Country	Key Organizations	Legislation	Regulations	Guidelines
NORTH AMERICA				
Canada				
General Note: Several Canadian provinces and territories also have human subject research standards.	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 2. National Defence 3. Correctional Service of Canada			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition (2010): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/ National Defence: Research Involving Human Subjects (1998): http://www.admfincs-smafinsm.forces.gc.ca/dao-doa/5000/5061-1-eng.asp Correctional Service of Canada: Commissioner's Directive - Research: DCOO9 (2004): http://www.csc-scc.gc.ca/acts-and-regulations/009-cde-eng.shtml
Drugs and Devices	*Drugs*			
	1. Health Canada, Therapeutic Products Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index		1. Good Clinical Practice Consolidated Guideline (1997): http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php 2. Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials) (2004): http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 11: Clinical Trials (2010)
	Devices			
	Health Canada, Medical Devices: http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php		Medical Devices Regulations (SOR/98-282) (1998): http://laws.justice.gc.ca/en/f-27/sor-98-282/text.html	
Research Injury	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Article 3.2(j) (2010):
Privacy/Data Protection	1. Office of the Privacy Commissioner of Canada (OPC):	1. Privacy Act, Sections 7-8 (1983):	OPC: SOR/2001-6, SOR/2001-7, and	PRE: Tri-Council Policy Statement: Ethical

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Note: Each of the Canadian provinces and territories also has enacted privacy legislation.	http://www.privcom.gc.ca/index_e.asp 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 3. Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html	http://www.privcom.gc.ca/legislation/02_07_01_e.asp 2. Personal Information Protection and Electronic Documents Act, Articles 5 and 7 (2001): http://www.privcom.gc.ca/legislation/02_06_01_e.asp	SOR/2001-8 (December 13, 2000)	Conduct for Research Involving Humans, 2nd Edition, Chapter 5: Privacy and Confidentiality (2010) CIHR: CIHR Best Practices for Protecting Privacy in Health Research (2005): http://www.cihr-irsc.gc.ca/e/29072.html
Human Biological Materials	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 12: Human Biological Materials Including Materials Related to Human Reproduction (2010)
Genetic Research	1. Canadian Biotechnology Advisory Committee (CBAC): http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/Home 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 3. Biologics and Genetic Therapies Directorate: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php			CBAC: Genetic Research and Privacy (2004) PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 13: Human Genetic Research (2010)
Embryos, Stem Cells, and Cloning	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/eng/index 2. Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html	Assisted Human Reproduction Act (2004): http://www.hc-sc.gc.ca/hl-vs/reprod/hc-sc/legislation/index_e.html	Assisted Human Reproduction (Section 8 Consent) Regulations (2007)	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, Chapter 12, Section F (2010) CIHR: Updated Guidelines for Human Pluripotent Stem Cell Research (2010): http://www.cihr-irsc.gc.ca/e/42071.html

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United States All of the following departments and agencies subscribe to subpart A, often referred to as the Common Rule (last updated in 2005) of the relevant section of the Code of Federal Regulations. As indicated below, some departments and agencies subscribe to additional subparts: • Subpart B: Additional Protections for Pregnant Women, Human Fetuses, and Neonates (2001) • Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (1978) • Subpart D: Additional Protections for Children Involved as Subjects in Research (1991) • Subpart E: Institutional Review Board Registration Requirements (2009)				
General	Agency for International Development: www.usaid.gov/		22 CFR 225, Subpart A	Protection of Human Subjects in Research Supported by USAID: A Mandatory Reference for ADS Chapter 200 (2006): http://www.usaid.gov/policy/ads/200/200mbe.pdf
	Central Intelligence Agency: www.odci.gov/		Executive Order 12333, Subparts A, B, C, and D	
	Consumer Product Safety Commission: www.cpsc.gov/		16 CFR 1028, Subpart A	
	Department of Agriculture: www.usda.gov/wps/portal/usdahome/		7 CFR 1c, Subpart A	
	Department of Commerce: www.commerce.gov/		15 CFR 27	
	Department of Defense, Human and Animal RDT&E Protection Programs: www.dtic.mil/biosys/org/regulatory.html	United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects	1. 32 CFR 219, Subpart A 2. DoD Directive 3216.02 (2011): http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf *Army:* Army Regulation 70-25: http://ahrpo.amedd.army.mil/Regulations/armyregs.cfm *Navy:* 1. SECNAVINST 3900.39 series: http://www.fas.org/irp/doddir/navy/secnavinst/3900_39d.pdf 2. Marine Corps Order: 3900.18 series: http://www.med.navy.mil/bumed/humanresearch/Documents/HRPP/Resources/ReferenceMaterial/MCO%203900.18%20-%2021%20Jan%202011.pdf	

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			Air Force: AFI 40-402 (2005): http://www.e-publishing.af.mil/shared/media/epubs/AFI40-402.pdf *Office of the Under Secretary of Defense for Personnel and Readiness:* Research Regulatory Oversight Office, Human Research Protection Program Operating Instruction: http://home.fhpr.osd.mil/resources/policies/policies.aspx *Defense Threat Reduction Agency:* 1. DTRA Directive 3216.1 2. DTRA Instruction 3216.2	
	Department of Education: www.ed.gov/	1. Protection of Pupil Rights Amendment (1974) 2. Family Educational Rights and Privacy Act (1974)	1. 34 CFR 97 subparts A (1991) and D (1997) 2. 34 CFR 98 (1984) 3. 34 CFR 99 (2000) 4. 34 CFR 350.4(c) (1991) 5. 34 CFR 356.3(c) (1991)	
	Department of Energy: www.humansubjects.energy.gov		1. 10 CFR 745 (1991), Subpart A 2. DOE Order 443.1B 3. DOE Order 481.1	
	Department of Health and Human Services, Office for Human Research Protections: www.hhs.gov/ohrp/	Public Health Service Act (1993): http://www.hhs.gov/ohrp/humansubjects/guidance/statute.htm	45 CFR 46, Subparts A, B, C, D, and E: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html	Various: http://www.hhs.gov/ohrp/policy/index.html
	Department of Homeland Security: www.dhs.gov/	Public Law 108-458, Section 8306	1. 45 CFR 46, Subparts A-D 2. DHS Directive 026-04, Human Subjects Research (2007): https://www.dhs.gov/xlibrary/assets/foia/mgmt-directive-026-04-protection-of-human-subjects.pdf	
	Department of Housing and Urban Development: www.hud.gov/		24 CFR 60, Subpart A	
	Department of Justice: www.usdoj.gov/		1. 28 CFR 22 (1976) 2. 28 CFR 46 (1991), Subpart A	

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			3. 28 CFR 512 (1994)	
	Department of Transportation: www.dot.gov/		49 CFR 11, Subpart A	
	Department of Veterans Affairs: 1. Office of Research Oversight (ORO): http://www1.va.gov/oro/ 2. Office of Research and Development: www.research.va.gov		1. 38 FR 16 (1991), Subpart A 2. 38 CFR 17.85 (1998)	
	Environmental Protection Agency, Program in Human Research Ethics: http://www.epa.gov/osa/phre/		40 CFR 26 1. Subpart A: Common Rule 2. Subpart B: Prohibition of Intentional Exposure Research Conducted or Supported by EPA in Children and Pregnant or Nursing Women (2006) 3. Subpart C: Additional Protections for Observational Research Conducted or Supported by EPA in Pregnant Women and Fetuses (2006) 4. Subpart D: Additional Protections for Observational Research Conducted or Supported by EPA in Children (2006) 5. Subpart K: Regulation of Third-Party Intentional Exposure Research for Pesticides in Non-Pregnant, Non-Nursing Adults (2006) 6. Subpart L: Prohibition of Third-Party Intentional Exposure Research for Pesticides in Children and Pregnant or Nursing Women (2006)	Scientific and Ethical Approaches for Observational Exposure Studies (2008): http://www.epa.gov/nerl/sots/SEAOES_doc20080707.pdf
	National Aeronautics and Space Administration: www.nasa.gov/		14 CFR 1230, Subpart A	
	National Science Foundation: www.nsf.gov/		45 CFR 690, Subpart A	
Drugs and Devices	*Drugs*			
	Food and Drug Administration: http://www.fda.gov/Drugs/default.htm	1. Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (2010):	1. 21 CFR 50 (2011) 2. 21 CFR 312 (2011) 3. 21 CFR 56 (2009)	1. General: Good Clinical Practice and Human Subject Protections in FDA-Regulated Clinical Trials:

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		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	4. 21 CFR 314 (2011)	http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm 2. Drug-Specific: Numerous: 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 (2010): http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm	1. 21 CFR 50 (2011) 2. 21 CFR 56 (2011) 3. 21 CFR 807, Subpart E (2010) 4. 21 CFR 812 (2010) 5. 21 CFR 814 (2011)	1. Good Clinical Practice and Human Subject Protections in FDA-Regulated Clinical Trials: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm 2. Other: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm
Research Injury	Same as "General," listed above.		Sections 116(a)(6) and (7) of the Common Rule Subpart A.	
	Department of Defense, Regulatory Affairs: www.dtic.mil/biosys/org/regulatory.html		DoD Directive 3216.02, paragraph 5.3.4 (2002) *Air Force Instruction 40-402*, Protection of Human Subjects in Biomedical and Behavioral Research (2000)	
	Department of Veterans Affairs: 1. Office of Research Oversight (ORO): www1.va.gov/oro/ 2. Office of Research and Development: www.research.va.gov	38 CFR 17.85: Treatment of Research-Related Injuries to Human Subjects	Handbook 1200.5, Appendix F, Paragraph 2a(11)	
Privacy/Data Protection	Department of Health and Human Services: 1. National Institutes of Health (NIH): http://privacyruleandresearch.nih.gov/ 2. Office for Civil Rights (OCR): http://www.hhs.gov/ocr/hipaa/	1. Privacy Act, 5 U.S.C. § 552a (1974): http://www.justice.gov/opcl/privacyact1974.htm 2. Health Insurance Portability and Accountability Act (1996): http://www.gpo.gov/fdsys/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf 3. Confidential Information Protection and Statistical Efficiency Act (2002): http://www.eia.doe.gov/oss/CIPSEA.pdf	1. HIPAA Privacy Rule: Standards for Privacy of Individually Identifiable Health Information, Final Rule, 45 CFR parts 160 and 164 (2002): http://www.hhs.gov/ocr/hipaa/privrulepd.pdf 2. HIPAA Security Rule, 45 CFR parts 160, 162, and 164: http://www.hhs.gov/ocr/privacy/hipaa/administrative/index.html	NIH: Various guidelines on the Privacy Rule: http://privacyruleandresearch.nih.gov/

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Human Biological Materials	1. Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/ 2. Food and Drug Administration a. Office of In Vitro Diagnostic Device Evaluation and Safety: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm b. Center for Biologics Research and Evaluation: - Office of Cellular, Tissue and Gene Therapies - Office of Blood Research and Review: http://www.fda.gov/BiologicsBloodVaccines/default.htm			OHRP: 1. Issues to Consider in the Research Use of Stored Data or Tissues (1997) 2. Guidance on Research Involving Coded Private Information or Biological Specimens (2008) FDA: 1. Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable (2006): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078384.htm 2. In Vitro Diagnostic (IVD) Device Studies - Frequently Asked Questions (2010) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071230.pdf 3. CBER-Specific: Various: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/ucm094338.htm
Genetic Research	Department of Health and Human Services: 1. Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/ 2. National Institutes of Health, Office of Biotechnology Activities: http://www4.od.nih.gov/oba/	1. Research on Transplantation of Fetal Tissue, Public Law 103-43 2. Genetic Information Nondiscrimination Act (2008): http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ233.110.pdf		OHRP: Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (2009): http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html NIH: NIH Guidelines for Research Involving Recombinant DNA Molecules, Appendix M (2009): http://oba.od.nih.gov/rdna/nih_guidelines_oba.html
Embryos, Stem Cells, and Cloning	1. Food and Drug Administration, Center for Biologics Evaluation and Research: http://www.fda.gov/BiologicsBloodVaccines/default.htm	Research on Transplantation of Fetal Tissue. Public Law 103-43		FDA: Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products. October 14, 1993. 58 FR 53248

Country	Key Organizations	Legislation	Regulations	Guidelines
	2. National Academy of Sciences (NAS): http://www.nationalacademies.org/nrc/ 3. National Institutes of Health: http://stemcells.nih.gov/index.asp			NAS: 1. Guidelines for Human Embryonic Stem Cell Research (2005): http://www.nap.edu/catalog.php?record_id=11278 2. 2007 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research: http://books.nap.edu/catalog.php?record_id=11871 3. 2008 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research: http://books.nap.edu/catalog.php?record_id=12260 4. 2010 Final Report of the National Academies Human Embryonic Stem Cell Research Advisory Committee and 2010 Amendments to the National Academies Guidelines for Human Embryonic Stem Cell Research: http://www.nap.edu/catalog.php?record_id=12923 NIH: 1. Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Executive Order 13505 (2009) 2. NIH Guidelines on Human Stem Cell Research (2009) 3. NIH Human Embryonic Stem Cell Registry (2009) *Access:* http://stemcells.nih.gov/policy