International Compilation of Human Research Standards

2017 Edition

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

PURPOSE

The International Compilation of Human Research Standards enumerates over 1,000 laws, regulations, and guidelines that govern human subjects research in 126 countries, as well as standards from a number of international and regional organizations. This Compilation was developed for use by researchers, IRBs/Research Ethics Committees, sponsors, and others who are involved in human subjects research around the world.

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

ORGANIZATION

The Table of Contents is on pages 3-4. For each country, the standards are categorized by row as:

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

These eight categories often overlap, so it may be necessary to review the other standards to obtain an accurate understanding of the country's requirements.

The information is then organized into four columns:

1. Key Organizations – include those groups that issue regulations or guidelines, or serve in a national oversight role for human subjects research.
2. Legislation – encompasses statutes, statutory instruments, and legislative decrees, as well as any pertinent constitutional provisions.
3. Regulations – refer to instruments that are created and issued in the name of governmental administrative bodies.
4. Guidelines – pertain to non-binding instruments.

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

HOW TO ACCESS A DOCUMENT

Documents can be accessed in four possible ways:

1. Link to the web address (URL).
2. Search for a document at the website of the agency listed in the Key Organizations column.
3. Perform an Internet search on the document title.
4. Request a local research ethics committee to provide the document.

In many cases the documents are available in English. Sometimes the English translation is a non-official version. When the citation links to a non-English document, the language is indicated in parenthesis, e.g., (Spanish).

TOPICS NOT COVERED

In order to focus its scope, the International Compilation of Human Research Standards does not include standards from the state, provincial, or local levels. Nor does the Compilation cover:

1. Enabling legislation, i.e., laws that authorize an agency to promulgate human subjects standards, but do not direct the content of those regulations.
2. Laws, regulations, or guidelines specific to research integrity, clinical bioethics, product liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, or informed consent in clinical practice.
3. Ethics codes of academic, medical, or other professional organizations – see the Ethics Codes Collection: http://ethics.iit.edu/ecodes/about
4. Working papers, drafts, commentaries, or discussion papers.

NEW STANDARDS, UPDATES, AND BROKEN LINKS

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

DISCLAIMER

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new standards are issued on a continuing basis, this Compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to human subject protections. While in-country persons have been requested to review listings to assure their accuracy and completeness, researchers and other individuals should check with local authorities and/or research ethics committees before commencing research activities.

TABLE OF CONTENTS

INTERNATIONAL 5

NORTH AMERICA 10

Canada 10
United States 12

EUROPE 19

Regionwide 19
Armenia 24
Austria 25
Belarus 26
Belgium 28
Bosnia and Herzegovina 30
Bulgaria 33
Croatia 35
Cyprus 37
Czech Republic 38
Denmark 39
Estonia 41
Finland 42
France 44
Georgia 45
Germany 46
Greece 49
Hungary 52
Iceland 54
Ireland 56
Italy 57
Latvia 59
Lithuania 61
Luxembourg 65
Macedonia 66
Malta 69
Moldova 71
Montenegro 72
Netherlands 74
Norway 75
Poland 77
Portugal 79
Romania 80
Russia 82
San Marino 84
Serbia 84
Slovakia 85
Slovenia 86
Spain 89
Sweden 92
Switzerland 94
Ukraine 98
United Kingdom 100

ASIA/PACIFIC 106

Australia 106
Bangladesh 109
Burma (Myanmar) 109
China, People's Republic of 109
India 112
Indonesia 115
Japan 115
Kazakhstan 117
Korea 118
Kyrgyzstan 121
Malaysia 122
Nepal 122
New Zealand 123
Pakistan 125
Philippines 125
Singapore 128
Sri Lanka 130
Taiwan 131
Tajikistan 133
Thailand 133
Uzbekistan 134
Vietnam 135

MIDDLE EAST 136

Egypt 136
Iran 136
Israel 136
Jordan 137
Kuwait 137
Qatar 137
Saudi Arabia 137
Turkey 137
United Arab Emirates 139

LATIN AMERICA AND THE CARIBBEAN 140

Regionwide 140
Argentina 140
Barbados 141
Bolivia 141
Brazil 141
Chile 145
Colombia 147
Costa Rica 149
Cuba 149
Dominica 150
Ecuador 150
Grenada 151
Guatemala 151
Haiti 151
Honduras 152
Jamaica 152
México 152
Panamá 153
Perú 154
Trinidad and Tobago 155
Uruguay 155
Venezuela 156

AFRICA 157

Regionwide 157
Benin 157
Botswana 157
Burkina Faso 157
Cameroon 158
Congo, Democratic Republic of 158
Côte-d'Ivoire 158
Ethiopia 158
Gambia 158
Ghana 159
Guinea 159
Kenya 159
Liberia 160
Malawi 160
Mozambique 161

Nigeria 161
Rwanda 162
Senegal 162
Sierra Leone 162
South Africa 163
Sudan 164
Tanzania 164
Tunisia 165
Uganda 165
Zambia 165
Zimbabwe 165

Country	Key Organizations	Legislation	Regulations	Guidelines
INTERNATIONAL				
General	Council for International Organizations of Medical Sciences (CIOMS): http://www.cioms.ch/			1. International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002): http://www.cioms.ch/publications/layout_guide2002.pdf 2. International Guidelines for Ethical Review of Epidemiological Studies (2009): http://www.ufrgs.br/bioetica/cioms2008.pdf
	World Medical Association: http://www.wma.net/e/			Declaration of Helsinki (2013): http://www.wma.net/en/30publications/10policies/b3/index.html
	World Health Organization: http://www.who.int/en/			1. Operational Guidelines for Ethics Committees that Review Biomedical Research (2000): http://whqlibdoc.who.int/hq/2000/TDR_PRD_ETHICS_2000.1.pdf 2. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011): http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf 3. Ethical Issues in Patient Safety Research: Interpreting Existing Guidance (2013): http://apps.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf
	United Nations Educational, Scientific, and Cultural Organization, Bioethics Program (UNESCO): http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html			Universal Declaration on Bioethics and Human Rights (2005): http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html
	UNAIDS: http://www.unaids.org/			1. Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials (2011): http://www.unaids.org/sites/default/files/media_asset/JC1853_GPP_Guidelines_2011_en_0.pdf 2. Ethical Considerations in Biomedical HIV Prevention Trials (2012): http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399_ethical_considerations_en.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
	Office of the United Nations High Commissioner for Human Rights (OHCHR): http://www.ohchr.org/english/	International Covenant on Civil and Political Rights, Article 7 (1976): http://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx		
	International Committee of the Red Cross (ICRC): www.icrc.org	1. Geneva Convention Relative to the Treatment of Prisoners of War, Articles 13 and 130 (1950): https://www.icrc.org/applic/ihl/ihl.nsf/7c4d08d9b287a42141256739003e636b/6fef854a3517b75ac125641e004a9e68 2. Additional Protocol I Relating to the Protection of Victims of International Armed Conflicts, Article 11 (1977): http://www.icrc.org/ihl.nsf/7c4d08d9b287a42141256739003e636b/f6c8b9fee14a77fdc125641e0052b079		
Drugs and Devices	*Drugs*			
	International Conference on Harmonization (ICH): http://www.ich.org/			E6 Good Clinical Practice: Consolidated Guidance (1996): http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
	World Health Organization (WHO): http://www.who.int/en/			1. Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation (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 Archived Documents from the Global Harmonization Task Force (GHTF),

Country	Key Organizations	Legislation	Regulations	Guidelines
				replaced by the IMDRF in 2012: 1. Reportable Events During Pre-Market Clinical Investigations (2012) 2. Clinical Evaluation (2007) 3. Clinical Evidence – Key Definitions and Concepts (2007) 4. Post-Market Clinical Follow-Up Studies (2010) 5. Clinical Investigations (2010) 6. Clinical Evidence for IVD Medical Devices (2012) 7. Scientific Validity Determination and Performance Evaluation (2012) 8. Clinical Performance Studies for IVD Medical Devices (2012) Access: http://www.imdrf.org/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/			E6 Good Clinical Practice: Consolidated Guidance, Section 5.8 (1996): http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html

Country	Key Organizations	Legislation	Regulations	Guidelines
	Council for International Organizations of Medical Sciences: http://www.cioms.ch/			International Ethical Guidelines for Biomedical Research Involving Human Subjects, Guideline 19 (2002): http://www.cioms.ch/publications/layout_guide2002.pdf
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-international.org/img/dna_1998.pdf 3. Statement on Gene Therapy Research (2001): http://www.hugo-international.org/img/gene_2001.pdf 4. Statement on Human Genomic Databases (2002): http://www.hugo-international.org/img/genomic_2002.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
	UNESCO Bioethics Program: http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html			1. Universal Declaration on the Human Genome and Human Rights Section 16 of III Programme for 1998-1999 (1997): http://unesdoc.unesco.org/images/0011/001102/110220e.pdf#page=47 2. International Declaration on Human Genetic Data: Section 22 of Major Programme III – Social and Human Sciences (2003): http://unesdoc.unesco.org/images/0013/001331/133171e.pdf#page=45
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 and Devices	*Drugs*			
	1. Health Canada, Therapeutic Products Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index		1. Good Clinical Practice Consolidated Guideline (2004): http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/e6-eng.pdf 2. Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials) (2001): http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/1024-eng.pdf	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 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	Health Canada Clinical Trial Database: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdonclin/index-eng.php			Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 11.3 (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-

Country	Key Organizations	Legislation	Regulations	Guidelines
				chapitre11/
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/
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 Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 13: Human Genetic Research (2014): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter13-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	PRE: Tri-Council Policy Statement: Ethical

Country	Key Organizations	Legislation	Regulations	Guidelines
			(2007): http://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-137/index.html	Conduct for Research Involving Humans, 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), 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): http://www.afm.ars.usda.gov/ppweb/PDF/605-1.pdf
	Department of Commerce: www.commerce.gov/		15 CFR 27	
	Department of Defense, Human and Animal RDT&E Protection Programs: http://www.acq.osd.mil/rd/hptb/programs/regulatory/	United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects	1. 32 CFR 219, Subpart A 2. DoDI 3216.02 (2011): http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf	
	Department of Education: www.ed.gov/	1. Protection of Pupil Rights Amendment (1974) 2. Family Educational Rights and Privacy Act (1974)	1. 34 CFR 97 subparts A (1991) and D (1997) 2. 34 CFR 98 (1984) 3. 34 CFR 99 (2000) 4. 34 CFR 350.4(c) (1991) 5. 34 CFR 356.3(c) (1991)	
	Department of Energy: http://science.energy.gov/ber/human-subjects/		1. 10 CFR 745 (1991), Subpart A 2. DOE Order 443.1B 3. DOE Order 481.1	

Country	Key Organizations	Legislation	Regulations	Guidelines
	Department of Health and Human Services, Office for Human Research Protections: www.hhs.gov/ohrp/	Public Health Service Act (1993): http://history.nih.gov/research/downloads/PL103-43.pdf	45 CFR 46, Subparts A, B, C, D, and E: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html	Various: http://www.hhs.gov/ohrp/regulations-and-policy/
	Department of Homeland Security: www.dhs.gov/	Public Law 108-458, Section 8306	1. 45 CFR 46, Subparts A-D 2. DHS Directive 026-04, Human Subjects Research (2007): https://www.dhs.gov/xlibrary/assets/foia/mgmt-directive-026-04-protection-of-human-subjects.pdf	
	Department of Housing and Urban Development: www.hud.gov/		24 CFR 60.101	
	1. Department of Justice Office of Justice Programs: http://ojp.gov/ 2. Bureau of Prisons: www.bop.gov		1. 28 CFR 22 Privacy Regulation (1976): http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr22_main_02.tpl 2. 42 U.S.C. § 3789g Confidentiality of Information (1984) http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap46-subchapVIII-sec3789g.htm 3. 28 CFR 46 (1991), Subpart A: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr46_main_02.tpl	
	Department of Transportation: www.dot.gov/		49 CFR 11, Subpart A	
	Department of Veterans Affairs: 1. Office of Research Oversight (ORO): http://www1.va.gov/oro/ 2. Office of Research and Development: www.research.va.gov		1. 38 FR 16 (1991), Subpart A 2. 38 CFR 17.85 (1998)	
	Environmental Protection Agency, Program in Human Research Ethics: https://www.epa.gov/osa/basic-information-about-human-subjects-research-0		40 CFR 26 1. Subpart A: Common Rule 2. Subpart B: Prohibition of Intentional Exposure Research Conducted or Supported by EPA in Children and Pregnant or Nursing Women (2006) 3. Subpart C: Additional Protections for Observational Research Conducted or	Scientific and Ethical Approaches for Observational Exposure Studies (2008): http://www.epa.gov/nerl/sots/SEAOES_doc20080707.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
			Supported by EPA in Pregnant Women and Fetuses (2006) 4. Subpart D: Additional Protections for Observational Research Conducted or Supported by EPA in Children (2006) 5. Subpart K: Regulation of Third-Party Intentional Exposure Research for Pesticides in Non-Pregnant, Non-Nursing Adults (2013) 6. Subpart L: Prohibition of Third-Party Intentional Exposure Research for Pesticides in Children and Pregnant or Nursing Women (2013)	
	National Aeronautics and Space Administration: www.nasa.gov/		14 CFR 1230, Subpart A	
	National Science Foundation: www.nsf.gov/		45 CFR 690, Subpart A	
	Social Security Administration: http://www.ssa.gov/		45 CFR 46, Subpart A: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html	
Drugs and Devices	*Drugs*			
	Food and Drug Administration: http://www.fda.gov/Drugs/default.htm	1. Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (2012): http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm 2. Public Health Service Act, 42 USC Section 262 (1998): http://www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm	1. 21 CFR 50 (2011) 2. 21 CFR 312 (2011) 3. 21 CFR 56 (2009) 4. 21 CFR 314 (2011)	1. General: Good Clinical Practice and Human Subject Protections in FDA-Regulated Clinical Trials: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm Other: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
	Devices			
	Food and Drug Administration, Center for Devices and Radiological Health: http://www.fda.gov/MedicalDevices/default.htm	Food, Drug, and Cosmetic Act, 21 USC Section 360 (2012): http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm	1. 21 CFR 50 (2011) 2. 21 CFR 56 (2011) 3. 21 CFR 807, Subpart E (2010) 4. 21 CFR 812 (2010) 5. 21 CFR 814 (2014)	1. Good Clinical Practice and Human Subject Protections in FDA-Regulated Clinical Trials: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm Other: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/def

Country	Key Organizations	Legislation	Regulations	Guidelines
				ault.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): http://www.fda.gov/RegulatoryInformation/Legislation/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		Food and Drug Administration: Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions: 2002: http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126838.pdf
	National Institutes of Health ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/home		1. Clinical Trials Regulation and Results Information Submission, 42 CFR 11 (2016): https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission 2. NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (2016): https://www.federalregister.gov/documents/2016/09/21/2016-22379/dissemination-of-nih-funded-clinical-trial-information	FAQs on ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/manage-recs/faq
	Department of Veterans Affairs: 1. Office of Research Oversight (ORO): http://www1.va.gov/oro/ 2. Office of Research and Development: www.research.va.gov			FAQ: http://www.research.va.gov/resources/ORD_Admin/clinical_trials/registration-faq.pdf
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)	

Country	Key Organizations	Legislation	Regulations	Guidelines
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): http://www.hhs.gov/hipaa/for-professionals/special-topics/HITECH-act-enforcement-interim-final-rule/index.html	1. HIPAA Privacy Rule: Standards for Privacy of Individually Identifiable Health Information, Final Rule, 45 CFR parts 160 and 164 (2002): http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html 2. HIPAA Security Rule, 45 CFR parts 160, 162, and 164: http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html 3. HIPAA Breach Notification Rule, 45 CFR §§164.400-414: http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html	NIH: Various: http://privacyruleandresearch.nih.gov/
	Department of Homeland Security: www.dhs.gov/	Public Law 107-347: https://www.gpo.gov/fdsys/pkg/PLAW-107publ347/pdf/PLAW-107publ347.pdf		
	Social Security Administration: http://www.ssa.gov/	Privacy Act (1974): http://www.hhs.gov/foia/privacy/index.html		
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:			1. Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable (2006): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078384.htm 2. In Vitro Diagnostic (IVD) Device Studies - Frequently Asked Questions (2010) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDoc

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.fda.gov/BiologicsBloodVaccines/default.htm			uments/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 Biotechnology Activities: http://www4.od.nih.gov/oba/	1. Research on Transplantation of Fetal Tissue, Public Law 103-43 (1993): http://www.hhs.gov/ohrp/regulations-and-policy/guidance/public-law-103-43/index.html 2. Genetic Information Nondiscrimination Act (2008): https://www.gpo.gov/fdsys/pkg/PLAW-110publ233/content-detail.html		OHRP: Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (2009): http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html NIH: NIH Guidelines for Research Involving Recombinant DNA Molecules, Appendix M (2009): http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc446948489
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

Country	Key Organizations	Legislation	Regulations	Guidelines
	National Institutes of Health: http://stemcells.nih.gov/	Research on Transplantation of Fetal Tissue. Public Law 103-43 (1993): https://history.nih.gov/research/downloads/PL103-43.pdf		1. Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Executive Order 13505 (2009): https://www.whitehouse.gov/the-press-office/removing-barriers-responsible-scientific-research-involving-human-stem-cells 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 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 Down Principles and Detailed Guidelines for Good Clinical Practice as Regards Investigational Medicinal		EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/health/documents/eudralex/vol-10/

Country	Key Organizations	Legislation	Regulations	Guidelines
		Products for Human Use, as Well as the Requirements for Authorization of the Manufacturing or Importation of Such Products: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2005_28/dir_2005_28_en.pdf 3. Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: http://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) 2. Reflection Paper on Ethical and GCP Aspects of Clinical Trials of Medicinal Products for Human Use Conducted Outside of the EU/EEA and Submitted in Marketing Authorization Applications to the EU Regulatory Authorities (2012): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/04/WC500125437.pdf 3. Questions and Answers on the European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use (2014): http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/10/news_detail_002181.jsp&mid=WC0b01ac058004d5c1#
	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		Various: http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
		Devices (IVD): https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en 3. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 Amending Council Directive 90/385/EEC on Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007L0047&from=EN		
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 Health and Food Safety: http://ec.europa.eu/health/index_en.htm	1. Clinical Trials Directive 2001/20/EC: http://ec.europa.eu/health/human-use/clinical-trials/directive/index_en.htm 2. Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf		
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics			1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, Article 13, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/

Country	Key Organizations	Legislation	Regulations	Guidelines
				2007&CL=ENG
Privacy/Data Protection	European Commission: Directorate-General for Justice and Consumers: http://ec.europa.eu/justice/mission/index_en.htm	1. Data Protection Directive 95/46/EC of the European Parliament and of the Council (1995): http://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf 2. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation): http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN		
	Council of Europe: Data Protection and Cybercrime Division: http://www.coe.int/t/dghl/standardsetting/dataprotection/default_EN.asp			1. Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=108&CL=ENG 2. Recommendation No. R (97) 5 on the Protection of Medical Data (1997): https://wcd.coe.int/ViewDoc.jsp?id=571075&Site=CM&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383 3. Article 29 Working Party Documentation: http://ec.europa.eu/justice/data-protection/article-29/index_en.htm
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		Ethical Aspects of Human Tissue Banking (1998)

Country	Key Organizations	Legislation	Regulations	Guidelines
	Council of Europe, Bioethics Unit: http://www.coe.int/bioethics			1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 2. Recommendation Rec (2006) 4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin (2006): http://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75
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. Recommendation No. R (92) on Genetic Testing and Screening for Health Care Purposes (1992): http://wcd.coe.int/ViewDoc.jsp?id=612007&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG 3. Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG 4. Recommendation Rec (2006)4 of the Committee of Ministers to Members States on Research on Biological

Country	Key Organizations	Legislation	Regulations	Guidelines
				Materials of Human Origin (2006): http://wcd.coe.int/ViewDoc.jsp?id=977859&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75
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
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 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		

Country	Key Organizations	Legislation	Regulations	Guidelines
		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 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			
	Same as Drugs.	Medical Devices Act (2014) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003		Various (German): http://www.basg.at/medizinprodukte/formulare/klinische-pruefung/
Research Injury	1. Austrian Agency for Health and Food Safety: http://www.ages.at/ages/en/ages-austrian-agency-for-health-and-food-safety/ 2. Austrian Federal Office for Safety in Health Care: http://www.basg.at/en/austrian-federal-office-for-safety-in-health-care/	1. Austrian Drug Law, Article 32 (2013) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True 2. Austrian Medical Devices Law, Article 47 (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen		

Country	Key Organizations	Legislation	Regulations	Guidelines
		&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/default.aspx	Gene Technology Act (2012) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826&ShowPrintPreview=True		
Embryos, Stem Cells, and Cloning	1. Ministry of Health (German): http://www.bmg.gv.at 2. Bioethics Commission: http://www.bundeskanzleramt.at/site/3575/default.aspx	Reproductive Medicine Act (2010) (German): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10003046&ShowPrintPreview=True		Bioethics Commission: 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,	MOH: 1. Ordinance No. 274 on Establishing the National Bioethics Committee (2006) 2. Decree No. No. 55 on Ethics Committees (2008) (Russian):	MOH: 1. Code of Medical Ethics (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37726.html 2. Guidelines for Ethics Committees on

Country	Key Organizations	Legislation	Regulations	Guidelines
		Articles 40, 46 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435	http://www.levonevski.net/pravo/norm2009/num05/d05639.html	Standard Operational Proceedings (No. 55-0004, 2000) (Russian): http://www.levonevski.net/pravo/norm2009/num35/d35896/index.html 3. Methodological Guidelines of Health Ministry (2000)
Drugs and Devices	*Drugs*			
	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. State Pharmacological Committee 3. Centre for Expertise and Testing in Health Care (Russian): http://rceth.by/	1. Law on Health Care System, Article 40 (2010) (Russian): http://pravo.by/webnpa/text.asp?RN=v19302435 2. Law on Drugs, Articles 15,16 (2009) (Russian): http://pravo.by/webnpa/text.asp?RN=h10600161	MOH: 1. Ordinance No. 254 on Clinical Drug Trials and Good Clinical Practice (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num36/d36922/index.html 2. Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999) (Russian): http://www.levonevski.net/pravo/norm2009/num37/d37336.html 3. Decree No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html 4. Decree No. 50 on Certain Aspects of Clinical Drug Trials (2009)	MOH: Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004) (Russian): http://www.levonevski.net/pravo/norm2009/num24/d24926.html
	Devices			
	1. Ministry of Health (MOH): http://minzdrav.by/en/ 2. Centre for Expertise and Testing in Health Care (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_p	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
			rikazmz/N216_2008.htm	
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): http://www.health.belgium.be/en	Law Relating to Experimentation on Humans (2004): http://www.erasme.ulb.ac.be/page.asp?id=11365&langue=EN		BACB: 1. Opinion No. 13: Regarding Experimentation on Man (2001) 2. Opinion No. 31: Regarding Experimentation Involving Pregnant and Breastfeeding Women (2004) 3. Opinion 36: Ethical Evaluation of Research in Certain Areas of the Humanities (French and Dutch) (2006) 4. Opinion No. 40: Scope of the Law Relating to Experimentation on Humans (French and Dutch) (2007) 5. Opinion No. 51: Publication of the Results of Human Experimentation (2012) Access: http://www.health.belgium.be/en/belgian-advisory-committee-bioethics

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs 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)		
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		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

Country	Key Organizations	Legislation	Regulations	Guidelines
		Transplantation of Organs (2006) 4. 2007 Amendment		CSS: Various: http://www.health.belgium.be/eportal/Aboutus/relatedinstitutions/SuperiorHealthCouncil/domains/cellstissuesorgans/index.htm#.Viovr88XQ0U
Embryos, Stem Cells, and Cloning	1. Federal Public Service: www.health.fgov.be 2. Federal Commission for Medical and Scientific Research on Embryos in Vitro: http://health.belgium.be/eportal/Healthcare/Consultativebodies/Commissions/Embryoinvitro/19076630?ie2Term=research&ie2section=83	1. Royal Decree Fixing the Criteria for the Program Applicable to the Care Programs 'Reproductive Medicine' (15/02/1999) 2. Act on Research on Embryos in Vitro (2003): http://www.eshre.com/ESHRE/English/Legal-Matters-and-Guidelines/Legal-documentation/Belgium/page.aspx/164 3. Law on Medically Assisted Reproduction and the Destination of Supernumerary Embryos and Gametes (2007) (French): http://www.staatsbladclip.be/lois/2007/07/17/loi-2007023090.html		Belgian Advisory Committee on Bioethics: Opinion No. 52: Use of Human Tissues and Cells in Reproductive Medicine (2012): http://www.health.belgium.be/en/opinion-no-52-use-human-tissues-and-cells-reproductive-medicine
Bosnia and Herzegovina Note: All websites and documents are in Bosnian.				
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/		

Country	Key Organizations	Legislation	Regulations	Guidelines
		zakoni-i-strategije/zakoni/zakon-o-zdravstvenoj-zastiti		
Drugs and Devices	*Federation of Bosnia and Herzegovina*			
	1. Ministry of Health: http://www.fmoh.gov.ba/ 2. Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Law on Drugs No. 58/08: http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf 2. Law on Changes and Amendments of the Law on Drugs No. 29/05: http://www.almbih.gov.ba/_doc/regulative/fbih/Zakon_o_lijekovima-sluzbene_novine_FBiH_broj_29-05.pdf 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	
	Republic of Srpska			
	1. Ministry of Health and Social Welfare (Bosnian): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx 2. Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Law on Drugs No. 58/08: http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf 2. Law on Changes and Amendments of Law on Drugs No. 34/08: http://www.almbih.gov.ba/_doc/regulative/rs/ID_Zakona_o_lijekovima_34_08.pdf	1. Regulation about Clinical testing of IMP and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf 2. Regulation about Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_ms_bos.pdf 3. Standards of GCP in Conducting CTs (2012): http://www.almbih.gov.ba/_doc/regulative/Smjernice_dobre_klinicke_prakse-bo.pdf	
Research Injury	*Federation of Bosnia and Herzegovina*			
	Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/	1. Medicinal Products and Medicinal Devices Act, Articles 52 and 116 2. Law on Health Insurance of the Federation of Bosnia and Herzegovina, Official Gazette No. 46/10	Regulation about Clinical Testing of IMP and Medical Devices, 4/10: http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf	
	Republic of Srpska			
	Ministry of Health and Social Welfare (Bosnian):	1. Medicinal Products and Medicinal Devices Act, Article	Regulation about Clinical Testing of IMP and Medical Devices,	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/OMin/Pages/Splash.aspx	52 and 116 2. Law on Health Insurance of the Republic of Srpska, Official Gazette Republic of Srpska No. 106/09: http://www.farmaceutska-komora.org/images/stories/5Zakon_o_zdravstvenoj_zastiti.pdf	4/10: http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf	
Privacy/Data Protection	Personal Data Protection Agency of Bosnia and Herzegovina: http://www.azlp.gov.ba/Default.aspx?langTag=en-US&template_id=147&pageIndex=1	1. Law on the Protection of Personal Data in Bosnia and Herzegovina (2001): http://www.azlp.gov.ba/images/PropisiBOS/Zakon_o_%20zastiti_licnih_podataka_u_BiH_BOS.pdf 2. Law about Amendments of Law on the Protection of Personal Data in Bosnia and Herzegovina, Official Gazette of Bosnia and Herzegovina No. 76/11	Regulation about Personal Data Collection and Form of Records (2009): http://www.azlp.gov.ba/images/PropisiBOS/Pravilnik_vodjenje_i_obrazac_BOS.pdf	
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/Doc		Rulebook about Testing Procedure for Donor of Transplant Organs in Terms of Diseases Which can be Transmitted by Transplantation (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/%d0%9f%d1%80%d0%b0%d0%b2%d0%b8%d0%bb%d0%bd%d0%b8%d0%ba_%d0%be_%d0%ba%d1%80%d0%b8%d1%82%d0%b5%d1%80%d0%b8%d1%98%d1%83%d0%bc%d0%

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

Country	Key Organizations	Legislation	Regulations	Guidelines
		0160308.pdf	Investigator or Sponsor for Obtaining an Ethics Committee Statement and on the Procedure for Safety Monitoring of Medical Devices During Clinical Investigations and Assessment of the Clinical Data Collected During such Investigations: http://en.bda.bg/images/stories/documents/legal_acts/Ordinance_Clinical_investigations_MD_EN.pdf	mid=117&lang=en
Research Injury	Bulgarian Drug Agency (BDA): http://en.bda.bg/	Medicinal Products in Human Medicine Act, Chapter 4, Articles 91 and 92 (2013): http://en.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf	Regulation 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice, Section 5.8 (2012) (Bulgarian): http://www.bda.bg/images/stories/documents/regulations/naredbi/naredba31.pdf	
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 (2013): https://www.cpdp.bg/en/index.php?p=element&aid=373		
Human Biological Materials:	1. Executive Agency for Transplantation (Bulgarian): http://bgtransplant.bg/ 2. Council of Ministers, Ethics Committee for Transplantation	1. Law on Transplantation of Organs, Tissues, and Cells (2013) (Bulgarian): http://bgtransplant.bg/iat/regulations.php 2. Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006) (Bulgarian): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf	Regulation No. 13 of 4 April 2007 for the Terms and Conditions of Informing Bulgarian Citizens on the Activities regarding the Transplantation of Organs, Tissues and Cells	
Embryos, Stem Cells, and Cloning	Ministry of Healthcare (Bulgarian): http://www.mh.government.bg/	1. Law on Transplantation of Organs, Tissues, and Cells (2013) (Bulgarian): http://bgtransplant.bg/iat/regulations.php		

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006) (Bulgarian): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf		
Croatia Note: All websites and documents are in Croatian. For an overview of human subject protections standards in Croatia, see the EFGCP Report: http://www.efgcp.eu/Downloads/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 and Devices	*Drugs*			
	1. Ministry of Health (MZSS): http://www.zdravlje.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.almp.hr/#	1. Medicinal Product Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html 2. Rule Book on Amendments to Medicinal Product Act (2014): http://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html	MZSS: Ordinance on Clinical Trials and Good Clinical Practice (2015): http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html	
	Devices			
	1. Ministry of Health and Social Welfare (MZSS): http://www.mzss.hr/ 2. Agency for Medicinal Products and Medical Devices: http://www.almp.hr/#	Medical Devices Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1521.html		

Country	Key Organizations	Legislation	Regulations	Guidelines
Research Injury	1. Agency for Medicinal Products and Medical Devices of Croatia: http://www.almp.hr/ 2. Ministry of Health: http://www.zdravlje.hr/ 3. Croatian Health Insurance Fund: http://www.hzzo.hr/en/	1. Law on Mandatory Health Insurance (2013): http://www.hzzo.hr/wp-content/uploads/2013/10/ZOZO_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	Ordnance on Clinical Trials and Good Clinical Practice, Articles 11 and 16, Act 5.8., 6.8. and 8.2.5 (2015): http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html	
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: http://www.zdravlje.hr/	1. Law about Blood and Blood Products (2006): http://narodne-novine.nn.hr/clanci/sluzbeni/2006_07_79_1916.html 2. Rule Book on Amendments to Law about Blood and Blood Products (2011): http://narodne-novine.nn.hr/clanci/sluzbeni/2011_11_124_2476.html 3. Law on the Implementation of Human Tissues and Cells (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3070.html 4. Law on Transplantation of Human Organs for the Purpose of Treatment: http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3071.html	Ordinance on the Conditions of Space, Professional Workers, Medical-Technical Equipment and Quality Assurance for Collection, Retrieval, Testing, Processing, Preservation, Storage and Allocation of Human Tissues and Cells (2013): http://www.propisi.hr/print.php?id=9354	
Embryos, Stem Cells, and Cloning	Ministry of Health: http://www.zdravlje.hr/	1. Additional Protocol to the Convention for the Protection of	Ordinance on the Conditions of Space, Professional Workers,	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2003): http://zakon.poslovna.hr/public/Konvencija-o-zastiti-ljudskih-prava-i-dostojanstva-ljudskog-bica-u-pogledu-primjene-biologije-i-medicine-u-vezi-presadivanja-organa-i-tkiva-ljudskog-porijekla/243337/zakoni.aspx 2. 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	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	
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 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)		
Research Injury	Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/moh/moh.nsf/ind	Legislation Concerning Medicinal Products of Human Use (Good Clinical Practice)		

Country	Key Organizations	Legislation	Regulations	Guidelines
	ex_en/index_en?OpenDocument	No. 452/2004, Regulation No. 11 (8)		
Privacy/Data Protection	Commissioner's Office for the Protection of Personal Data: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/index_en/index_en?opendocument	1. Processing of Personal Data (Protection of Individuals) Law of 2001: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/138(I)-2001_en.pdf 2. 2003 Amendments: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$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 and Devices	*Drugs*			
	1. Ministry of Health (MOH) (Czech): http://www.mzcr.cz 2. State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lred=1	Act No. 378/2007 Collection on Pharmaceuticals	MOH: Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products	SUKL: Various: http://www.sukl.cz/medicinal-products-clinical-trials-guidelines-1

Country	Key Organizations	Legislation	Regulations	Guidelines
	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: http://www.uoou.cz/uoou.aspx	Act No. 101/2000 Coll., On Protection of Personal Data and Amending Certain Laws, As Amended (2015) (Czech): http://www.uoou.cz/uoou.aspx?menu=4&submenu=5	Position No. 3/2004 Personal Data Processing in the Context of Clinical Testing of Drugs and Other Medical Substances	
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://dnvk.dk/CVK/Home/English.aspx	Act on Research Ethics Review of Health Research Projects (2011): http://www.dnvk.dk/English/actonabiomedicalresearch.aspx	Executive Order No. 710 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects (2004) (Danish): http://www.dnvk.dk/English/ministerialorder806.aspx	Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics, and Appendices (2011): http://www.dnvk.dk/English/guidelinesaboutnotification.aspx
Drugs and Devices	Danish Medicines Agency: http://www.dkma.dk	1. Medicinal Product Act No. 506 (2013) 2. Act on Clinical trials on Medical Products No. 620 (2016)	1. Executive Order on Clinical Trials on Medicinal Products, Human Use (2004) 2. Executive Order No. 710 on Informed Consent from Patients	

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

Country	Key Organizations	Legislation	Regulations	Guidelines
Embryos, Stem Cells, and Cloning	Danish Council of Ethics: http://www.etiskraad.dk/da-DK.aspx?sc_lang=en	Act on Danish Council of Ethics No. 440 (2004)	Executive Order on Medically Assisted Procreation No. 93 (2015)	
Estonia For an overview of human subject protections in Estonia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Estonia%20definitive.pdf				
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 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: Requirements for Membership of Medical Ethics Committees for Clinical Trials, Rules of Procedures for Committee, Rate of Fee for Evaluation of Clinical Trials, and List of Information to be Submitted in Order to Obtain Approval (2005) 2. Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 (2005): https://firstclinical.com/regdocs/doc/?db=INT_Estonia_Regulation_23	
	Devices: Estonian Health Board: http://www.terviseamet.ee/en/medical-devices.html		Same as above.	
Research Injury	1. Minister of Social Affairs (MSA): https://www.sm.ee/en 2. Estonian Health Insurance Fund: https://www.haigekassa.ee/en	Medicinal Products Act, Section 90: https://www.riigiteataja.ee/en/eli/ee/525112013005/consolide/current	Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 of the Minister of Social Affairs of (2005): http://www.sam.ee/en/clinical-trials-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):		

Country	Key Organizations	Legislation	Regulations	Guidelines
		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 For an overview of human subject protections in Finland, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Finland%20definitive%20Updated.pdf				
General	1. Ministry of Social Affairs and Health (MSAH): http://www.stm.fi/en/frontpage 2. National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en 3. National Advisory Board on Research Ethics (TENK): http://www.tenk.fi/en	Medical Research Act No. 488/1999 (Amended 295/2004, 794/2010, and 143/2015): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488	1. Decree on the National Research Ethics Council of Finland No. 1347/2002 2. Decree on Medical Research Nos. 986/1999, 313/2004, and 65/2016 3. Decree on the National Committee on Medical Research Ethics No. 820/2010 4. Decree on Fees, No. 1168/2014	TUKIJA: 1. Report on Children in Medical Research (2003) 2. Report on Ethical Evaluation of Research in Finland (2006) 3. Operating Procedures of the National Committee on Medical Research Ethics (2016) Access*:* http://tukija.fi/en/publications1
Drugs 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 Research Ethics (TUKIJA): http://www.tukija.fi/en	Medicines Act No. 395/1987 (Finnish): http://www.finlex.fi/fi/laki/smur/1987/19870395	1. Decree on Clinical Trials on Medicinal Products No. 841/2010 2. Other Decrees: http://www.finlex.fi/fi/laki/smur/1987/19870395#nojalla FIMEA: Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2012 (Finnish): http://www.fimea.fi/download/22302_Maarays_2-2012_kliiniset_laaketutkimukset.pdf	TUKIJA: 1. Consent to Participate in the Clinical Trial 2. Templates for Clinical Trial Information Leaflet and Consent Form (2016) Access*:* http://tukija.fi/en/publications1

Country	Key Organizations	Legislation	Regulations	Guidelines
	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	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 (2016): http://www.laakevahinko.fi/in-english/terms-and-conditions/
Privacy/Data Protection	Office of the Data Protection Ombudsman: http://www.tietosuoja.fi/1560.htm	Personal Data Act No. 523/1999 (Finnish): http://www.finlex.fi/fi/laki/ajantasa/1999/19990523		
Human Biological Materials	National Supervisory Authority for Welfare and Health: 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 688/2012 (Finnish and Swedish): http://www.finlex.fi/fi/laki/ajantasa/2012/20120688	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 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 and 794/2010): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488 2. Gene Technology Act No. 377/1995: https://www.finlex.fi/fi/laki/ajantasa/1995/19950377		
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	1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002)		TUKIJA: Report on Stem Cells, Cloning, and Research (2005): http://tukija.fi/documents/1481661/1546647/2005cells.pdf/c14b7dd0-11b4-428d-bdae-539566ade614

Country	Key Organizations	Legislation	Regulations	Guidelines
	3. National Advisory Board on Research Ethics (TENK): http://www.tenk.fi/en/index.html 4. National Advisory Board on Social Welfare and Health Care Ethics (ETENE): http://www.etene.fi/en	2. Medical Research Act No. 488/1999 (amended 295/2004, 749/2010, and 143/2015): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488 3. Act on Assisted Fertility Treatments No. 1237/2006: http://www.finlex.fi/fi/laki/ajantasa/2006/20061237		

France For an overview of human subject protections in France, see the EFGCP Report: http://www.efgcp.eu/Downloads/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/	Law No. 2004-806 of 9 August 2004 on Biomedical Research: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000441469&dateTexte=&categorieLien=id	Public Health Code Articles R1121-1 and subsequent sections: http://legifrance.gouv.fr/	CCNE: Various: http://www.ccne-ethique.fr/en/type_publication/avis
Drugs and Devices	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr 2. National Health Products Safety Agency (ANSM): http://ansm.sante.fr/	Medications for Human Use, Articles L5121-11, L5124-1, and L5126-1) (2004): http://www.legifrance.gouv.fr/	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)
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	Law 2004-801 of August 6, 2004 Modifying Law 78-17 of January 6, 1978 Relating to the Protection of Data Subjects as Regards the Processing of Personal Data	CNIL: Decree No. 2005-1309 of 20 October 2005 Enacted for the Application of Act No. 78-17 of 6 January 1978 on Data Processing, Files and Individual Liberties (Amended by Decree 2007-451 of 25 March 2007): http://www.cnil.fr/fileadmin/documents/en/Decree%202005-1309.pdf	CCNE: 1. Ethical Questions Arising from the Transmission of Scientific Information Concerning Research in Biology and Medicine (1995) 2. Biometrics, Identifying Data and Human Rights (2007)
Human Biological Materials	National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr	1. Donation and Use of the Components and Products of the Human Body, Articles L1211-1 to L1274-3 (2004) (French): http://www.legifrance.gouv.fr/		CCNE: 1. Umbilical Cord Blood Banks for Autologous Use for Research (2002) 2. Ethical Issues Raised by Collections of Biological Material and Associated Information Data: "Biobanks,"

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Public Health Code Articles L1241-1 and following sections: (2010) (French): http://www.legifrance.gouv.fr/initRechCodeArticle.do		"Biolibraries" (2003)
Genetic Research	National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr	Civil Code Articles 16-10 to 16-13 (French): http://www.legifrance.gouv.fr/affichCode.do;jsessionid=D2DE023194483D3384DE19DE8959BDDA.tpdjo17v_3?idSectionTA=LEGISCTA000006136513&cidTexte=LEGITEXT000006070721&dateTexte=20131006		Various: http://www.ccne-ethique.fr/en/type_publication/avis
Embryos, Stem Cells, and Cloning	National Consultative Bioethics Committee for Health and Life Sciences (CCNE) (French): http://www.ccne-ethique.fr	Law No. 2013-715 of 6th August 2013: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000027811435&dateTexte=&categorieLien=id	Decree N° 2015-155 of 11 February, 2015 Public Health Code on Research on Embryos Article R2151-1 and Following Sections: http://legifrance.gouv.fr/affichCode.do?idArticle=LEGIARTI000030233469&idSectionTA=LEGISCTA000006190409&cidTexte=LEGITEXT000006072665&dateTexte=20151015	1. Commercialization of Human Stem Cells and Other Cell Lines (2006) 2. Opinion on the Ethical Reflection Concerning Research on Human Embryonic Cells and on Human Embryos in Vitro (2010) Access: http://www.ccne-ethique.fr/en/type_publication/avis
Georgia For an overview of human subject protections in Georgia, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 4: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf				
General	Bioethics and Health Law Studies Society: http://www.patientsrights.ge/index.php?page=385&lang=geo	1. Law on Health Care, Chapter XIX (1997) (Georgian): http://rama.moh.gov.ge/res/docs/janmrtelobis.pdf 2. Oviedo Convention on Human Rights and Biomedicine ETS No.164 (2001) 3. Additional Protocol to the Convention's on Human Rights and Biomedicine, concerning Biomedical Research, ETS No. 195 (2010)		
Drugs 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	1. Drug and Pharmacy Law No. 659 (1997) (Georgian): http://rama.moh.gov.ge/res/docs/wamali.pdf 2. Licenses and Approvals Law (2005)	Regulation about the Rules and Conditions of Issuing of the Approval of Clinical Trials Approved #176 (2005) (Georgian): http://rama.moh.gov.ge/res/docs/2016	Order of Health Minister about Implementation of "ICH: E6 Good Clinical Practice: Consolidated Guidance" (1996) including WMA: Declaration of Helsinki (2010) (Georgian): http://rama.moh.gov.ge/res/docs/9539N233.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Law of Medicines and Pharmaceutical Activity (2009) (Georgian): http://rama.moh.gov.ge/res/docs/wamali.pdf	0809105943176.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 (2014): https://personaldata.ge/manage/res/docs/unofficial%20translations/PDP%20LAW%20ENG%20%20-.pdf		
Embryos, Stem Cells, and Cloning		1. Law on Health Care, Article 142 (1997) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning ETS No. 168 (2001)		
Germany For an overview of human subject protections in Germany, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Germany%20definitive%20Updated.pdf				
General	1. German Medical Association (BÄK): http://www.bundesaerztekammer.de/page.asp?his=4.3569 2. Central Ethics Committee of the BÄK (German): www.zentrale-ethikkommission.de/ 3. Working Group of the Medical Ethics Committees in Germany (German): http://www.ak-med-ethik-komm.de/ 4. German Ethics Council: http://www.ethikrat.org/?set_language=en 5. Federal Ministry of Health: http://www.bmg.bund.de/ministerium/english-version.html			BÄK: (Model) Professional Code for Physicians in Germany, Article 15 (2011) (German): http://www.bundesaerztekammer.de/downloads/MBOen2012.pdf
Drugs and Devices	*Drugs*			
	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html 2. Federal Ministry of Education and Research (BMBF):	Medicinal Products Act, Sections 40-42 (2014): http://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p0917	BfArM : 1. Promulgation on the Principles of the Conduct of Clinical Trials of Drugs According to the Rules (1987) 2. Second Promulgation on the	BfArM and PEI: Third Notification on Clinical Trials of Medicinal Products for Humans (2006): http://www.pei.de/SharedDocs/Downloads/EN/pu/clinical-trials/3rd-notification-clinical-trials-2006-08-10.pdf?__blob=publicationFile&v=1

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.bmbf.de/en/index.php 3. Paul Ehrlich Institute (PEI): http://www.pei.de/EN/home/node.html;jsessionid=8A56CBB11CA133D70C010434A47D96B7.1_cid329 4. Federal Ministry of Health (BMG): http://www.bmg.bund.de/ministerium/english-version.html		Clinical Trial of Drugs in Human (1997) 3. Regulation for the Application of Good Clinical Practice of Clinical Medications for Human Use (2012) (German): http://www.gesetze-im-internet.de/bundesrecht/gcp-v/gesamt.pdf BMBF: Principles and Responsibilities When Carrying Out Clinical Studies (2013) (German): http://www.gesundheitsforschung-bmbf.de/_media/Grundsaetze_und_Verantwortlichkeiten_20130424.pdf	
	Devices			
	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html 2. Paul Ehrlich Institute (PEI) http://www.pei.de/EN/home/node.html	Act on Medical Devices (2014) (German): http://bundesrecht.juris.de/mpg/index.html Also see (German): http://www.dimdi.de/static/de/mpg/recht/index.htm	Various: http://www.dimdi.de/static/de/mpg/recht/index.htm	
Clinical Trials Registry	German Clinical Trials Register: https://drks-neu.uniklinik-freiburg.de/drks_web/			FAQs: https://drks-neu.uniklinik-freiburg.de/drks_web/navigate.do?navigationId=faq&messageDE=FAQ&messageEN=FAQ
Research Injury		Medicinal Products Act, Sections Section 40, Sub-section 3 (2014): http://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p0917		
Privacy/Data Protection Note: The 16 German states also have data protection laws (German): http://www.datenschutz-bayern.de/infoquel/ds-	Federal Commissioner for Data Protection and Freedom of Information (German): http://www.bfdi.bund.de/DE/Home/home_node.html	Federal Data Protection Act, as Amended (2009): http://www.gesetze-im-internet.de/englisch_bdsg/		

Country	Key Organizations	Legislation	Regulations	Guidelines
inst/deutschland.html				
Human Biological Materials	German Ethics Council (DER): http://www.ethikrat.org/welcome?set_language=en	1. Act of Quality and Security of Human Tissue and Cells (2007) (German): http://www.gesetze-im-internet.de/gewebeg/BJNR157400007.html 2. Transfusion Law (2009) (German): http://www.gesetze-im-internet.de/bundesrecht/tfg/gesamt.pdf 3. Transplantation Law (2013) (German): http://www.gesetze-im-internet.de/tpg/		Opinion on Human Biobanks for Research (2010): http://www.ethikrat.org/files/der_opinion_human-biobanks.pdf
	Central Ethics Committee of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/			Opinion of the Central Ethics Commission (2003) (German): http://www.zentrale-ethikkommission.de/downloads/Koerpermat.pdf
	German Society of Surgery (DGCH) (German): http://www.dgch.de/index.php?id=118		DGCH Guidelines on Good Professional Practice (GPP) for the Procurement of Human Tissue and Cells for Drug Production (German): http://www.dgch.de/fileadmin/media/pdf/servicemeldungen/069_Gewebegesetz_GFP-Leitfaden_der_DGCH_fuer_die_Gewinnung_menschlicher_Gewebe.pdf	
	German Institute for Cell and Tissue Replacement (DIZG): http://www.dizg.de/en/institute.html			1. Ethical Code (2000) 2. Common Standards: Tissues and Cell Banking (2004)
Genetic Research	Paul-Ehrlich-Institut (PEI): http://www.pei.de/EN/home/node.html	Law of 20 June 1990/16.12.1993 to Regulate Matters Related to Gene Technology (2013): http://www.gesetze-im-internet.de/bundesrecht/gentg/gesamt.pdf		Various: http://www.pei.de/DE/service/linklisten/links-gentherapie/links-thema-gentherapie-node.html
	German Society of Human Genetics: http://www.gfhev.de/en/gfh/			1. DNA Banking and Personal Data in Biomedical Research: Technical, Social, and Ethical Questions (2004) http://www.medgenetik.de/sonderdruck/en/DNA%20Banking_engl_060605.pdf 2. Position Paper of the German Society of Human Genetics (2007) (German)

Country	Key Organizations	Legislation	Regulations	Guidelines
				http://www.medgenetik.de/sonderdruck/2007_gfh_positionspapier.pdf
Embryos, Stem Cells, and Cloning	Federal Ministry of Education and Research (BMBF): http://www.bmbf.de/en/index.php	1. Embryo Protection Act (2011): http://www.gesetze-im-internet.de/bundesrecht/eschg/gesamt.pdf 2. Law on the Protection of Embryos in connection with the Import and Use of Human Embryonic Stem Cells (Stem Cell Act) (2013) (German): http://www.gesetze-im-internet.de/bundesrecht/stzg/gesamt.pdf English: http://www.drze.de/in-focus/stem-cell-research/modules/german-stem-cell-act?set_language=en	Implementation Regulation for the Stem Cell Act (German): http://bundesrecht.juris.de/zesv/index.html	
	German Ethics Council: http://www.ethikrat.org/welcome?set_language=en			1. Cloning for Reproductive Purposes and Cloning for the Purposes of Biomedical Research (2004): http://www.ethikrat.org/dateien/pdf/klonen-zu-fortpflanzungszwecken.pdf 2. Position Paper on Changes to the Stem Cell Act (2007): http://www.ethikrat.org/dateien/pdf/Stn_Stammzellgesetz.pdf
	Central Ethics Committee of the German Medical Association (ZEKO) (German): http://www.zentrale-ethikkommission.de/			Statement on Stem Cell Research (2002) (German): http://www.zentrale-ethikkommission.de/downloads/Stammzell.pdf
	German Research Foundation (DFG): http://www.dfg.de/en/			Opinion on Stem Cell Research (2006) (German): http://www.dfg.de/download/pdf/dfg_magazin/forschungspolitik/stammzellforschung/stammzellforschung_deutschland_lang_0610.pdf
	Central Ethics Committee for Stem-Cell Research (ZES): http://www.rki.de/EN/Content/Institute/DepartmentsUnits/StemCell/StemCell_node.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 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/Documents/Eng/2472engl_all.doc 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) (Greek): http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ENGLISH_INDEX/LEGAL%20FRAMEWORK/LAW%202472-97-NOV2013-EN.PDF 4. Act 3418/2005 Code on Medical Ethics		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
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 of Medically Assisted Reproduction		NBC: 1. Recommendation on the Use of Stem Cells in Biomedicine and Clinical Medicine 2. Recommendation on Human Reproductive Cloning 3. Opinion on Prenatal and Pre-implantation Diagnosis and Embryo Treatment Access: http://www.bioethics.gr/index.php/gnomes

Country	Key Organizations	Legislation	Regulations	Guidelines
Hungary For an overview of human subject protections in Hungary, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Hungary%20definitive%20Updated.pdf				
General	1. Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Research Ethics Committees (KFEB, TUKEB, HRB) (Hungarian): http://www.ett.hu/	1. Fundamental Law of Hungary, Articles II-III 2. Act CLIV of 1997 on Health Care, Chapters VIII and IX 3. Act VI. of 2002 on the Promulgation of the Oviedo Convention on Human Rights and Biomedicine 4. Act LXXXI of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research 5. Act C of 2012 on the Criminal Code, Chapter XVI Medical Procedures and Criminal Offenses Against the Order of Research, Sections 168-175	1. Decree 23/2002 (V. 9.) of the Minister of Health on Biomedical Research on Human Beings (Hungarian): http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam 2. Decree 35/2005 (VIII.26.) of the Minister of Health on the Clinical Trials of Investigational Medicinal Products for Human Use and on the Application of Good Clinical Practice 3. Decree No. 235/2009 (X.20.) from the Hungarian Government on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products, and for the Clinical Studies of the Medical Devices (Hungarian): http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900235.KOR&celpara=#xcelparam	
Drugs 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) (Hungarian): http://www.ett.hu/kfeb.htm	*Clinical Trials:* Act XCV of 2005 on Medicinal Products for Human Use, Section 3: http://net.jogtar.hu/jr/gen/getdoc.cgi?docid=a0500095.tv&dbnum=62 *Non-Interventional Trials:* Act CLIV of 1997 on Health Care, Chapter VIII, Section 164/A: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV	*Clinical Trials:* Decree 35/2005 (VIII. 26) of the Minister of Health on the Clinical Trial and Application of Correct Clinical Practices of Investigational Medicinal Products Intended for Use in Humans: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM&celpara=#xcelparam *Non-Interventional Trials:* Decree 23/2002. (V. 9) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/jr/gen/hjegy_doc.c	

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

Country	Key Organizations	Legislation	Regulations	Guidelines
		para=#xcelparam		
Human Biological Materials	Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma	Act LXXX of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Transplantation of Organs and Tissues of Human Origin: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0600080.TV&celpara=#xcelparam	Decree 18/1998 (XII 27) EüM on Implementing Act CLIV of 1997 on Health Care as Regards Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam	
Genetic Research	1. Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Committee for Human Reproduction (HRB) (Hungarian): http://www.ett.hu/hrb.htm	Act XXI of 2008 on the Rules of Protection of Human Genetic Data, of Human Genetic Examinations and Research and of the Operation of Biobanks: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0800021.TV&celpara=#xcelparam		Decree 60/2003. (X. 20.) of the Minister of Health, Social and Family Affairs on the Minimum Professional Requirements Necessary for Providing Health Services: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0300060.ESC&celpara=#xcelparam
Embryos, Stem Cells, and Cloning	1. Ministry of Human Resources (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma 2. Medical Research Council, Research Ethics Committees (KFEB, TUKEB, HRB) (Hungarian): http://www.ett.hu/	1. 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 (NBC): http://www.vsn.is/en	1. Act on the Rights of Patients No. 74/1997, Article 10 (2009): http://eng.velferdarraduneyti.is/media/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)		NBC: 1. Vulnerable Groups Including Children: http://www.vsn.is/en/content/vulnerable-groups-including-children 2. Informed Consent: http://www.vsn.is/en/content/informed-consent 3. Withdrawal of Consent: http://www.vsn.is/en/content/withdrawal-consent 4. Duty to Report Unexpected Events: http://www.vsn.is/en/content/duty-report-unexpected-events 5. Advertising to Recruit Participants: http://www.vsn.is/en/content/advertising-recruit-participants

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs 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. 112/2008 (2012): https://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Act-on-Health-Insurance-No-112-2008-16.pdf	Regulation on Clinical Trials of Medicinal Products in Humans No 443/2004 (2010): http://eng.velferdarraduneyti.is/media/Reglugerdir-enska/Regulation-on-clinical-trials-of-medicinal-products-in-humans-no-443-2004-as-amended.pdf	
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/		

Country	Key Organizations	Legislation	Regulations	Guidelines
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/
Drugs 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,	

Country	Key Organizations	Legislation	Regulations	Guidelines
			Section 13(6)(k) and Schedule 1, Part 2, Paragraph 4 (S.I. No. 190 of 2004): http://www.irishstatutebook.ie/eli/2004/si/190/made/en/html	
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 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): http://www.agenziafarmaco.it/ 3. Ministry of Health (MOH) (Italian): http://www.ministerosalute.it	1. Decree of the President of the Republic: Regulations to Simplify the Procedures and to Verify and Check New Systems and Experimental Therapeutic Protocols (September 21, 2001) (Italian) 2. Legislative Decree No. 211: Transposition of Directive 2001/20/EC Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Clinical Use (2003) 3. Legislative Decree No. 200: Transposition of Directive	1. Ministerial Decree of 21 December 2007: Directions for Submitting the Request for Authorisation of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authority, for Communicating Substantial Amendments, for Declaring the End of the Trial and for the Request of an Opinion to the Ethics Committee 2. Ministerial Decree of 31 March 2008: Definition of the Minimum Requirements that Contract Research Organisations (CROs) Shall Satisfy in Order to	

Country	Key Organizations	Legislation	Regulations	Guidelines
		2005/28 EC Laying down Principles and Detailed Guidelines as Regards Investigational Medical Products for Human Use, as Well as the Requirements for Authorizing of Manufacturing or Importing of such Products (2007) (Italian): http://www.aifa.gov.it/allegati/dlgs_200-6nov2007.pdf	Work within Clinical Trials on Medicinal Products	
	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)	
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

Country	Key Organizations	Legislation	Regulations	Guidelines
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 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 (2006): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Medical_Treatment_Law.pdf	Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for Human Use (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._891_-_Procedures_for_the_Clinical_Trial_of_Medical_Devices.doc	
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	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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 (2010): http://www.dvi.gov.lv/en/wp-content/uploads/legal-acts/Personal_Data_Protection_Law.doc 2. Law on the Rights of Patients, Section 10 (2010): http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Likumi/Law_On_the_Rights_of_Patients.doc		
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_Decea	Cabinet Regulation No. 1176 (2013) Procedures for Use of Human Tissues and Cells (Latvian): http://likumi.lv/ta/id/261810-cilveka-audu-un-sunu-izmantosanas-kartiba	

Country	Key Organizations	Legislation	Regulations	Guidelines
		sed_Human_Beings_and_the_Use_of_Human_Tissues_and_Organs_in_Medicine.doc		
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. 716: Order of Medically-Assisted Procreation, Donor Registry, and Donor Bank (2003) (Latvian): http://www.likumi.lv/doc.php?id=82281&from=off	
Lithuania Note: All standards are in Lithuanian. For an overview of human subject protections in Lithuania, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Lithuania%20definitive%20Updated.pdf				
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	1. Decree No. V-405 on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage, and Providing Information on Biomedical Research (2010): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=372121&p_query=&p_tr2= 2. Government of the Republic of Lithuania: Decree No. 1458 on State Fees (2015): https://www.e-tar.lt/portal/lt/legalAct/TAR.E3A145C8DD49/CQWiEHsWLL 3. Decree on the Procedure for Calculating and Paying Compensation for the Expenses Incurred Due to Participation in Biomedical Research and the Time Spent (2016): https://www.e-	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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?-1073108465		1. Decree on the Detailed Requirements for the Content of a Person's Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent, No. V-28 (2016): https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/b9895bf0ba3811e5be9bf78e07ed6470?positionInSearchResults=0&searchModelUUID=a4086949-b1f3-429e-8197-870c6122d393 2. Decree on the Procedure to Conduct Biomedical Research on Medical Documents, No. V-28	Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical Research of the LBEC (2010): bioetika.sam.lt/get_file.php?file=Y3BUSHk1YWhrNlZ1bTJKbXhwZHJsWlprYWNOb3ltVFR5cHhxMnBlZGxhU2V4cFdTbHA5cFoyMmpscGFjbTNDWm1LR2F4cGJVbXBPWHJwck14SjNJcFhIS25kYVlZV2FlYTU5cW81cWFjV0tkYm1XYWFJOXR5TWFtY2NtYmI1ZDZjYTZZcWNaU1lxcHBtMmFpeUtTYm5acWFtODlseFpyRm01cHR6NVNlbDZodzJKcURuV1NWYUhCbmttZWJWWEZnblc2WWdaYVRhNXlaVjJtb3g0R2JqWnFGbDhySXBHYXRhYWFTbk1tb2JsQ2VwV3JDWmRXYTJzaWdjTmpEcUphW10UEsxNVNUazVOeVoyS1VsMk5zbEpla204U1puR3VmbWclM0QlM0Q=

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

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

Country	Key Organizations	Legislation	Regulations	Guidelines
Human Biological Materials	Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG	Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL		
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	1. Decree No. V-660 on the Procedure to Issue Authorization for the Transit of Tissues of Human Embryonic Tissue, Embryonic Stem Cells and their Lines, Fetal Tissue, and Fetal Stem Cells throughout the Territory of the Republic of Lithuania (2007): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=302906&p_query=&p_tr2= 2. Decree No. V-659 on the Procedure for Importing of the Stem Cells Taken from the Umbilical Cord or Placenta after the Birth of a Child and the Samples Taken for Genetic Research into the Territory of the Republic of Lithuania and Exporting Therefrom (2015): http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=302907&p_query=&p_tr2=	
Luxembourg For an overview of human subject protections in Luxembourg, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Luxembourg%20definitive%20Updated.pdf Note: All websites and documents are available in French.				
General	National Ethics Consultative Commission: http://www.cne.public.lu/fr/commission/statut.html			Various: http://www.cne.public.lu/fr/publications/avis.html
Drugs 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-	Hospitals Act of 1998, Article 25 (2010): http://www.legilux.public.lu/leg/a/archives/1998/0078/a078.pdf	Grand-Ducal Decree of May 30, 2005 on the Conduct of Clinical Trials on Medicinal Products for Human Use: http://www.legilux.public.lu/leg/a/archives/2005/0084/2005A15161.html	

Country	Key Organizations	Legislation	Regulations	Guidelines
	sante/ministere-sante/direction-sante/div-pharmacie-medicaments/index.html			
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/	Law on Medicinal Products and Medical Devices (Official Gazette No.106/2007) and Laws Amending and Supplementing the Law (2010-2016): Click on file folder 1., then open sub-folders: https://lekovi.zdravstvo.gov.mk/documents/2	1. Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2009): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/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 Ameding and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2012): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/880033320?t:ac=1/1 1.3. Rulebook on Amending and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents and Annex No.3 (Guideline for the Clinical Trial	Guideline for the Clinical Trial Applicant (Annex 3) (2012): https://lekovi.zdravstvo.gov.mk/documents/1/1 (Sub-folder 23.2)

Country	Key Organizations	Legislation	Regulations	Guidelines
			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 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):	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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 of Macedonia: http://www.fzo.org.mk	1. Law on Health Protection: (Official Gazette No. 43/2012) and Laws Amending and Supplementing the Law (2012-2015): http://zdravstvo.gov.mk/zakon-za-zdravstvenata-zashtita/ 2. Law on Taking and Transplanting of Human Body Organs (Official Gazette No. 47/2011) and Laws Amending and Supplementing the Law (2011-2015): http://zdravstvo.gov.mk/zakon-za-zemanje-i-presaduvanje-na-delovi-	Regulations for Transplantation of Tissues and Organs: http://www.fzo.org.mk/default.asp?ItemID=6541AC10FFC3C5498F0887C57131D996	Regulation on Criteria Relating to Space, Personnel and Equipment for Collection, Transplantation and Exchange of Organs and Tissues, the Necessary Space, Equipment and Staff Required to be Provided by the Health Institution for the Collection, Transfer, Exchange and Storage of Organs and Tissues from Human Body for Treatment Purposes (2012): http://zdravstvo.gov.mk/wp-content/uploads/2012/12/za_pobliskite_kriteriumi_vo_odnos_na_prostorot_kadarot_i_opremata_za_zemawe_presaduvawe_i_razmenuvawe_na_organite_i_tkivata_za_potrebniot_pr.pdf

Country	Key Organizations	Legislation	Regulations	Guidelines
		na-chovechkoto-telo-zaradi-lekuvanje/ Sub-Law Acts : http://www.fzo.org.mk/default.asp?ItemID=6541AC10FFC3C5498F0887C57131D996 3. Law on Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, With Additional Protocol on the Prohibition of Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin: http://www.pravo.org.mk/documentDetail.php?id=5543		
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: http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-za-zastita-na-pravata-na-pacientite-precisten.pdf		
Embryos, Stem Cells, and Cloning	Ministry of Health of the Republic of Macedonia: http://moh.gov.mk/	Law on Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, With Additional Protocol on the Prohibition of Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin: http://www.pravo.org.mk/documentDetail.php?id=5543		
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.as			Various: http://health.gov.mt/en/regcounc/Bioethics-Committee/Pages/Opinions.aspx

Country	Key Organizations	Legislation	Regulations	Guidelines
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Drugs and Devices	*Drugs*			
	Medicines Authority: http://medicinesauthority.gov.mt/	1. Medicines Act, 2003: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8924&l=1 2. Subsidiary Legislation, 458.43, Clinical Trials Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11281&l=1 3. Subsidiary Legislation, 458.47, Good Clinical Practice and Requirements for Manufacturing or Import Authorisation of Investigational Medicinal Products (Human Use) Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11285&l=1		Guidance Notes on Good Clinical Practice (2010): http://medicinesauthority.gov.mt/clinicaltrials.htm
	Devices			
	1. Medicines Authority: http://medicinesauthority.gov.mt/ 2. Malta Competition and Consumer Affairs Authority, Technical Regulations Division, Regulatory Affairs Directorate: http://www.mccaa.org.mt/en/regulatory-affairs-directorate	1. Product Safety Act, 2001: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8893&l=1 2. Subsidiary Legislation, 427.16, *In Vitro* Diagnostic Medical Devices Regulations, 2003 http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10756&l=1 3. Subsidiary Legislation, 427.44, Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10781&l=1 4. Subsidiary Legislation, 427.10, Active Implantable Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemi		

Country	Key Organizations	Legislation	Regulations	Guidelines
		d=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 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&lang=1	1. Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Expertise of Clinical Trials: http://lex.justice.md/md/362783/ 2. Order No. 648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in the Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf	
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):	Decision of Government No. 1123 Dated 14.12.2010 on the Approval of the Requirements for the Assurance of Personal Data	

Country	Key Organizations	Legislation	Regulations	Guidelines
		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	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 Biological Security: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=303353	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being, on the Prohibition of Cloning Human Beings (2002) 2. Law No. 42 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 and Devices	1. Ministry of Health of Montenegro: http://www.mzd.gov.me/en/ministry?alphabet=lat	1. Law on Medicines ("Official Gazette of Montenegro", No.	Rulebook on More Detailed Conditions and Documentation	

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. Agency for Medicines and Medical Devices: https://www.calims.me/Portal/faces/glavna?_adf.ctrl-state=rsbe35pln_83	56/2011), Articles 60 – 83: https://www.calims.me/Portal/faces/servlet1?putanja=Law%2520on%2520medicines%2520Montenegro%2520202011.pdf&_afrWindowMode=0&_afrLoop=13118320360550956&_adf.ctrl-state=vn1r9i5df_417 2. Law on Medical Devices ("Official Gazette of Montenegro" No. 79/2004), Articles 46 – 50: https://www.calims.me/Portal/faces/servlet1?putanja=Law%2520on%2520medical%2520devices%25202004.pdf&_afrWindowMode=0&_afrLoop=13119103630157953&_adf.ctrl-state=vn1r9i5df_799 3. Law on Amendments to the Law on Medical Devices ("Official Gazette of Montenegro", No. 53/2009), Articles 34 – 38: https://www.calims.me/Portal/faces/servlet1?putanja=Law%2520on%2520amendments%2520to%2520the%2520Law%2520on%2520medical%2520devices_2009.pdf&_afrWindowMode=0&_afrLoop=13119388662995839&_adf.ctrl-state=vn1r9i5df_809	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), Article 77: https://www.calims.me/Portal/faces/servlet1?putanja=Law%2520on%2520medicines%2520Montenegro%2520202011.pdf&_afrWindowMode=0&_afrLoop=13118320360550956&_adf.ctrl-state=vn1r9i5df_417 2. Law on Medical Devices ("Official Gazette of Montenegro" No. 79/2004), Article 47: https://www.calims.me/Portal/faces/servlet1?putanja=Law%2520on%2520medical%2520devices%25202004.pdf&_afrWindowMode=0&_afrL		

Country	Key Organizations	Legislation	Regulations	Guidelines
		oop=13119103630157953&_adf.ctrl-state=vn1r9i5df_799		
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)		
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)		
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)		
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)	
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 Involving Human Subjects (CCMO): http://www.ccmo.nl/en/	1. Population Screening Act (1996): http://wetten.overheid.nl/BWBR0005699/geldigheidsdatum_24-09-2015 2. Medical Research Involving Human Subjects Act (2012): 2006 English version: http://www.ccmo.nl/attachments/files/wmo-engelse-vertaling-29-7-2013-afkomstig-van-vws.pdf	1. Concerning the Use of a Special Form (2002) 2. Concerning Requirements of Expertise of Accredited Review Board Members (2002) 3. Concerning the Organization and Working Method of Accredited Review Board Members (2003) 4. External Review Guideline (2004) 5. Research Contract Review Guideline (2009)	Various (Dutch): http://www.ccmo.nl/en/publications-of-the-ccmo
Drugs 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	Netherlands Trial Register (Dutch): http://www.trialregister.nl/trialreg/index.asp			

Country	Key Organizations	Legislation	Regulations	Guidelines
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
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/codeproperssecondaryuseofhumantissue1_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		1. Guidelines for Research on Persons with Impaired Informed Consent Capacity (2005) 2. Payment for Research Participants in Medical and Health Research (2009) 3. Guidelines for Research Ethical and

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Act on Health Care Research (2008) (Norwegian): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&		Scientific Evaluation of Qualitative Research Projects in Medical and Health Research (2009) (Norwegian): https://www.etikkom.no/forskningsetiske-retningslinjer/Medisin-og-helse/Kvalitativ-forskning/
	National Committee for Research Ethics in the Social Sciences and the Humanities: http://www.etikkom.no/en/In-English/			Guidelines for Research Ethics in the Social Sciences, Law, and the Humanities (2001)
	National Committee for Research Ethics in Science and Technology: https://www.etikkom.no/en/In-English/Committee-for-Research-Ethics-in-Science-and-Technology/			Research Ethics Guidelines for Science and Technology (2007) (Norwegian): https://www.etikkom.no/Forskningsetikk/Etiske-retningslinjer/Naturvitenskap-og-teknologi/
Drugs and Devices	*Drugs*			
	Norwegian Medicines Agency: http://www.legemiddelverket.no/English/Sider/default.aspx		Regulation Relating to Clinical Trials on Medicinal Products for Human Use (2009) (Norwegian): http://lovdata.no/dokument/SF/forskrift/2009-10-30-1321?q=forskrift+om+kliniske+utpr%C3%B8vning	Guidelines for the Regulations Concerning Clinical Trials of Human Drugs (1999) (Norwegian): http://www.legemiddelverket.no/Godkjenning_og_regelverk/Klinisk-utproving/Regelverk%20og%20veiledninger/Documents/Veiledning%20-%20revidert%20versjon%202.2%2006.11.2012.pdf
	Devices			
	1. Norwegian Directorate of Health: http://www.helsedirektoratet.no/kvalitet-planlegging/medisinsk-utstyr/klinisk-utprovning/Sider/default.aspx 2. Regional Committees for Medical and Health Research Ethics: https://helseforskning.etikkom.no/ikbViewer/page/forside	Act of 12 January 1995 No. 6 Relating to Medical Devices (1995) (Norwegian): http://lovdata.no/dokument/NL/lov/1995-01-12-6?q=lov+om+medisinsk+utstyr	Regulation of December 15th 2005 No. 1690 Relating to Medical Devices (2005) (Norwegian): http://lovdata.no/dokument/SF/forskrift/2005-12-15-1690?q=forskrift+medisinsk+utstyr	Guidelines on Notification for Clinical Investigation of Medical Devices in Norway (2010): 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)		
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):	1. Act on Biobanks (February 21, 2003, No. 12):	MHCS: Guidelines for the Norwegian Act	

Country	Key Organizations	Legislation	Regulations	Guidelines
	https://www.regjeringen.no/en/dep/hod/id421/ 2. Ministry of Education and Research (MER): http://www.regjeringen.no/en/dep/kd.html?id=586	http://lovdata.no/dokument/NL/lov/2003-02-21-12?q=biobank 2. Act Relating to the Application of Biotechnology in Human Medicine, etc. (December 5, 2003, No. 100) 3. Act on Health Care Research (2008) (Norwegian): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&	on Biobanks (2003)	
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

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs and Devices	*Drugs*			
	Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.mz.gov.pl/en	1. Pharmaceutical Law (2015): isap.sejm.gov.pl/Download?id=WDU20011261381&type=3 2. Law of 20/04/2004 on Amendment of the Pharmaceutical Law, Law on the Profession of Medical Doctor, and Regulations Introducing the Pharmaceutical Law, Law on Medical Devices, and Law on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws No. 92, Item 882)	1. Order of the Minister of Health in the Matter of Central Register of Clinical Trials (2004) 2. Decree of the Minister of Health on Clinical Trials on Minors (2004) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20041041108 3. March 11, 2005 Order of the Minister of Health Concerning Detailed Requirements of Good Clinical Practice (2005) (Polish): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20120000489 4. February 16, 2016 Regulation of the Minister of Health on Detailed Requirements for Planning, Conducting, Monitoring, and Documenting the Clinical Study of a Medical Device: http://isap.sejm.gov.pl/DetailsServlet?id=WDU20160000209	
	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: isap.sejm.gov.pl/DetailsServlet?id=WDU20150001918	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	

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

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 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):	Decree-Law No. 102/2007 of April 2	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/portaria_57-2005.pdf		
	Devices			
	National Institute of Pharmacy and Medicines: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS	Various: http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_V/TITULO_V_CAPITULO_II		Various: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS/NOTAS_INFORMATIVAS
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001)		
Privacy/Data Protection	National Data Protection Commission: http://www.cnpd.pt/english/index_en.htm	1. Constitution, Article 35 (1997) 2. Act on the Protection of Personal Data, No. 67/98 (1998): http://www.cnpd.pt/english/bin/legislation/Law6798EN.HTM		
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%20Updated.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	

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs 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 (Romanian): http://www.bioetica-medicala.ro/		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 -- Transposition of 2001/20/EC Directive Access: http://www.anm.ro/anmdm/med_legislatie_ordine.htm	MOH: Guideline for Clinical Trials in Pediatric Populations (CPMP/ICH/2711/99) (1999)
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)		

Country	Key Organizations	Legislation	Regulations	Guidelines
		2. Law No. 301 from 2004 Penal Code – Chapter IV – Crimes and Felonies Regarding Genetic Manipulation: http://www.codpenal.ro/legislatie/document/lege-301-din-2004-codul-penal-capitol-4-crime-si-delicte-privind-manipularea-genetica-1260-63259.html		
Russia For an overview of human subject protections in Russia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Russia%20definitive%20Updated.pdf				
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 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):	Federal Law #61FZ "On Circulation of Medicines" (2011): http://acto-russia.org/files/zakon_ob_obr_ls_en.docx	MOH: 1. Ministry of Health Order No. 753n (August 26, 2010) "On Assertion of Order of Organization and Carrying out of Ethical Review…" (Russian): http://base.garant.ru/12178437/ 2. Ministry of Health Order No.	

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.gost.ru/wps/portal/pages.en.Main		774n (August 31, 2010) "On Council of Ethics" (Russian): http://www.rg.ru/2013/02/22/etika-dok.html 3. Ministry of Health Order of April 1, 2016 № 200н "On Approval of the Rules of Good Clinical Practice: http://acto-russia.org/files/prikaz_200n.docx GOST: Good Clinical Practice. GOST-R 52379-2005 (September 27, 2005) (Russian): http://acto-russia.org/index.php?option=com_content&task=view&id=17	
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		

Country	Key Organizations	Legislation	Regulations	Guidelines
		of the Federal Law "On Temporary Ban on Human Cloning" (2010) (Russian): http://base.garant.ru/184467/		
San Marino				
General	San Marino Bioethics Committee (Italian): http://www.sanita.sm/on-line/home/comitato-bioetica/comitato-sammarinese-di-bioetica.html	Oviedo Convention on Human Rights and Biomedicine (1998)		
Research Injury		Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1999)		
Serbia For an overview of human subject protections in Serbia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Serbia%20definitive%20Updated.pdf				
Drugs and Devices	1. Ministry of Health (MOH): http://www.zdravlje.gov.rs/ 2. Serbian Drug Agency http://www.alims.gov.rs/eng/	Law on Medicines and Medical Devices, Official Gazette of RS No. 30/2010 and 107/2012: http://www.alims.gov.rs/ciril/files/2012/11/zakon-30-2010-107-2012.pdf	MOH: 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.parlament.gov.rs/upload/	

Country	Key Organizations	Legislation	Regulations	Guidelines
			archive/files/lat/pdf/zakoni/2013/1283-13Lat.pdf	
Privacy/Data Protection	Commissioner for Information of Public Importance and Personal Data Protection: http://www.poverenik.rs/en/the-commissioners-authority-di.html	Law on the Protection of Personal Data, Official Gazette 97/08, 104/09, 68/20 and 107/12 (Serbian): http://www.minrzs.gov.rs/files/doc/porodica/ostali/Zakon%20o%20zastiti%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 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 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.	

Country	Key Organizations	Legislation	Regulations	Guidelines
			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 Materials		1. Act No. 576/2004 Coll. on Health Care, Sections 35-39. 2. Act No. 489/2008 Coll. on Drugs and Medical Devices, Section 18 (29b).	Governmental Regulation No. 20/2007 Coll. on Tissue and Cell Collection	
Embryos, Stem Cells, and Cloning		1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998) 2. Act No. 576/2004 Coll. on Health Care, Section 26.10.a.		
Slovenia For an overview of human subject protections in Slovenia, see the EFGCP Report: http://www.efgcp.eu/Downloads/EFGCPReportFiles/Slovenia%20definitive%20Updated.pdf 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)

Country	Key Organizations	Legislation	Regulations	Guidelines
Drugs 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. On the Ethical Review of Phase IV Clinical Studies (2003): http://www.mf.uni-lj.si/kme-nmec/Docu/Ocenjevanje_klin_studij_IV_faze.pdf 3. Rules on the Composition, Duties, Responsibilities, and Working Methods of the Commission for Medical Ethics, Official Gazette Nos. 30/1995 and 69/2009	
	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	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-	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999)

Country	Key Organizations	Legislation	Regulations	Guidelines
		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: http://www.uradni-list.si/1/objava.jsp?sop=2015-01-2357	nmec.sazu.si/Docu/O_truplih_Isis.pdf	
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-		

Country	Key Organizations	Legislation	Regulations	Guidelines
		3297 4. Rules on Donation and Procurement of Human Tissues and Cells, Official Gazette Nos. 70/2008, 67/2014, and 79/2014		
Spain For an overview of human subject protections in Spain, see the EFGCP Report: http://www.efgcp.eu/Downloads/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/ceic/home.htm 3. Institute of Health Carlos III, Ministry of Science and Innovation http://www.isciii.es/htdocs/en/index.jsp	1. Oviedo Convention on Human Rights and Biomedicine (1999): http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/ETS164Spanish.pdf 2. Law 14/2007 on Biomedical Research: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf		
Drugs and Devices	*Drugs*			
	Spanish Agency of Medicines and Medical Devices (Spanish): http://www.aemps.gob.es/en/investigacionClinica/medicamentos/home.htm	1. Royal Decree 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.ph	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	

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

Country	Key Organizations	Legislation	Regulations	Guidelines
	idphp.php	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	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 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	Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples (2006) (Spanish): http://www.boe.es/boe/dias/2006/02/07/pdfs/A04626-04636.pdf	
Genetic	Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US	Law 14/2007 of July 3 on Biomedical Research, Title I, Articles 6-9; Title V:		

Country	Key Organizations	Legislation	Regulations	Guidelines
		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 4. National Stem Cell Bank: http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/fd-organizacion/fd-estructura-directiva/fd-subdireccion-general-investigacion-terapia-celular-medicina-regenerativa/fd-centros-unidades/banco-nacional-lineas-celulares.shtml	1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2000) 2. Law 14/2006 on Methods of Assisted Human Reproduction, Chapters IV and V 3. Law 14/2007 of July 3 on Biomedical Research, Title III: http://www.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 Boards (2007): http://www.epn.se/media/1202/1068.pdf 3. Statute No. 2007:1069 Containing Instructions for	Information for Research Participants

Country	Key Organizations	Legislation	Regulations	Guidelines
			Regional Ethical Review Boards (2007): http://www.epn.se/media/1203/1069.pdf	
	Swedish Research Council: http://www.vr.se/english		Regulations and General Counsel VRFS 2012:1 on Ethical Vetting of Human Subjects Research (Swedish): http://www.vr.se/download/18.7ef6967137344838702801340207447175/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 (2011): https://publikationer.vr.se/en/product/good-research-practice/
Drugs and Devices	*Drugs*			
	Medical Products Agency: https://lakemedelsverket.se/english/	1. Pharmaceuticals Act No. No 2015:315 (Swedish): http://www.notisum.se/rnp/sls/lag/20150315.htm 2. Pharmaceuticals Ordinance 2015:458 (Swedish): http://www.notisum.se/rnp/sls/lag/20150458.htm	MPA Regulations on Clinical Trials in Humans -- LVFS 2011:19 (Swedish): http://www.lakemedelsverket.se/upload/lvfs/LVFS_2011_19.pdf	
	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)	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	
Privacy/Data Protection	1. Swedish Data Inspection Board: http://www.datainspektionen.se/in-english/ 2. Swedish Research Council (SRC): http://www.vr.se/english	1. Patient Data Act: SFS 2008:355 (Swedish): http://www.notisum.se/rnp/sls/lag/20080355.htm 2. SFS 2009:400 - Public Access to Information and Secrecy Act (Swedish): http://www.notisum.se/rnp/sls/lag/20090400.htm 3. Act on Certain Health Research Registers, SFS 2013:794 (Swedish): http://www.notisum.se/Pub/Doc.aspx?url=/rnp/sls/lag/20130794.htm	SFS 2009:641 - Public Access to Information and Secrecy Ordinance (Swedish): http://www.notisum.se/rnp/sls/lag/20090641.htm	Swedish Data Inspection Board Report 2004:2: http://www.datainspektionen.se/Documents/rapport-biobanker.pdf SRC: Policy Document: Handling Personal Data (2003) (Swedish): http://www.vr.se/download/18.6b2f98a910b3e260ae28000342/Personuppgifter_7.pdf
Human Biological Materials	1. National Board of Health and Welfare (SOS):	1. Biobanks in Medical Care Act No. 297 (2002):	SOS: Consolidated regulations	SRC: Research Ethics Guidelines for Using

Country	Key Organizations	Legislation	Regulations	Guidelines
	http://www.socialstyrelsen.se/english 2. Swedish Research Council (SRC): http://www.vr.se/english 3. BBMRI Sweden: http://bbmri.se/en/	http://vavnad.se/files/live/sites/Biobanken/files/biobanksverige/9.%20Documetns%20in%20English/Biobanks%20in%20medical%20care%20act%20(2002-297).pdf 2. Regulation No. 746 (2002): http://www.notisum.se/rnp/sls/lag/20020746.htm	(Swedish): http://www.socialstyrelsen.se/sosfs/2002-11	Biobanks (Swedish) (2003) http://www.vr.se/download/18.6b2f98a910b3e260ae28000350/Riktlinjer_Biobanker_11.pdf
Genetic Research	1. Ministry of Health and Social Affairs: http://www.sweden.gov.se/sb/d/2061 2. National Board of Health and Welfare: http://www.socialstyrelsen.se/english	Act on Genetic Integrity (2006:351) (Swedish): http://www.notisum.se/rnp/sls/lag/20060351.htm	Drug Administration Regulations and Guidelines (LVFS 2004:10) on the Intentional Release of Clinical Trials of Medicinal Products Containing or Consisting of Genetically Modified Organisms: http://www.lakemedelsverket.se/upload/lvfs/LVFS_2004-10.pdf	Genetics and Gene Technology in the Health Care: State of the Art and Guidelines for Ethical Considerations (1999)
Embryos, Stem Cells, and Cloning	Swedish Research Council (SRC): http://www.vr.se/english	Act on Genetic Integrity (2006:351) (Swedish): http://www.notisum.se/rnp/sls/lag/20060351.htm	1. Legal Regulation of Stem Cell Research 2002:119 (Swedish): http://www.regeringen.se/sb/d/108/a/2717 2. Regulations and Guidelines for the Use of Tissues and Cells in Healthcare and Clinical Research - SOSFS 2009:32 (Swedish): http://www.socialstyrelsen.se/sosfs/2009-32	SRC: Guidelines for Ethical Vetting of Human Stem Cell Research (2004) (Swedish): http://www.vr.se/download/18.6b2f98a910b3e260ae28000362/human_stamcellsforskning_16.pdf
Switzerland For an overview of human subject protections in Switzerland, see: http://kofam.ch/en/home/				
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	1. Ordinance of 20 September 2013 on Clinical Trials in Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html 2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO), RS 810.305: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html 3. Ordinance of 20 September	Swiss Clinical Trial Organisation, Guidelines for Good Operational Practice (GGOP) (2014): http://www.scto.ch/dms/SCTO/de/Publikationen/Richtlinien/Guidelines-for-Good-Operational-Practice_V2-0/Guidelines%20for%20Good%20Operational%20Practice_V2.0.pdf Access: http://www.scto.ch/en/News.html

Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	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	
Drugs and Devices	*Drugs*			
	1. Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en 2. Federal Office of Public Health (FOPH): http://www.bag.admin.ch/index.html?lang=en	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	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	Swissmedic Guide to the Regulation of Medical Devices: https://www.swissmedic.ch/medizinprodukte/00287/index.html?lang=en

Country	Key Organizations	Legislation	Regulations	Guidelines
		Research Act, HRA), RS. 810.30: https://www.admin.ch/opc/en/classified-compilation/20061313/index.html	Ordinance, ClinO), RS 810.305 articles 20, 32, 37, 42-45 and Annexes 1, 3 and 4: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html 3. Ordinance of 20 September 2013 on Organisation Aspects of the Human Research Act (HRA Organisation Ordinance, OrgO-HRA), RS 810.308, Articles 6-7: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html	
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 (2011)		
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	Federal Data Protection and Information Commissioner (FDPIC): http://www.edoeb.admin.ch/index.html?lang=en	1. Federal Act of 19 June 1992 on Data Protection (FADP), RS 235.1: http://www.admin.ch/opc/en/classified-compilation/19920153/index.html 2. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS	1. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 5 - 8, 10, 15, 21, 24-34, 37-39, 41, and 44-45, and Annex 2: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html	

Country	Key Organizations	Legislation	Regulations	Guidelines
similar to the FADP.		810.30, Articles 2, 3, 8, 16-18, 31-35, 41-45, 47, 49, 58-60, and 63: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	2. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305 Articles 5, 7, 9, 12, 16-18, and 25, and Annexes 2-3: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html	
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	1. Ordinance of 14 February 2007 on Human Genetic Testing, RS 810.122.1 (French): http://www.admin.ch/opc/fr/classified-compilation/20051790/index.html 2. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 28 - 32: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html	

Country	Key Organizations	Legislation	Regulations	Guidelines
		Human Beings (Human Research Act, HRA), RS 810.30, Articles 3, 32 - 35, 42, and 49: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html	3. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305 Articles 22 and 35, and Annexes 3 and 4: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html	
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 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-	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/sho	1. Ukrainian Ministry of Health Order No. 95 About Approval of Documents Related to the Quality Assurance of Medicines (2009) (Ukrainian): http://zakon5.rada.gov.ua/rada/show/	Bioethics Committee: 1. Information Letters on Ethics Questions of Clinical Trials and Implementation of Medicines (2006) 2. Ethics Expertise of Clinical Trials Medicines (2007)

Country	Key Organizations	Legislation	Regulations	Guidelines
	en/bioethics-committee	w/z1010-09 2. On Medicines, Articles 7 and 8 No. 123/96BP (2014): http://zakon4.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80	v0095282-09 2. Ministry of Health Act 14.12.2009 N 944 on Approval of the Clinical Trial and Expertise of Clinical Trials (Ukrainian): http://zakon4.rada.gov.ua/laws/show/z0053-10	3. Methodological Aspects of Central EC Activity of Ukrainian Ministry of Health (2007) 4. Ethical Aspects of Placebo Controlled Clinical Trials in Patients with MS (2008) 5. Optimization of Local Ethics Committee Activities (2009) Guidelines for Pre-Clinical and Clinical Trials (Ukrainian): http://www.dec.gov.ua/index.php/ekspertiza-materialiv-doklinichnikh-ta-klinichnikh-viprobuvan/metodichni-rekomendatsiji-shchodo-provedennya-doklinichnikh-ta-klinichnikh-viprobuvan
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):	Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) with Changes from 23.09.2009 No. 690 (Ukrainian): http://zakon1.rada.gov.ua/laws/show/z1206-07	

Country	Key Organizations	Legislation	Regulations	Guidelines
		http://zakon3.rada.gov.ua/laws/show/z1124-12		
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-en/bioethics-committee 2. Ukrainian Ministry of Health: http://www.moz.gov.ua/en/	1. Act on the Banning of Human Reproductive Cloning (2004) (Ukrainian): http://zakon0.rada.gov.ua/laws/show/2231-15 2. Act on Organs and Other Human Materials Transplantology No. 1007-XIV (2007) (Ukrainian): http://zakon0.rada.gov.ua/laws/show/1007-14	1. Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) (Ukrainian): http://zakon1.rada.gov.ua/laws/show/z1206-07 2. Ukrainian Ministry of Health Order No. 787 on Approval of the Use of Reproductive Technologies in Ukraine 09.09.2013: http://zakon4.rada.gov.ua/laws/show/z1697-13	
United Kingdom Unless otherwise noted, all laws, regulations, and guidelines listed for England apply to the entire United Kingdom. For an overview of clinical research regulations in the United Kingdom, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=226				
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):			1. Good Research Practice: Principles and

Country	Key Organizations	Legislation	Regulations	Guidelines
	https://www.mrc.ac.uk/			Guidelines (2012): http://www.mrc.ac.uk/research/research-policy-ethics/good-research-practice/ 2. Research Involving Human Participants in Developing Societies (2004): http://www.mrc.ac.uk/news/publications/research-involving-human-participants-in-developing-societies/ 3. Medical Research Involving Children (2004): https://www.mrc.ac.uk/documents/pdf/medical-research-involving-children/ 4. Medical Research involving Adults Who Cannot Consent (2007): http://www.mrc.ac.uk/documents/pdf/medical-research-involving-adults-who-cannot-consent/
	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 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	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)	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
	(ARSAC) (UK): https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee		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 (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	
	Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk			Guidelines for Phase I Clinical Trials (2012): http://www.abpi.org.uk/our-work/library/guidelines/Pages/phase-1-trials-2012.aspx
	National Institute for Health Research: http://www.nihr.ac.uk/			Clinical Trials Toolkit: http://www.ct-toolkit.ac.uk/
	Health Research Authority (HRA): http://www.hra.nhs.uk/			Clinical Trials of Investigational Medicinal Products (CTIMPs) – Resource page: http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/clinical-trials-of-investigational-medicinal-products/

Country	Key Organizations	Legislation	Regulations	Guidelines
	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): http://www.abpi.org.uk			1. Insurance and Compensation in the Event of Injury in Phase I Clinical Trials (2012): http://www.abpi.org.uk/our-work/library/guidelines/Pages/clinical-trials-insurance.aspx 2. Clinical Trial Compensation Guidelines (2014): http://www.abpi.org.uk/our-work/library/guidelines/Pages/ct-compensation.aspx

Country	Key Organizations	Legislation	Regulations	Guidelines
	Association of the British Healthcare Industry (ABHI): http://www.abhi.org.uk/			Clinical Investigations Compensation Guidelines (2014): http://www.abhi.org.uk/multimedia/groups/clinical-investigations/ci_compensationguidelines.doc
Privacy/Data Protection	*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:			
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Country	Key Organizations	Legislation	Regulations	Guidelines
		3. Statutory Instrument 2006 No. 1659: The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 *(Different provisions apply to England, Wales, Northern Ireland, and/or Scotland.):* http://www.legislation.gov.uk/uksi/2006/1659/contents/made		
	Medical Research Council (MRC): https://www.mrc.ac.uk/			Human Tissue and Biological Samples for Use in Research (2014)
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