: http://www.kantei.go.jp/jp/singi/kenkouiryou/en/	1. Amended Act on the Protection of Personal Information (2017): https://www.ppc.go.jp/files/pdf/Act_on_the_Protection_of_Personal_Information.pdf 2. Act Regarding Anonymized Medical Data to Contribute to R&D in the Medical Field (2017) (Japanese): http://www.kantei.go.jp/jp/singi/kenkouiryou/jisedai_kiban/pdf/170310_shiryou3.pdf	1. Amendment to the Cabinet Order to Enforce the Act on the Protection of Personal Information (2016): https://www.ppc.go.jp/files/pdf/Cabinet_Order.pdf 2. Enforcement Rules for the Act on the Protection of Personal Information (2016): https://www.ppc.go.jp/files/pdf/PPC_rules.pdf	Guideline for Act on the Protection of Personal Information (2016)(Japanese): https://www.ppc.go.jp/files/pdf/guidelines01.pdf https://www.ppc.go.jp/files/pdf/guidelines02.pdf https://www.ppc.go.jp/files/pdf/guidelines03.pdf https://www.ppc.go.jp/files/pdf/guidelines04.pdf
Research Injury	Ministry of Health, Labor, and	Pharmaceuticals, Medical	1. Ministerial Ordinance on Good	Ethics Guidelines for Medical and Health

Country	Key Organizations	Legislation	Regulations	Guidelines
	Welfare (MHLW): http://www.mhlw.go.jp/english/index.html	Devices, and Other Therapeutic Products Act (2016) (Japanese): http://law.e-gov.go.jp/htmldata/S35/S35HO145.html	Clinical Practice for Drugs, Article 14 (2016): http://law.e-gov.go.jp/htmldata/H09/H09F03601000028.html 2. Ministerial Ordinance on Good Clinical Practice for Medical Devices, Article 14 and 23 (2016): http://law.e-gov.go.jp/htmldata/H17/H17F19001000036.html	Research Involving Human Subjects, Chapter 2, No. 5, 1-(3) and No. 6, 2-(2) (2017) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1500_01.pdf
Human Biological Materials	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
Genetic Research	1. Council for Science, Technology, and Innovation (CSTI): 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/			CSTI: Fundamental Principles of Research on the Human Genome (2000): http://www.lifescience.mext.go.jp/files/pdf/43_137.pdf MEXT, MHLW, and METI: Ethics Guidelines for Human Genome/Gene Analysis Research (2017) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1432_01_01.pdf 2008 version (English): http://www.lifescience.mext.go.jp/files/pdf/n796_00.pdf MHLW: Guidelines for Clinical Research in Gene Therapy and Others (2017) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/150812_rinrisisin.pdf
Embryos, Stem Cells, and Cloning	1. Council for Science, Technology, and Innovation (CSTI): 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 2000 version (English):	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	CSTP: Fundamental Philosophy on Handling of Human Embryo (2004) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/6_28.pdf MEXT:

Country	Key Organizations	Legislation	Regulations	Guidelines
		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	Act on Safety of Regenerative Medicine (2014) (Japanese): http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000065532.pdf	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 2010 version (English): 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 (2017) (Japanese): http://www.lifescience.mext.go.jp/files/pdf/n1492_03.pdf 2010 version (English): 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				
General	Ministry of Healthcare and Social Development, Central Commission on Research Ethics: http://www.mzsr.gov.kz/en			1. Guidelines on Ethics in Health Research. (2007) 2. Local Ethics Committees: Policy, Rules and Procedures (2014) 3. Guidelines on Ethics in Biomedical Research (2015)
Drugs, Biologics, and Devices	Ministry of Healthcare and Social Development, Control Committee of Medical and Pharmacy Activity:	Code of the Republic of Kazakhstan "On People's Health and the Health Care System"	1. Order of the MHSD of the RK Dated 12.11.2009 No. 697 on the Approval of Regulations on the	Guidelines on Clinical Trials in Kazakhstan (2003)

Country	Key Organizations	Legislation	Regulations	Guidelines
	https://www.mzsr.gov.kz/en/taxonomy/term/674	(18.09.2009 No.193-IV), Articles 74 and 180 (2015): http://online.zakon.kz/Document/?doc_id=30479065#pos=1;-8	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	
Privacy/Data protection	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 28 (2015): http://online.zakon.kz/Document/?doc_id=30479065#pos=1;-8		
Korea Note: All documents are in Korean.				
General	Ministry of Health and Welfare: http://www.mohw.go.kr/eng/	Bioethics and Safety Act No. No. 14839 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률	1. Enforcement Decree of Bioethics and Safety Act No. No. 28211 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행령 2. Enforcement Rule of Bioethics and Safety Act No. 419 (2016): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙	
Drugs, Biologics, and Devices	*Drugs*			
	1. Ministry of Health and Welfare (MOHW): http://www.mohw.go.kr/eng/ 2. Ministry of Food and Drug Safety (MFDS) (2013): http://www.mfds.go.kr/eng	MOHW: Pharmaceutical Affairs Act No. 14839 (2017): http://www.law.go.kr/법령/약사법	MOHW: 1. Enforcement Decree of Pharmaceutical Affairs Act No. 28211 (2017): http://www.law.go.kr/법령/약사법시행령 2. Enforcement Rule of	MFDS: Guidelines on Human Research Protection Program (2014): http://www.mfds.go.kr/index.do?mid=1162&seq=7877&cmd=v 2. IND regulations No 2017-23 (2017): http://www.law.go.kr/admRulSc.do?menuId=1

Country	Key Organizations	Legislation	Regulations	Guidelines
			Pharmaceutical Affairs Act No. 503 (2017): http://www.law.go.kr/법령/약사법시행규칙 MFDS: 1. Enforcement Rule of Medicinal Product Safety No. 1330 (2017): http://www.law.go.kr/법령/의약품등의안전에관한규칙 2. 임상시험 및 생물학적 동등성시험 종사자 교육 및 교육실시기관 지정에 관한 규정 2. Regulations for Clinical Trial Personnel Education and Certification for the Educational Institution No. 2016-133 (2016): http://www.law.go.kr/행정규칙/임상시험및생물학적동등성시험종사자교육및교육실시기관지정에관한규정	&query=%EC%9D%98%EC%95%BD%ED%92%88%20%EC%9E%84%EC%83%81%EC%8B%9C%ED%97%98%20%EA%B3%84%ED%9A%8D%20%EC%8A%B9%EC%9D%B8%EC%97%90%20%EA%B4%80%ED%95%9C%20%EA%B7%9C%EC%A0%95#liBgcolor0
	Devices			
	Ministry of Food and Drug Safety: http://www.mfds.go.kr/eng	Medical Device Act No. 14330 (2016): http://www.law.go.kr/법령/의료기기법	1. Enforcement Decree of the Medical Device Act No. 28224 (2017): http://www.law.go.kr/법령/의료기기법시행령 2. Enforcement Regulations of the Medical Device Act No. 1389 (2017): http://www.law.go.kr/법령/의료기기법시행규칙	
Clinical Trials Registry	Korea Centers for Disease Control and Prevention (KCDC), Clinical Research Information Service: https://cris.nih.go.kr/cris/en/use_guide/cris_introduce.jsp			
Research Injury	Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng		Enforcement Rule of Medicinal Product Safety No. 1330 (2017): http://www.law.go.kr/법령/의약품등의안전에관한규칙	Guidelines for Clinical Trial Indemnity and Its Process (2013): http://www.mfds.go.kr/index.do?x=0&searchkey=title:contents&mid=1769&searchDivision=&searchClass=&searchword=임상시험%20피

Country	Key Organizations	Legislation	Regulations	Guidelines
				해자&y=0&searchSubDivision=&pageNo=1&seq=13069&sitecode=2017-06-01&cmd=v 2. Guidance for Sponsors; Safety Reporting Requirements (2017): http://www.mfds.go.kr/index.do?x=0&searchkey=title:contents&mid=1769&searchDivision=&searchClass=&searchword=임상시험&y=0&searchSubDivision=&pageNo=1&seq=13317&sitecode=2017-08-31&cmd=v
Privacy/Data Protection	1. Ministry of the Interior and Safety (MOIS): http://www.mois.go.kr/eng/ 2. Ministry of Health and Welfare (MOHW): http://www.mohw.go.kr/eng/	MOIS: Personal Information Protection Act No. 14839 (2017): http://www.law.go.kr/법령/개인정보보호법 MOHW: Bioethics and Safety Act No. 14839 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률	MOIS: 1. Enforcement Rules to Personal Information Protection Act No. 28211 (2017): http://www.law.go.kr/법령/개인정보보호법시행령 2. Enforcement Decrees to Personal Information Protection Act No. 26140 (2017): http://www.law.go.kr/법령/개인정보보호법시행규칙 MOHW: Enforcement Rule of Bioethics and Safety Act No. 419 (2016): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙	MOIS: Guidelines on Standard Personal Information Protection (2017): http://www.law.go.kr/행정규칙/표준개인정보보호지침
Human Biological Materials	1. Ministry of Health and Welfare (MOHW): http://www.mohw.go.kr/eng/ 2. Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng	MOHW: Bioethics and Safety Act No. 14839 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률	1. Enforcement Decree of Bioethics and Safety Act No. 28211 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행령 2. Enforcement Rule of Bioethics and Safety Act No. 419 (2016): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙	
Genetic Research	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. 14839 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률	MOHW: 1. Enforcement Decree of Bioethics and Safety Act No. 28211 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률시행령 2. Enforcement Rule of Bioethics and Safety Act No. 419 (2016): http://www.law.go.kr/법령/생명윤리	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=유전&x=0&mid=1769&pageNo=1&seq=12480&sitec

Country	Key Organizations	Legislation	Regulations	Guidelines
			및안전에관한법률시행규칙	ode=2006-01-01&cmd=v 2. Guidelines on the Evaluation of Quality, Safety, and Efficacy of Recombinant Protein Products (2014): http://www.mfds.go.kr/index.do?searchkey=title:contents&searchClass=&searchSubDivision=&searchDivision=&y=0&searchword=유전&x=0&mid=1769&pageNo=1&seq=12542&sitecode=2017-06-01&cmd=v
Embryos, Stem Cells, and Cloning	1. Ministry of Health and Welfare (MOHW): http://www.mohw.go.kr/eng/ 2. Ministry of Food and Drug Safety (MFDS): http://www.mfds.go.kr/eng	Bioethics and Safety Act No. 14839 (2017): http://www.law.go.kr/법령/생명윤리및안전에관한법률	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
Kyrgyzstan Note: All websites and documents are in Russian.				
General	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 04.08.1998г. (Updated June 11, 2008 N 115 and June 23, 2008 N 136) Chapters 7 and 10: http://www.pharm.kg/ru/legislation/	
Drugs, Biologics, and Devices	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee 3. Pharmaceutical Union of Kyrgyzstan, Ethics Committee: http://farmunion.kg/o-nas/eticheskij-komitet/	Law on the Circulation of Medicinal Products of the Kyrgyz Republic (August 2, 2017 No. 165) Chapter VII, Articles 24-25.	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:	

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.pharm.kg/ru/legislation/	
Research Injury	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on the Circulation of Medicinal Products of the Kyrgyz Republic (August 2, 2017 No. 165) Chapter VII, Articles 24-25.	DDMDP: National Standard KMC 1195:2010: Medical Devices, Rules for Clinical Trials, Paragraphs 3, 4, and 6 (2010): http://www.pharm.kg/ru/legislation/	
Human Biological Materials	1. Ministry of Health, Department of Drug and Medical Devices Provision: http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on 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/	
Social-Behavioral Research	Ministry of Justice	Law On the Protection of Traditional Knowledge (2014): http://cbd.minjust.gov.kg/act/view/ru-ru/202149/20?cl=ru-ru		
Privacy/Data Protection	1. Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): http://www.pharm.kg 2. Ministry of Health, National Bioethics Committee	Law on 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 Medical Application, Approved by the Governmental Order #74 from February 1, 2012: http://www.pharm.kg/ru/legislation/	
Malaysia				
Drugs, Biologics, and Devices	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
Privacy/Data Protection		Act 709: Personal Data Protection Act 2010: http://www.pdp.gov.my/images/LAWS_OF_MALAYSIA_PDPA.pdf		
Human Biological Materials	National Committee for Clinical Research: http://www.nccr.gov.my/	1. Act 130: Human Tissues Act (1974):	DNA Identification Regulations 2012. Malaysian Government	Guideline on the Use of Human Biological Tissues for Research (2006):

Country	Key Organizations	Legislation	Regulations	Guidelines
		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	Gazette of 30 Aug 2012.	http://www.nccr.gov.my/index.cfm?menuid=25&parentid=17
Genetic Research	Malaysian Medical Council: http://www.mmc.gov.my/v1/			Medical Genetics and Genetic Services. MMC Guidelines 010/2006: http://www.mmc.gov.my/v1/docs/Medical%20Genetics%20&%20Genetic%20Services.pdf
Embryos, Stem Cells and Cloning	Ministry of Health, Medical Research and Ethics Committee			Checklist for Research on Stem Cell and Cell-Based Therapies: http://www.nih.gov.my/mrec/documents/Research_On_Stem_cell_and_Cell_based_Therapies.pdf
Nepal				
General	Nepal Health Research Council, 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
Drugs, Biologics, and Devices	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
New Zealand				
General	1. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ 2. National Ethics Advisory Committee (NEAC): http://www.neac.health.govt.nz/ 3. Ministry of Health (MOH): http://www.moh.govt.nz/ 4. Health and Disability Commissioner (HDC): http://www.hdc.org.nz/ 5. Health and Disability Ethics Committees: http://www.ethics.health.govt.nz/ 6. Ministry of Business, Innovation and Employment: http://www.mbie.govt.nz/	1. Health Research Council Act 1990, Sections 24 and 25 2. New Zealand Bill of Rights Act, Article 10 (1990) 3. Health and Disability Commissioner Act 1994 4. New Zealand Public Health and Disability Act 2000, Section 16 5. Accident Compensation Act 2001 Access: All New Zealand acts, bills, and regulations can be found here: http://www.legislation.govt.nz/	HDC: The Code of Health and Disability Services Consumers' Rights (the Code of Rights) (2004): http://www.hdc.org.nz/the-act--code/the-code-of-rights	HRC: 1. Guidelines for Researchers on Health Research Involving Māori (2010) 2. Te Ara Tika. Guidelines for Māori Research Ethics: A Framework for Researchers and Ethics Committee Members (2010) 3. HRC Research Ethics Guidelines (2017) 4. Pacific Health Research Guidelines (2014) Access: http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval NEAC: 1. Goals, Objectives, and Desired Outcomes of an Ethical Review System

Country	Key Organizations	Legislation	Regulations	Guidelines
				(2003) 2. Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (2012) 3. Ethical Guidelines for Intervention Studies (2012) Access*:* http://www.neac.health.govt.nz/moh.nsf/indexcm/neac-resources-publications MOH: Standard Operating Procedures for Health and Disability Ethics Committees (2012): http://www.ethics.health.govt.nz/operating-procedures
Drugs, Biologics, and Devices	*Drugs*			
	1. New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz 2. Medicines New Zealand: http://www.medicinesnz.co.nz/ 3. Health Research Council (HRC), Standing Committee on Therapeutic Trials: http://www.hrc.govt.nz/about-us/committees/standing-committee-therapeutic-trials-scott	1. Accident Compensation Act 2001, Section 32 (2010) 2. Medicines Act 1981(2012)	Medsafe: Medicines Regulations 1984 http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM95668.html	Medsafe: Good Clinical Research Practice and Obtaining Approval for Clinical Trials (2013): http://www.medsafe.govt.nz/medicines/clinical-trials.asp 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-compensation-guidelines.pdf
	Devices			
	New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz		Medicines (Database of Medical Devices) Regulations (2003): http://www.legislation.govt.nz/regulation/public/2003/0325/latest/DLM224223.html	1. Standard Operating Procedures for Health and Disability Ethics Committees (2012): http://www.ethics.health.govt.nz/operating-procedures 2. Various: http://medsafe.govt.nz/regulatory/DevicesNew/13ConductingClinicalTrials.asp
Clinical Trials Registry	Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/			FAQs: http://www.anzctr.org.au/Faq.aspx
Privacy/Data Protection	Privacy Commissioner: http://www.privacy.org.nz/	1. Official Information Act 1982 (2012)	Health Information Privacy Code 1994: http://www.privacy.org.nz/assets/File	

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Public Records Act (2005) 3. Privacy Act 1993 (2012)	s/Codes-of-Practice-materials/Health-Information-Privacy-Code-1994-including-Amendment.pdf	
Human Biological Materials	1. Ministry of Health (MOH): http://www.moh.govt.nz/ 2. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval 3. Te Puni Kokiri (TPK): http://www.tpk.govt.nz/ 4. Office of the Health and Disability Commissioner (HDC): http://www.hdc.org.nz 5. Ministry of Business, Innovation and Employment: http://www.mbie.govt.nz/	1. Health Act 1956 (2012) 2. Human Tissue Act 2008		MOH: Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (2007): http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes
Genetic Research	1. Environmental Protection Authority: http://www.epa.govt.nz/ 2. Health Research Council (HRC), Gene Technology Advisory Committee: http://www.hrc.govt.nz/about-us/committees/gene-technology-advisory-committee-gtac	Hazardous Substances and New Organisms Act 1996 (2012)		
Embryos, Stem Cells, and Cloning	1. Advisory Committee on Assisted Reproductive Technology (ACART): http://acart.health.govt.nz/ 2. Ethics Committee on Assisted Reproductive Technology (ECART): http://ecart.health.govt.nz/ 3. Ministry of Health: http://www.moh.govt.nz/	Human Assisted Reproductive Technology Act 2004 (2009)	Human Assisted Reproductive Technology (HART) Order (2005): http://www.legislation.govt.nz/regulation/public/2005/0181/latest/DLM335192.html	ACART: 1. Guidelines on the Use, Storage, and Disposal of Sperm from a Deceased Man (2000) 2. Guidelines for Research on Gametes and Non-viable Embryos (2005) 3. Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research (2005) 4. Guidelines on Embryo Donation for Reproductive Purposes (2008) 5. Guidelines on Extending the Storage Period of Gametes and Embryos (2012) 6. Guidelines on Donation of Eggs or Sperm between Certain Family Members (2013) 7. Guidelines on Surrogacy Arrangements Involving Assisted Reproductive Procedures (2013) 8. Guidelines on Preimplantation Genetic

Country	Key Organizations	Legislation	Regulations	Guidelines
				Diagnosis with Human Leucocyte Antigen Tissue Typing (2014) Access: https://acart.health.govt.nz/publications-and-resources/guidelines-and-advice-issued-ecart
Pakistan				
General	National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Various: http://nbcpakistan.org.pk/guidelines.html
Drugs, Biologics, and Devices	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
Human Biological Materials	National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Ethical Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials (HBM): http://nbcpakistan.org.pk/assets/hbm-nbc-guidelines-final-18june-2016.pdf
Embryos, Stem Cells, and Cloning	National Bioethics Committee (NBC): http://nbcpakistan.org.pk/			Protocol/Guidelines for Stem Cell Research/Regulation in Pakistan: http://nbcpakistan.org.pk/?page_id=61
Philippines				
General	1. Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph 2. Department of Science and Technology (DOST): http://www.dost.gov.ph/ 3. Department of Health (DOH): 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:pub-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://ethics.healthresearch.ph/index.php/component/content/article/2-uncategorised/111-ao-001 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 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 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	
Drugs, Biologics, and Devices	*Drugs*			
	Food and Drug Administration (FDA): http://www.fda.gov.ph/		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	Ethical Guidelines for Clinical Trials on Drugs, Devices, and Diagnostics (2006): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
			Order No. 47-a) (2001) 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 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 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	
	Devices			
	Food and Drug Administration: http://www.fda.gov.ph/			FDA Guidelines: Regulation of Clinical Trials in the Philippines http://www.pcrp.org.ph/pdf/GuidelinesversionLR.PDF
Clinical Trials Registry	Philippine Health Research Registry: http://registry.healthresearch.ph/			FAQs: http://registry.healthresearch.ph/index.php?option=com_content&view=article&id=7&Itemid=185
Research Injury	1. Department of Science and Technology (DOST): http://www.dost.gov.ph/ 2. Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph			PHREB: National Ethical Guidelines for Health Research, pages 19-20 (2011): http://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=9:pub-ethics-guidelines-2011

Country	Key Organizations	Legislation	Regulations	Guidelines
Social-Behavioral Research	Philippine Council for Health Research and Development			Ethical Guidelines for Social and Behavioral Research (2006): https://www.pogsinc.org/files/research/pnhrs-national-ethical-guidelines.pdf
Embryos, Stem Cells, and Cloning	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:pub-ethics-guidelines-2011
Singapore				
General	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Ministry of Health, National Medical Ethics Committee (NMEC) 3. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	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: 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: 1. Research Involving Human Subjects: Guidelines for IRBs (2004): http://www.bioethics-singapore.org/index/publications/reports/172-

Country	Key Organizations	Legislation	Regulations	Guidelines
				research-involving-human-subjects-guidelines-for-irbs.html 2. Ethics Guidelines for Human Biomedical Research (2015): http://www.bioethics-singapore.org/index/publications/reports/86-reports/ethics-guidelines-for-human-biomedical-research.html
Drugs, Biologics, and Devices	*Drugs*			
	1. Health Sciences Authority of Singapore (HSA): http://www.hsa.gov.sg 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	Medicines Act (1975): http://statutes.agc.gov.sg/	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	HSA: Singapore Guideline for Good Clinical Practice (1990): http://www.pacra.org/dev-pacra/images/pdf-files/singapore/sg-gcp.pdf 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
	Devices			
	1. Health Sciences Authority (HSA): http://www.hsa.gov.sg 2. National Environment Agency, Centre For Radiation Protection And Nuclear Science: http://www.nea.gov.sg/anti-pollution-radiation-protection/radiation-protection	1. Health Products Act (2007): http://statutes.agc.gov.sg/ 2. Radiation Protection Act (2007): http://statutes.agc.gov.sg/	1. Health Products (Medical Device) Regulations (2010): http://www.emergogroup.com/sites/default/files/file/singapore-health-products-medical-devices-regulations-2010.pdf 2. Radiation Protection Regulations (2014): http://www.nea.gov.sg/anti-pollution-radiation-protection/radiation-protection/regulatory/summary-of-radiation-protection-(amendment)-act-2014	
Research Injury	1. Health Sciences Authority: http://www.hsa.gov.sg 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	1. Medicines Act (1975): http://statutes.agc.gov.sg/ 2. Radiation Protection Act (2007): http://statutes.agc.gov.sg/	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	HSA: Singapore Guideline for Good Clinical Practice (1999): http://www.pacra.org/dev-pacra/images/pdf-files/singapore/sg-gcp.pdf NMEC: Recommendations On Clinical Trials: Update Focusing On Phase I Trials (2007)
Privacy/Data Protection	1. Ministry of Communications and Information (MCI): http://www.mci.gov.sg/web	1. Computer Misuse Act (Cap. 50A) (1993): http://statutes.agc.gov.sg/		BAC: Personal Information in Biomedical Research (2007): http://www.bioethics-

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org	2. Personal Data Protection Act (2012): http://statutes.agc.gov.sg/		singapore.org/index/publications/reports/170-personal-information-in-biomedical-research.html
Human Biological Materials	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
Genetic Research	1. Ministry of Health, National Medical Ethics Committee (NMEC) 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org			NMEC: Ethical Guidelines for Gene Technology (2001): 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
Embryos, Stem Cells, and Cloning	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org/	Human Cloning and Other Prohibited Practices Act (2004): http://statutes.agc.gov.sg/	Licensing Terms and Conditions on Assisted Reproduction Services (2011): http://www.moh.gov.sg/content/dam/moh_web/Publications/Guidelines/Private%20healthcare%20institutions/2011/AR_LTCs_260411.pdf	BAC: 1. Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning (2002): 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				

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	Cosmetics, Devices, and Drugs Regulatory Authority, Subcommittee on Clinical Trials: http://www.cdda.gov.lk/index.php?option=com_content&view=article&id=78&Itemid=115&lang=en	National Medicines Regulatory Authority Act of 2015: http://www.cdda.gov.lk/images/stories/new/pdf/legislations/5e_nmdra.pdf		Guidelines for the Conduct of Clinical Trials in Sri Lanka (2014): http://www.cdda.gov.lk/images/pdf/clinical%20trials%20guidelines_oct2014.pdf
Clinical Trials Registry	Sri Lanka Clinical Trials Registry: http://www.slctr.lk/			FAQs: http://slctr.lk/faq
Taiwan				
General	Ministry of Health and Welfare: http://www.mohw.gov.tw/EN/Ministry/Index.aspx	1. Human Subjects Research Act (2011): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020176 2. Medical Care Act (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
Drugs, Biologics, and Devices	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Taiwan Food and Drug	MOHW: Medical Care Act (2014): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020021	MOHW: 1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Administration (FDA): http://www.fda.gov.tw/EN/index.aspx	FDA: Pharmaceutical Affairs Act (2015): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0030001	2. Pharmaceutical Affairs Act Enforcement Rules (2012): http://law.moj.gov.tw/Eng//LawClass/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	
Research Injury	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Food and Drug Administration (FDA), MOHW: http://www.fda.gov.tw/EN/index.aspx	Medical Care Act (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	
Social-Behavioral Research	Ministry of Health and Welfare		Exempt Review Categories for Human Research (2012) http://www.mohw.gov.tw/EN/Ministry/	
Privacy/Data Protection	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		
Human Biological Materials	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	1. Regulations on Human Trials (2009): http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162	1. Good Tissue Practice (2002) (Chinese): http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1153&chk=342a5c73-c206-4756-ade9-9c63265c859d&mid=46&name=fdContent 2. Guidelines for Collection and Use of

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Human Biobank Management Act (2012): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020164 3. Medical Care Act (2015): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020021	2. Administrative Regulations on the Establishment of Human Biobanks (2011) http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020173	Human Specimens for Research (2006) (Chinese): http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1598&chk=6056f7dd-eb0a-48bf-ae7e-8a2a5875e6e0&mid=46&name=fdContent
Genetic Research	1. Ministry of Health and Welfare (MOHW): http://www.mohw.gov.tw/EN/Ministry/Index.aspx 2. Food and Drug Administration (FDA): http://www.fda.gov.tw/EN/index.aspx 3. 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
Embryos, Stem Cells, and Cloning	Health Promotion Administration, MOHW: http://www.hpa.gov.tw/BHPNet/English/Index.aspx	Artificial Reproduction Act (2007): http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0070024		
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.				
General	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: https://clinregs.niaid.nih.gov/single_country.php?c_id=213				
General	1. National Research Council of Thailand (NCRT): http://en.nrct.go.th/en/home.aspx 2. Medical Council of Thailand (MCT): http://www.tmc.or.th/en_home.php 3. Forum for Ethical Review	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:	MCT: National Guideline for Ethical Research on Human Subjects (2002) FERCIT: Ethical Guidelines for Research on Human Subject in Thailand (2007):

Country	Key Organizations	Legislation	Regulations	Guidelines
	Committees in Thailand (FERCIT) (Thai): http://www.fercit.org/		Rule of the Medical Council on the Observance of Medical Ethics (1983): http://thailaws.com/law/t_laws/tlaw0510.pdf	http://www.fercit.org/file/Guideline_English_version.pdf
Drugs, Biologics, and Devices	*Drugs*			
	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)
	Devices			
	Food and Drug Administration, Medical Device Control Division: http://www.fda.moph.go.th/eng/medical/pre.stm	1988 Medical Device Act: http://www2.fda.moph.go.th/Exporters/law/Document/Mdc/36-MEDICAL%20DEVICE%20ACT.htm		
Clinical Trials Registry	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
Privacy/Data Protection	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.				
General	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		
Drugs, Biologics, and Devices	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)	
Human Biological	1. Ministry of Health,		1. Guidelines on Conducting	

Country	Key Organizations	Legislation	Regulations	Guidelines
Materials	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		Clinical Trials and Determining Clinical Sites (2001) 2. National Standard of Uzbekistan: Good Clinical Practice (2013)	
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				
General	1. Ministry of Health (MOH): http://www.moh.gov.vn/homebyt/en/portal/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	
Drugs, Biologics, and Devices	Ministry of Health: http://www.moh.gov.vn/homebyt/en/portal/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/NORTH AFRICA				
Egypt				
General	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)	
Drugs, Biologics, and Devices	Egyptian Drug Authority: http://www.eda.mohp.gov.eg/			
Iran				
General	Ministry of Health and Medical Education, Office for the Study of Humanistic and Islamic Science in Medicine and Medical Ethics: http://www.mohme.gov.ir/		Protection Code for Human Subjects in Medical Research (1999)	
Clinical Trials Registry	Iranian Registry of Clinical Trials: http://www.irct.ir/			FAQs: http://www.irct.ir/faq.php
Israel				
General	Ministry of Health: http://www.health.gov.il/english/		Public Health Regulations (Medical Experiments Involving Human Subjects) (1999) (Hebrew)	
Drugs, Biologics, and Devices	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
Privacy/Data Protection	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/ProtectionofPrivacyLaw57411981unofficialtranslatio.pdf 2. Protection of Privacy Law No. 5741, as Amended by Law No. 5745 (1985)		
Genetic Research	Ministry of Health: http://www.health.gov.il/english/	Genetic Information Law (2000) (Hebrew): http://www.moital.gov.il/NR/exeres/66F4DD4E-FA4A-4B76-94BC-DC29543471DE.htm		1. The Instruction of the Supreme Committee for Clinical Studies on Humans Regarding Establishment and Usage of Genetic Samples Reservoir

Country	Key Organizations	Legislation	Regulations	Guidelines
				(2005) 2. Amendment (2007)
Embryos, Stem Cells, and Cloning		Genetic Intervention Prohibition Law (Human Cloning and Genetic Changes in Reproduction Cells) (1999)		
Jordan Note: All documents are in Arabic.				
Drugs, Biologics, and Devices	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) http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/50_211.pdf 2. Drug and Pharmacy Law No. 12 (2013) http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugDirectorate/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D8%AF%D9%88%D8%A7%D8%A1%20%D9%88%D8%A7%D9%84%D8%B5%D9%8A%D8%AF%D9%84%D8%A9.pdf 3. Narcotic and Psychotropic Law No. 23 (2016) http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugsAndPsychotropicSubstances/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D9%85%D8%AE%D8%AF%D8%B1%D8%A7%D8%AA%20%D9%88%D8%A7%D9%84%D9%85%D8%A4%D8%AB%D8%B1%D8%A7%D8%AA%20%D8%A7%D9%84%D8%B9%D9%82%D9%84%D9%8A%D8%A9.pdf		
Research Injury			Regulations for Insurance on Research-Related Injury (2013):	

Country	Key Organizations	Legislation	Regulations	Guidelines
			http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/22_252.pdf	
Embryos, Stem Cells, and Cloning		Stem Cell By-law No. 10 (2014)		
Kuwait				
General	Ministry of Health, Kuwait Institute for Medical Specialization: http://www.kims.org.kw/			Ethical Guidelines for Biomedical Research: http://www.kims.org.kw/Ethical%202.doc
Qatar				
General	Supreme Council of Health: https://www.sch.gov.qa/home-en			Various: https://www.sch.gov.qa/about-sch/departments/research
Saudi Arabia				
General	National Committee of BioEthics: http://bioethics.kacst.edu.sa/?lang=en-US	Law of Ethics of Research on Living Creatures (Arabic): http://bioethics.kacst.edu.sa/getattachment/4bd0d4e2-1b93-4c32-b483-57902227fae2/Bioethic-Rgl-fin-bks.aspx	Implementing Regulations of the Law of Ethics of Research on Living Creatures (2016): http://prod.kau.edu.sa/Med/ali/files/Publications/Guide/National_Committe_of_BioEthics-Regulations_of_the_Law_of_Ethics_of_Research_on_Living_Creatures.pdf	
Social-Behavioral Research	National Committee of BioEthics		Implementing Regulations of the Law of Ethics of Research on Living Creatures, Expedited Research (Article 10.18g) and Categories of social-behavioral research that do not require continuing review (Article 10.32) (2016): http://prod.kau.edu.sa/Med/ali/files/Publications/Guide/National_Committe_of_BioEthics-Regulations_of_the_Law_of_Ethics_of_Research_on_Living_Creatures.pdf	
Sudan				
General	Federal Ministry of Health: http://www.fmoh.gov.sd/			1. National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): http://sites.google.com/site/healthresearchlibrary/national-guidelines 2. National Accreditation Guidelines for Ethics Committees (2016)

Country	Key Organizations	Legislation	Regulations	Guidelines
				3. Operation Guidelines, Functions, and Procedures (2016)
Drugs, Biologics, and Devices	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		
Human Biological Materials	1. Federal Ministry of Health: http://www.fmoh.gov.sd/ 2. National Council on Biosafety	1. Human Organs and Tissues Transplant Legislation, Chapter 2, Articles 3 and 4 (1978) Act on Biosafety (2010)		
Genetic Research	University of Khartoum, Institute of Endemic Diseases: http://iend.uofk.edu/index.php?lang=en			Guidelines for Genetics Research on Sudanese Subjects (2005)
Tunisia				
Drugs, Biologics, and Devices	Ministry of Public Health, Institut Pasteur: www.pasteur.tn		Conditions of Contract and Specifications Related to Medical or Scientific Experimentation of Medicines Intended for Humans	Disposals and Director's Principles Related to Good Practices in Clinical Trials
Clinical Trials Registry	Tanzania Clinical Trial Registry: http://www.tzctr.or.tz/			FAQs: http://www.tzctr.or.tz/faq.php
Turkey For an overview of human subject protections in Turkey, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Turkey%20definitive%20Updated.pdf				
General	Ministry of Health (Turkish): http://www.saglik.gov.tr/	1. Turkish Constitution, Article 17 2. Health Services Basic Law No. 3359 (1987) 3. Oviedo Convention on Human Rights and Biomedicine (2004) 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	1. Regulation on Medical Deontology, Article 11 (1960) 2. Bylaw on Patient Rights No. 23420 (1998)	
Drugs, Biologics, and Devices	*Drugs*			
	1. Turkey Pharmaceuticals and Medical Devices Agency (Turkish) (TITCK): http://www.titck.gov.tr 2. Clinical Research Association (CRA): http://www.klinikarastirmalar.org.tr/en/	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=klinik_mevzuat&lang=tr-TR&thelawtype=1&thelawId=347 2. Regulation on Clinical Trials	CRA: Various: http://www.klinikarastirmalar.org.tr/en/documents.php?dok_cat=0

Country	Key Organizations	Legislation	Regulations	Guidelines
			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	
	Devices			
	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr		Regulation on Research on Medical Devices (2014) (Turkish): http://www.klinikarastirmalar.org.tr/doc/file_318.pdf	
Research Injury	Turkey Pharmaceuticals and Medical Devices Agency (TITCK): http://www.titck.gov.tr	Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2004)		Guidance on Insuring Volunteers in a Clinical Trial (2011)
Human Biological Materials		1. Law on Procurement, Preservation, Grafting, and Transplantation of Organs and Tissues, No. 2238 (1979) 2. Law on Blood and Blood Products, No. 2857 (1983)	Regulation on Blood and Blood Products, No. 7314 (1983)	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999) 2. Good Clinical Practice Guidelines for Advanced Therapy Medicinal Products (2011)
Genetic Research			Regulation on Centers for Diagnosis and Genetic Diseases, No. 23368 (1998)	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14 (1999)
Embryos, Stem Cells, and Cloning			1. Regulation on Centers for Medically Assisted Procreation, No. 19551 (1987) 2. Regulation on Organ and Tissue Transplantation Services (2005) 3. Regulation on Cordon Blood Banks (2005)	1. Circular on Research of Embryonic Stem Cells (2005) 2. Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)

Country	Key Organizations	Legislation	Regulations	Guidelines
United Arab Emirates				
General	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=UL7o8f5mukc%3D&tabid=820

Country	Key Organizations	Legislation	Regulations	Guidelines
LATIN AMERICA and the CARIBBEAN				
Regionwide				
General	Caribbean Public Health Agency: http://carpha.org/What-We-Do/Research-Training-and-Policy-Development			
Drugs, Biologics, and Devices	*Drugs*			
	Pan American Health Organization: http://www.paho.org/			Good Clinical Practices: Document for the Americas (2004): http://www.paho.org/english/ad/ths/ev/GCP-Eng-doct.pdf
	Devices			
	Pan American Health Organization: http://www.paho.org/			A Model Regulatory Program for Medical Devices: An International Guide (2001): http://www.paho.org/English/HSP/HSE/medical_devices.pdf
Argentina Notes: Several provinces have their own regulations pertaining to human subjects research. All websites and documents are in Spanish.				
General	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
Drugs, Biologics, and Devices	*Drugs*			
	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	
	Devices			
	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 Nº 969/97(Including Modifications of Disposition ANMAT Nº 6550/2008)	
Privacy/Data Protection	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				
General	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				
General	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
Drugs, Biologics, and Devices	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				
General	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html		CNS/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 Nº 001/2013: http://conselho.saude.gov.br/arquivos/NO_01-12_english.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			Foreign Cooperation: http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/regulation_res_292_english.doc 3. Resolution CNS No. 304/2000: http://conselho.saude.gov.br/resolucoes/2000/Res304_en.pdf 4. Internal CONEP Regulation (2001) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/aquivos/conep/regimento.doc 5. Resolution CNS No. 301, 16th March 2002: http://conselho.saude.gov.br/resolucoes/2000/Res301_en.pdf 6. Resolution CNS No. 346/2005 on Multicenter Research: http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf 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 8. Resolution CNS No. 446/2011on Composition of the National Commission on Research Ethics: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf 9. Resolution CNS No. 466/2012 on Guidelines and Rules for Research Involving humans Subjects: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf 10. Resolution CNS Nº 506/2016 Accreditation of CEP: http://conselho.saude.gov.br/resolucoes/2016/Reso_506.pdf 11. Operational Rule 001/2013 (Intern Norm): http://conselho.saude.gov.br/web_co	

Country	Key Organizations	Legislation	Regulations	Guidelines
			missoes/conep/aquivos/CNS%20%20Norma%20Operacional%20001%20-%20conep%20finalizada%2030-09.pdf	
Drugs, Biologics, and Devices	*Drugs and Biologics*			
	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. Brazilian Health Surveillance Agency: http://portal.anvisa.gov.br/wps/portal/anvisa-ingles 3. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 4. National Secretary on Science, Technology and Innovation (Portuguese): http:www.saude.gov.br/sctie/	Law Nº 9782/99 Defining the National Health Surveillance System (Portuguese): http://www.planalto.gov.br/ccivil_03/leis/L9782.htm	CNS: 1. Resolution CNS No. 251/1997: On Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests: http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf 2. Resolution CFM Nº 1.885, 2008 (Portuguese): http://www.portalmedico.org.br/resolucoes/cfm/2008/1885_2008.htm 3. Resolution ANVISA 09/15 - Regulations for Clinical Trials with Drugs (Portuguese): https://clinregs.niaid.nih.gov/documents/brazil/ResolutionNo9-English.pdf 4. Resolution RDC No. 9, 20 February 2015 Regarding Regulation for Realization of Clinical Trials of Medication in Brazil: https://clinregs.niaid.nih.gov/documents/brazil/ResolutionNo9-English.pdf	
	Devices			
			Resolution ANVISA 10/15 - Regulations for Clinical Trials with Medical Devices (Portuguese): http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=03/03/2015&jornal=1&pagina=73&totalArquivos=140	
Clinical Trials Registry	Brazilian Clinical Trials Registry: http://www.ensaiosclinicos.gov.br/			FAQs: http://www.ensaiosclinicos.gov.br/assistance/faq/
Research Injury	1. Brazilian Health Surveillance Agency: http://portal.anvisa.gov.br/wps/portal/anvisa-ingles	ANVISA: Law Nº 6360/76 (Portuguese): http://www.planalto.gov.br/ccivil_03/leis/l6360.htm	CNS/CONEP: 1. Standards Survey of New Drugs, Medicines, Vaccines, and Diagnostic Tests Involving	CNS/CONEP: Orientation of Adverse Event Reporting in Clinical Trials (2011) (Portuguese): http://conselho.saude.gov.br/web_comissoes/co

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 3. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html		Human Beings - Resolution CNS No. 251/97 (Portuguese): http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf 2. Resolution CNS No. 346/2005 on Multicenter Research (Portuguese): http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf 3. Resolution MS/CNS No. 466/2012 - Guidelines and Rules for Research Involving Human Subjects: http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf	nep/carta_circular/Informacoes_sobre_o_formulario_para_submissao_de_Eventos_Adversos_Serios_a_CONEP.pdf ANVISA: Manual of Adverse Event Notification and Safety Monitoring in Clinical Trials Involving Medical Devices (2016) (Portuguese): http://portal.anvisa.gov.br/documents/33912/2785629/MANUAL+PARA+NOTIFICA%C3%87%C3%83O+DE+EVENTOS+ADVERSOS+E+MONITORAMENTO+DE+SEGURAN%C3%87A+EM+ENSAIOS+CL%C3%8DNICOS+ENVOLVENDO+DISPOSITIVOS+M%C3%89DICOS+EM+INVESTIGA%C3%87%C3%83O/df22b9ac-688d-4e6a-8207-faf862a05994
Social-Behavioral Research	National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html		Resolution No. 510 of April 7, 2016: http://conselho.saude.gov.br/resolucoes/2016/Reso510.pdf	
Privacy/Data Protection	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 Nº 1.821, 23 November 2007 (Portuguese): http://www.portalmedico.org.br/resolucoes/cfm/2007/1821_2007.htm	
Human Biological Materials	1. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/ 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 3. National Secretary on Science, Technology and Innovation (Portuguese): http:www.saude.gov.br/sctie/	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: 1. Resolution CNS No. 441 of 12 May 2011: http://conselho.saude.gov.br/web_comissoes/conep/aquivos/resolucoes/Resolution441_English_contribuicao_pesquisadora.doc 2. 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	
Genetic Research	1. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 2. National Biosafety Technical	1. Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/12847.html 2. Decree No. 5,591, of	CTNBio: 1. Instruction CTNBio No. 8 of 9 July 1997 (Portuguese): http://www.ctnbio.gov.br/index.php/content/view/11971.html	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/co

Country	Key Organizations	Legislation	Regulations	Guidelines
	Commission (CTNBio) (Portuguese): http://www.ctnbio.gov.br 3. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/	November 22, 2005 (Portuguese): http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/Decreto/D5591.htm	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	nep/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
Embryos, Stem Cells, and Cloning	1. National Biosafety Technical Commission (Portuguese): http://www.ctnbio.gov.br 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/web_comissoes/conep/index.html 3. National Health Council (CNS) (Portuguese): http://www.conselho.saude.gov.br/	1. Biosafety Law 11.105/05 (2005): http://www.ctnbio.gov.br/index.php/content/view/12847.html 2. Decree No. 5,591, of November 22, 2005 (Portuguese): http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/Decreto/D5591.htm	1. Resolution RDC No. 9, 14 March 2011 (Portuguese): http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2011/prt0009_14_03_2011.html 2. Resolution RDC No. 29, 12 May 2008 (Portuguese): http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2008/rdc0029_12_05_2008.html	
Chile Note: All websites and documents are in Spanish.				
General	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 Nº 30/2013 Regulation on Law Nº20.120 Modifying Supreme decree Nº114/2010, 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&	
Drugs, Biologics, and Devices	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):	1. Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.leychile.cl/Navegar?idNorma=1058373	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 Diary of June 25, 2011: http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/ds_minsal_3_2010.pdf 3. Exempt Resolution 2263, July 30th 2015 Modifying Resolution Nº 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	
Research Injury	1. Ministry of Health: http://www.minsal.cl 2. Institute of Public Health: http://www.ispch.cl	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	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 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 3. Resolution No. 441, Notification of Adverse events in Clinical Research in Chile, February13, 2012: http://www.ispch.cl/sites/default/files/res_441.pdf	
Privacy/Data Protection	1. Ministry of Health: http://www.minsal.cl	1. Law for the Protection of Private Life No. 19.628 (1999):	Supreme Decree No. 41 of 2012: Regulation Regarding Clinical	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Ministry of the Secretary General of the Government: http://www.msgg.gob.cl	http://www.bcn.cl/leyes/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	Records of December 15, 2012: http://www.leychile.cl/Navegar?idNorma=1046753	
Genetic Research	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	
Embryos, Stem Cells, and Cloning	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.				
General	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/formatotramite/ASS-RSA-GU040.pdf 2. Guide for Assessing and Monitoring of Research Protocols. Code: ASS-RSA-GU039 Version: 02 (2016): https://www.invima.gov.co/images/stories/formatotramite/ASS-RSA-GU039.pdf
Drugs, Biologics, and Devices	*Drugs*			
	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/sisj	1. ABC Good Clinical Practice (2009) https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/ABCBPCultima_version.pdf 2. Circular No 600-5776-14: Processes of Good Clinical Practice (2014):

Country	Key Organizations	Legislation	Regulations	Guidelines
			ur/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?option=com_content&view=article&id=725:resolucion-no-2011020764-del-10-de-junio-de-2011&catid=58:2011&Itemid=105	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/formatotramite/ASS-RSA-GU045.pdf 4. Guide for the Evaluation and Follow-up of Research Protocols (2016): https://www.invima.gov.co/images/stories/formatotramite/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
	Devices			
	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.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF	
Research Injury	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.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF	
Privacy/Data Protection	Ministry of Health and Social Protection: http://www.minsalud.gov.co	1. Constitution of Colombia, Article 15 (2003): http://www.corteconstitucional.gov.	Scientific, Technical, and Administrative Regulations for Health Research, Resolution No.	

Country	Key Organizations	Legislation	Regulations	Guidelines
		co/inicio/Constitucion%20politica%20de%20Colombia%20-%202015.pdf 2. Law 1581 of 2012: General Regimen of Protection of Personal Data: https://www.mintic.gov.co/portal/604/articles-4274_documento.pdf	008430, Title II, Chapter I, Article 8 (1993)	
Human Biological Materials	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): https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF	
Genetic Research	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.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF	
Costa Rica Note: All websites and documents are in Spanish.				
Drugs, Biologics, and Devices	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

Country	Key Organizations	Legislation	Regulations	Guidelines
Clinical Trials Registry	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.				
Drugs, Biologics, and Devices	Center for State Control of Medications: http://www.cecmed.cu/			Various: http://www.cecmed.cu/ensayos-clinicos/autorizos
Clinical Trials Registry	Public Cuban Registry of Clinical Trials: http://registroclinico.sld.cu/en/home			
Dominica				
General	Ministry of Health: http://www.dominica.gov.dm/cms/index.php?q=node/21			Guidelines for the Conduct of Research on Human Subjects (2005)
Dominican Republic				
General	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	
Biological Materials		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.				
General	Ministry of Public Health : http://www.salud.gob.ec/	1. 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: http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf		National Policy on Scientific Research. Ministerial Agreement 209, Public Registry No. 87 of August 23, 2005
Drugs, Biologics, and Devices	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 for the Approval, Development, Oversight, and Control of Clinical Trials (2017): http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/	

Country	Key Organizations	Legislation	Regulations	Guidelines
			08/Normativa-Ensayos-Cli%CC%81nicos-Registro-Oficial.pdf 2. Regulation for the Approval of Ethics Committees (2014): http://instituciones.msp.gob.ec/images/Documentos/CNBS/1%20normativa/Registro%20Oficial%20Comites%20de%20Etica%20julio%202014.pdf 3. Regulation on Research, Ministerial Agreement No. 0066, Public Registry No. 292 (March 11, 2008): http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/01/A.M.-66-REGLAMENTO-DE-PROYECTOS-EN-INVESTIGACION-DE-SALUD.pdf	
Privacy/Data Protection	Ministry of Public Health: http://www.salud.gob.ec/	Constitution of the Republic of Ecuador 2008 (Article: 92): http://www.asambleanacional.gob.ec/sites/default/files/documents/old/constitucion_de_bolsillo.pdf	Ministerial Agreement No. 005216, Public Registry No. 427, Confidential Information in National Health System (January, 29, 2015): http://instituciones.msp.gob.ec/cz6/images/lotaip/Enero2015/Acuerdo%20Ministerial%205216.pdf	
Biological Materials	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: 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): http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_de_donacion_y_trasplantes.pdf	1. Executive Order 1205, July 13, 2012: Regulation for the Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells: http://www.donaciontrasplante.gob.ec/indot/wp-content/uploads/downloads/2013/11/ley_y_reglamento_a_la_ley_organica_de_donacion_y_trasplantes.pdf 2. Import and Export of Human Biological Samples for research. Ministerial Agreement No. 0088, Public Registry No. 34, (July 12, 2017): http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/08/Acuerdo-Ministerial-0088-	

Country	Key Organizations	Legislation	Regulations	Guidelines
			2017_Autorizaci%C3%B3n-de-importaci%C3%B3n-y-exportaci%C3%B3n-de-muestras-biol%C3%B3gicas.pdf	
Genetic Research	Ministry of Public Health: http://www.salud.gob.ec/	Organic Health Law, December 22, 2006, Articles 209-210 (2011): http://www.vertic.org/media/National%20Legislation/Ecuador/EC_Ley_Organica_de_Salud.pdf		
Embryos, Stem Cells, and Cloning	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				
General	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				
General			Medical Research Involving Human Subjects Regulations (2007)	
Guatemala Note: All websites and documents are in Spanish.				
Drugs, Biologics, and Devices	Ministry of Public Health and Social Assistance: http://www.mspas.gob.gt/		Rules for the Regulation of Human Clinical Trials. Ministerial Accord SP-M-466-2007: http://medicamentos.com.gt/index.php/legislacion-vigente/acuerdos	
Haiti				
General	Ministry of Public Health and Population (French): http://mspp.gouv.ht/newsite/			Internal Regulations (2010) (French)

Country	Key Organizations	Legislation	Regulations	Guidelines
Honduras Note: All websites and documents are in Spanish.				
General	Secretariat of Health: http://www.salud.gob.hn/		Health Code, Decree No. 65-91, Articles 175 and 176	
Human Biological Materials		Law of Donation and Transplantation of Anatomical Organs in Human Beings (2014): http://www.tsc.gob.hn/leyes/Ley_donacion_transp_organos_2014.pdf n. 329-2013		
Jamaica				
General	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/
Drugs, Biologics, and Devices	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.				
General	1. Secretariat of Health: http://www.salud.gob.mx/ 2. General Health Council: www.csg.salud.gob.mx/ 3. National Bioethics Commission (CNB): http://www.conbioetica-mexico.salud.gob.mx/ 4. Federal Commission for Protection Against Health Risks: http://www.cofepris.gob.mx/Paginas/Inicio.aspx	General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2014)	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: 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
Drugs, Biologics, and Devices	Federal Commission for Protection Against Health Risks (COFEPRIS): http://www.cofepris.gob.mx/Paginas/Inicio.aspx	General Health Law, Title V, Chapter I, Articles 96-103: Health Research (2014)	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/Moléculas%20Nuevas/Formatos/CONFIDENCI

Country	Key Organizations	Legislation	Regulations	Guidelines
				ALIDAD%20CMN%20CAS-CAS-P-02-F-02.pdf
Privacy/Data Protection	Federal Institute on Access to Public Information (Spanish): www.ifai.org.mx/	1. Federal Law for the Protection of Personal Data in the Possession of Private Individuals (2010): http://www.diputados.gob.mx/LeyesBiblio/pdf/LFPDPPP.pdf 2. Federal Law on Transparency and Access to Public Information (2017): http://www.diputados.gob.mx/LeyesBiblio/pdf/244_140714.pdf		
Human Biological Materials	Secretariat of Health: http://www.salud.gob.mx/	General Health Law, Title XIV, Articles 313-342 (2005): http://www.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	
Genetic Research	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				
General	1. Ministry of Health (MINSA) (Spanish): http://www.minsa.gob.pa/ 2. ICGES Bioethics Research Committee (CBI): http://www.gorgas.gob.pa/index.php?option=com_content&view=article&id=54&Itemid=103&lang=es		MINSA: 1. Resolution No. 390 Adopting the Operational Guide for Research Bioethics, Official Gazette 24,938 (2003) 2. Executive Decree N°1843 on the National Research Ethics Committee of Panama (2014) (Spanish): https://www.gacetaoficial.gob.pa/.../GacetaNo_27716_20150206.pdf	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
			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	
Drugs, Biologics, and Devices		Law 1 of 2001, Official Gazette 24,218 (Spanish): http://www.perezcarrera.com/leyes/ley-registro-sanitario-panama.pdf		
Privacy/Data Protection		Law 68 of 2003, Official Gazette 24,935		
Human Biological Materials		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		
Embryos, Stem Cells, and Cloning			Executive Decree No. 2 on Stem Cells (2013) (Spanish): http://www.gacetaoficial.gob.pa/pdfTemp/27207/40367.pdf	
Perú For an overview of clinical research regulations in Peru, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=170				
General	National Institute of Health (Spanish): http://www.ins.gob.pe/	General Health Law No. 26842, Article 28 (1997) (Spanish): http://www.wipo.int/wipolex/en/text.jsp?file_id=203140		
Drugs, Biologics, and Devices	1. National Institute of Health (Spanish): http://www.ins.gob.pe/ 2. National Directorate of Drugs and Medical Devices: www.digemid.minsa.gob.pe		Supreme Decree No. 021-2017-SA. Regulation of Clinical Trials (2017) (Spanish): http://busquedas.elperuano.com.pe/download/url/aprueban-reglamento-de-ensayos-clinicos-decreto-supremo-n-021-2017-sa-1538902-2	Various: http://www.ensayosclinicos-repec.ins.gob.pe/otros-repec/216-comunicados
Clinical Trials Registry	Peruvian Registry of Clinical Trials: http://www.ensayosclinicos-repec.ins.gob.pe/en/about-repec/clinical-trial-search		Supreme Decree No. 021-2017-SA. Regulation of Clinical Trials, Title III, Chapter I, Articles 16 - 32 (2017) (Spanish): http://busquedas.elperuano.com.pe/download/url/aprueban-reglamento-de-ensayos-clinicos-decreto-supremo-n-021-2017-sa-1538902-2	
Research Injury	National Institute of Health (Spanish):		Regulation on Clinical Trials in	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.ins.gob.pe/		Peru: Articles 26, 27 and 28 (Spanish): http://www.ins.gob.pe/portal/jerarquia/2/990/reglamento-de-ensayos-clinicos/jer.990	
Privacy/Data Protection	National Directorate of Drugs and Medical Devices: www.digemid.minsa.gob.pe	1. Law 29733 for the Protection of Personal Information: http://www.minjus.gob.pe/legislacion/ 2. Law for Electronic Medical Charts (2013): http://elperuanolegal.blogspot.com/2013/05/ley-30024-ley-que-crea-el-registro.html		
Saint Lucia				
Drugs, Biologics, and Devices		Clinical Trials Act (2016): http://slugovprintery.com/template/files/document_for_sale/laws/3742/Act%2010%20of%202016.pdf		
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.				
General	Ministry of Public Health: http://www.msp.gub.uy/	1. Decree 189/998 http://www.mercosur.int/msweb/Normas/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	
Drugs, Biologics, and Devices	Ministry of Public Health: http://www.msp.gub.uy/	Decree 189/998: http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF		
Research Injury	Ministry of Public Health: http://www.msp.gub.uy/	1. Decree 189/998 http://www.mercosur.int/msweb/No		

Country	Key Organizations	Legislation	Regulations	Guidelines
		rmas/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		
Privacy/Data Protection	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		
Human Biological Materials	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.				
General	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
Drugs, Biologics, and Devices	National Institute of Hygiene "Rafael Rangel": http://www.inhrr.gob.ve/	Medicines Act, Title III, Chapter II: http://www.ginecoweb.com/PDF/Ley-del-Ejercicio-de-la-Medicina.pdf		
Genetic Research	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				
Clinical Trials Registry	Pan African Clinical Trials Registry: http://www.pactr.org/		1. Order No. 387 of July 31, 2006 Regarding Clinical Trials: http://www.ands.dz/pharmacie-med/arr%C3%AAt%C3%A9_n%C2%B0387-388_31_juil_2006.pdf 2. Order No. 00200 of July 25, 2009 Modfying Order No. 112 of October 22, 1995 Establishing Rules on Good Clinical Practice: http://www.ands.dz/pharmacie-med/arr%C3%AAt%C3%A9_n%C2%B0200%20_25_Juil_2009.pdf	FAQs: http://www.pactr.org/ATMWeb/appmanager/atm/atmregistry?_nfpb=true&_pageLabel=atmportal_page_FAQ
Algeria				
Drugs, Biologics, and Devices	Directorate of Pharmacy and Medicine: http://www.ands.dz/		1. Order No. 387 of 31 July 2006 Relating to Clinical Trials: http://www.ands.dz/pharmacie-med/arr%C3%AAt%C3%A9_n%C2%B0387-388_31_juil_2006.pdf 2. Order No. 00200 of 25 July 2009 Amending Order No. 112 of 22 October 1995 Setting the Rules of Good Clinical Practice: http://www.ands.dz/pharmacie-med/arr%C3%AAt%C3%A9_n%C2%B0200%20_25_Juil_2009.pdf	
Benin				
General		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				
General	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. Guide for a Consent Form (2005) 3. Guidelines for the Review of Research Proposals (2005)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs, Biologics, and Devices	Ministry of Health, Drug Regulatory Unit: http://www.moh.gov.bw/		Drugs and Related Substances Regulations (1993)	1. SADC Guidelines for Regulating Clinical Trials in Human Subjects (2006) 2. Guideline for Regulating the Conduct of Clinical Trials Using Medicines in Human Participants (2012): http://www.moh.gov.bw/Publications/drug_regulation/CLINICAL%20TRIAL%20GUIDELINES%20botswana%20v4-060312.pdf
Social-Behavioral Research	Ministry of Health and Wellness, Research and Development Committee	Anthropological Research Act 45 (1967): http://webcache.googleusercontent.com/search?q=cache:A7aea2ZEMhkJ:static1.1.sqspcdn.com/static/f/723732/25889598/1422112465653/ch59-02%2BANTHROPOLOGICAL%2BRESEARCH.pdf%3Ftoken%3DTSMJNydkWHdUJ7iPvvm7Qkzk4uU%253D+&cd=1&hl=en&ct=clnk&gl=us		
Burkina Faso Note: All websites and documents are in French.				
General	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	
Drugs, Biologics, and Devices			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	
Cameroon For an overview of human subject protections in Cameroon, see: http://elearning.trree.org/mod/nationalsupplement/view.php?id=227				
General	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

Country	Key Organizations	Legislation	Regulations	Guidelines
Congo, Democratic Republic of				
General		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.				
Drugs, Biologics, and Devices	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				
General	Ethiopian Science and Technology Commission, Health Department: http://www.most.gov.et/	Proclamation 60/1999, Section 21		National Health Research Ethics Review Guideline, Fourth Edition (2014): http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf
Drugs and Devices	Food, Medicine, and Health Administration and Control Authority: www.fmhaca.gov.et		Drug Administration and Control Proclamation No. 176/1999, Article 21	
Human Biological Materials	Ethiopian Science and Technology Commission, Health Department: http://www.most.gov.et/			National Health Research Ethics Review Guideline, Fourth Edition, Chapter 9 (2005): http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf
Gambia				
Genetic Research	MRC: Gambia Unit: http://www.mrc.gm/			Guidelines of the National DNA Bank (2001)
Ghana For an overview of the clinical trial information in Ghana, see: http://www.fdaghana.gov.gh/index.php?option=com_content&view=article&id=71&Itemid=55				
Drugs, Biologics, and Devices	Food and Drugs Authority: http://www.fdaghana.gov.gh	Public Health Act, 2012	Act 851, Sections 150-166: http://www.fdaghana.gov.gh/images/stories/pdfs/Clinical%20Trials/REGULATION%20OF%20CLINICAL%20TRIALS%20IN%20GHANA.pdf	1. Guidelines for Good Clinical Practice in Ghana (2015): http://www.fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/Clinical%20Trials/GUIDELINES%20ON%20GOOD%20CLINICAL%20PRACTICE%20IN%20GHANA.pdf 2. Guidelines for Authorization of Clinical Trials of Medicines, Food Supplements, Vaccines, and Medical Devices (2015):

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/Clinical%20Trials/GUIDELINES%20FOR%20AUTHORIZATION%20OF%20CLINICAL%20TRIALS%20OF%20MEDICINES,%20GHANA.pdf 3. Guidelines for Conduct of Clinical Trials in Paediatric Population (2016): http://www.fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/Clinical%20Trials/GUIDELINES%20FOR%20CONDUCT%20OF%20CLINICAL%20TRIALS%20WITH%20PAEDIATRIC%20POPULATION%20IN%20GHANA.pdf 4. Guidelines for Conduct of Clinical Trials During Emergencies (2016): http://www.fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/GUIDELINES%20FOR%20TRIALS%20IN%20EMERGENCIES1.pdf
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.				
General	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/
Research Injury	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				
General	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
Drugs, Biologics, and Devices	Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/	Pharmacy and Poisons Act, Chapter 244 (2009):	MOH: Kenya National Guidelines for	Guidelines for Applications to Conduct Clinical Trials in Kenya (2014):

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://apps.who.int/medicinedocs/documents/s18245en/s18245en.pdf	Research and Development of HIV/AIDS Vaccines (2005)	http://pharmacyboardkenya.org/downloads/?file=Clinical%20Trial%20Guidelines%202014.pdf
Human Biological Materials	Ministry of Health (MOH): www.health.go.ke/		Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, page 44 (2005)	
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				
General	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	
Drugs, Biologics, and Devices	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
Madagascar				
Drugs and Devices		Law No. 2011-002, Article 122 Regarding Clinical Trials (French): https://www.ilo.org/dyn/natlex/docs/ELECTRONIC/97799/116199/F1071917999/MDG-97799.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				
General	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):	1. Presidential Decree on 30th March 1974 2. Malawi Government Gazette, June 11, 1976, General Notice No. 398 3. Constitution of Malawi, Article 19(5) (1994)		NCST: 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

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	http://www.medcol.mw/ 4. Ministry of Health: www.malawi.gov.mw			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
Drugs, Biologics, and Devices	Pharmacy, Medicines, and Poisons Board of Malawi	1. Pharmacy, Medicines, and Poisons Act, Act 15 of 1988: http://www.google.com/url?sa=t&rct=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-Y4F7y3eoC6DV0H7Jr77s5Msg 2. Section 42(1) of PMPB Act, 2003 Supplement		
Social-Behavioral Research	National Committee on Research in the Social Sciences and Humanities			Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011): http://www.ncst.mw/wp-content/uploads/2014/03/NATIONAL-FRAMEWORK-OF-GUIDELINES-IN-SSH.pdf
Human Biological Materials	National Commission for Science and Technology: www.ncst.mw		National Regulatory Requirement and Position on Accessing, Collection, Storage, and Use of Human Biological Specimens for Research (2014): https://www.ncst.mw/wp-content/uploads/2014/03/National-regulatory-requirement-on-human-	

Country	Key Organizations	Legislation	Regulations	Guidelines
			samples.pdf	
Genetic Research	National Research Council of Malawi (NRCM): www.sdnp.org.mw/nrcm/		Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002)	
Mali For an overview of human subject protections in Mali, see: https://clinregs.niaid.nih.gov/single_country.php?c_id=132&utm_medium=GovDelivery&utm_source=ClinRegs&utm_campaign=MaliPublication#_top				
Drugs, Biologics, and Devices	Directorate of Pharmacy and Medicine	Law No. 09-059 of 28 December 2009 Governing Biomedical Research on Humans (French): https://clinregs.niaid.nih.gov/documents/LawNo09-059.pdf		
Mozambique For an overview of human subject protections in Mozambique, see: http://elearning.trree.org/course/view.php?id=14&lang=en				
General				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				
General	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/
Drugs, Biologics, and Devices	National Agency for Food, Drug Administration and Control (NAFDAC): http://www.nafdac.gov.ng/	Decree No. 15 of 1993		Good Clinical Practice Guidelines (2016): http://www.nafdac.gov.ng/images/GUIDELINES/DRUG%20GUIDELINES/NAFDAC%20GOOD%20CLINICAL%20PRACTICE%20GUIDELINES%202016%20V%2013.pdf
Clinical Trial Registries	National Health Research Ethics Committee: http://nhrec.net/			Frequently Asked Questions: http://nhrec.net/nctr/FAQ.php
Social-Behavioral Research	National Health Research Ethics Committee			Nigerian Code of Health Research Ethics (2007): http://www.nhrec.net/nhrec/NCHRE_10.pdf
Human Biological Materials	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				
General	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				
General	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				
General	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
Drugs, Biologics, and Devices	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 2. Guideline for Conducting Clinical Trials: http://pharmacyboard.gov.sl/site/LinkClick.aspx?fileticket=YrGQkXzfLP8%3d&tabid=316&portalid=1&mid=934&forcedownload=true 3.	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				
General	1. Department of Health (DH): http://www.doh.gov.za 2. National Health Research Ethics Council: http://www.nhrec.org.za/ 3. Medical Research Council of South Africa (MRC): http://www.mrc.ac.za 4. Human Sciences Research Council (HSRC): http://www.hsrc.ac.za/index.phtml	1. Constitution of South Africa, Section 12 (2) (1996) 2. National Health Act No. 61, Chapter 9 (2003): http://www.saflii.org/za/legis/consol_act/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-notices/61-of-2003-national-health-act-regs-gnr-719-19-sept-2014-to-date-pdf/download&rct=j&frm=1&q=&esrc=s&sa=U&ei=W6UtVOOvLa6S7Aa34YDwAg&ved=0CBUQFjAA&usg=AFQjCNFpKA9W0jNyeWhk0n0l0Q-WxazBtg	DH: Ethics in Health Research: Principles, Structures, and Processes (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)
Drugs, Biologics, and Devices	1. Department of Health (DH): http://www.doh.gov.za 2. Medicines Control Council: http://www.mccza.com	Medicines and Related Substances Control Act, 101 of 1965 http://www.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
Clinical Trials Registry	South African National Clinical Trials Register: http://www.sanctr.gov.za/			FAQs: http://www.sanctr.gov.za/InvestigatorbrnbspInformation/FAQ/tabid/200/Default.aspx
Social-Behavioral Research	Department of Health			Ethics in Health Research: Principles, Processes, and Structures, Section 3.3.7(i) (2015): http://www.commerce.uct.ac.za/Downloads/Ethics%20in%20Health%20Research%20Final%20A%20used.pdf
Human Biological Materials	Department of Health (DH): http://www.doh.gov.za	National Health Act No. 61, Chapter 8, Sections 53-68 (2003): http://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	

Country	Key Organizations	Legislation	Regulations	Guidelines
			2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf 4. Regulations Relating to Artificial Insemination of Persons, 2 March 2012: http://www.sashg.org/documents/GovGazette2Mar2012.pdf	
Genetic Research	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za			Guidelines on Ethics in Reproductive Biology and Genetic Research (2002): http://www.sahealthinfo.org/ethics/book2.htm
Embryos, Stem Cells, and Cloning	Medical Research Council of South Africa (MRC): http://www.mrc.ac.za	National Health Act No. 61, Chapter 8, Section 57 (2003): http://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
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				
General	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)
Drugs, Biologics, and Devices	*Drugs*			
	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003): http://www.tfda.or.tz/index.php?option=com_phocadownload&view=category&download=44:tfdc-acts-2003&id=52:tfdc-acts-2003&Itemid=417		
	Devices			
	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Medical Device Act (1988)		

Country	Key Organizations	Legislation	Regulations	Guidelines
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				
General	Uganda National Council for Science and Technology (UNCST): http://www.uncst.go.ug/	Uganda National Council for Science and Technology Act (CAP 209)		National Guidelines for Research Involving Humans as Research Participants (2014): http://www.uncst.go.ug/dmdocuments/Human%20Subjects%20Protection%20Guidelines%20July%202014.pdf
Drugs, Biologics, and Devices	National Drug Authority: http://www.nda.or.ug/	National Drug Policy and Authority Act (CAP 206) (1993)		
Zambia				
General	Ministry of Health: http://www.moh.gov.zm/	National Health Research Act (2013): http://www.parliament.gov.zm/sites/default/files/documents/acts/Health%20%20Research%20%20Act%202013.pdf		
Drugs, Biologics, and Devices	Zambia Medicines Regulatory Authority: http://www.zamra.co.zm/	Medicines and Allied Substances Act, Part VI: Regulation of Clinical Trials, 2013: http://www.zamra.co.zm/wp-content/uploads/2016/10/MASA-No-3-2013.pdf		Guidelines on Regulating the Conduct of Clinical Trials in Human Participants: http://www.zamra.co.zm/wp-content/uploads/2016/10/Guidelines-on-Application-for-Clincal-Trial-Authorisation.pdf
Human Biological Materials		National Health Research Act, Part VI (2013): http://www.parliament.gov.zm/sites/default/files/documents/acts/Health%20%20Research%20%20Act%202013.pdf		
Zimbabwe				
General	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/
Drugs, Biologics, and Devices	*Drugs*			
	Medicines Control Authority of Zimbabwe: http://www.mcaz.co.zw/	Medicines and Allied Substances Control Act, Chapter 15:03 (1997)	1. Medicines and Allied Substances Control Act, General Regulations (1991) 2. Statutory Instrument 150 of 1991	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): http://www.mcaz.co.zw/index.php/downloads/file/114-pharmacy-guidelines-for-investigational-drugs-draft-1
	Devices			

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

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