International Compilation of Human Subject Research Protections

Second Edition

Compiled By:
Office for Human Research Protections
Department of Health and Human Services
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INTRODUCTION

This Compilation was developed for IRBs/Ethics Committees, researchers, funding agencies, and others who are involved in international research. The purpose is to help these groups familiarize themselves with the laws, regulations, and guidelines where the research will be conducted, to assure that those standards are followed appropriately.

Scope
This Compilation lists those countries for which laws, regulations, or guidelines pertaining to human subjects research could be identified. Countries for which no research standards could be identified are listed at the end of the Compilation.

The first edition of the Compilation (dated June 20, 2005) covered General and Drug research in 54 countries. This edition represents an expansion over the prior version in several respects:

1. Expands the listings to encompass 72 countries
2. Lists standards issued by international organizations
3. Includes updated information for General and Drug research
4. Provides a listing of the laws, regulations, and guidelines on the following additional topics:
    a. Privacy/data protection
    b. Human biological materials
    c. Genetic research

In order to focus the scope of the information, the table does not include:

1. Laws, regulations, or guidelines specific to:
    a. clinical bioethics
    b. medical devices
    c. adverse event reporting or insurance requirements
    d. clinical trial inspection procedures
    e. stem cell or embryo research
    f. assisted reproduction
    g. human tissue engineering
    h. research integrity, scientific misconduct, or conflict of interest
    i. informed consent or patient confidentiality in medical practice

2. Laws that represent enabling legislation, i.e., authorize an agency to promulgate human subjects regulations, but do not direct the content of those regulations.
3. Working papers, drafts, or discussion papers.

ORGANIZATION

The countries are listed alphabetically within their respective continents. The listing for each country can be accessed by going to page 5 and clicking on the name of the desired country.

Organization of Columns
The information is organized into four columns:

1. Key Organizations – include those groups that develop regulations and/or issue guidelines for human subjects research.
2. Legislation -- includes laws, legislative decrees, and constitutional provisions, if any, that relate to human subject protections.
3. Regulations -- refer to instruments that are created and issued under the name of governmental administrative bodies, or other instruments that have the force of regulation by virtue of being required in order to receive research funding or governmental approval.
4. Guidelines -- refer to non-binding instruments.

When available, the year of the document's initial approval or most recent modification is indicated.

Organization of Rows
The rows categorize standards as pertaining to General, Drug, Privacy/Data Protection, Human Biological Materials, or Genetic Research.

1. General

This section includes standards that apply to the full range of research issues. In some countries, condition-specific (e.g., HIV infection) and/or population-specific guidelines also have been developed. In most countries, standards that govern drug research are different than the general research standards.

2. Drugs

This section lists the standards specific to pharmaceutical research.

3. Privacy/Data Protection

This section lists the laws, regulations, and guidelines that address the collection, storage, and use of data with personal information. In most cases these standards apply to electronic databases established for research purposes.

4. Human Biological Materials

Human biological materials are often stored in a repository referred to as "biobank" or "tissue bank." Because biobanks usually attach personal identifiers to the biological materials, biobanks also need to follow appropriate data protection standards. In some countries, laws and regulations regarding blood banking, transplantation, and/or autopsies may also influence the operations of research biobanks. This section does not include guidelines from medical specialty organizations.

5. Genetic Research

This section addresses research to elucidate or modify (often referred to as “gene therapy” or “genetic engineering”) a research subject’s genetic make-up. The laws, regulations, and guidelines on privacy/data protection and human biological materials sometimes cover genetic research, as well. This section does not address embryonic stem cell research.

HOW TO ACCESS A DESIRED DOCUMENT

In most cases, the documents are available in English. When the link is to a non-English language website or document, the language is indicated in parenthesis.

Documents can be accessed in several ways:

1. For laws, the web address is listed whenever available. Note that in some cases the laws are not available in English, or the English translation may be a non-official version.
2. For regulations and guidelines, there are three ways to access the desired document:
    a. Go to the website of the agency listed in the Key Organizations column and look for the sub-page labeled “guidance,” “regulations,” or similar terms.
    b. Go to the website of the corresponding agency and e-mail a request for the document.
    c. Perform a web search on the document title.
3. The local research ethics committee also should be able to provide information about applicable laws, regulations, and guidelines.

Note that in a few countries, the pertinent laws, regulations, or guidelines are available only by purchase.

DATA COLLECTION AND VERIFICATION

To compile this information, numerous published documents were reviewed and pertinent information was extracted. Then, internet searches were performed by cross-referencing the country name with the following search terms: “human subject protections,” “bioethics,” and “drug research.” National bioethics committees, persons listed in the UNESCO Bioethics Database, and/or other knowledgeable persons were contacted. Whenever possible, the compiled information was then verified by one or more in-country persons.

A number of groups provided useful data:

1. Canadian Interagency Advisory Panel on Research Ethics
2. Canadian National Council on Ethics in Human Research
3. Comac Medical (Bulgaria)
4. Council of Europe Bioethics Division
5. Federation of Latin American and Caribbean Bioethics Institutions
6. Food and Drug Administration, Office of International Programs
7. Fred Hutchinson Cancer Research Center
8. Global Forum on Health

9. India Council of Medical Research
10. National Institutes of Health, Office of Biotechnology Activities
11. Pan American Health Organization, Bioethics Unit
12. Research Ethics in Central and Eastern Europe, Advanced Certificate Program
13. South African AIDS Vaccine Programme
14. South African Research Ethics Training Initiative
15. Swedish Research Council
16. University of Miami Ethics Programs

Much of the information about privacy/data protection was obtained from three sources:

1. Privacy Exchange: http://www.privacyexchange.org/legal/nat/omni/nol.html
2. Privacy International: http://www.privacyinternational.org/index.shtml
3. PRIVIREAL: http://www.privireal.group.shef.ac.uk/

A useful document in compiling the information on genetic research was the European Commission's Survey on National Legislation and Activities in the Field of Genetic Testing in EU Member Countries: http://europa.eu.int/comm/research/biosociety/pdf/bioethics-survey-test2106.pdf

OTHER INFORMATION

Updates and Broken Links

Compilation updates and broken links should be reported to the attention of Edward E. Bartlett, PhD, Office for Human Research Protections, International Activities Program, at: ebartlett@osophs.dhhs.gov

Disclaimer

Though 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 laws, regulations, and guidelines are issued on a continuing basis, this Compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to international human subject research protections. While reasonable efforts have been made to assure the accuracy and completeness of the information provided, researchers and other individuals should check with local authorities and/or research ethics committees before starting research activities.

LISTING BY REGION

LISTING BY COUNTRY

Country	Key Organizations	Legislation	Regulations	Guidelines
INTERNATIONAL				
General	1. Office of the United Nations High Commissioner for Human Rights (OHCHR): http://www.ohchr.org/english/ 2. UNAIDS: http://www.unaids.org/en/default.asp 3. Council for International Organization of Medical Sciences (CIOMS): http://www.cioms.ch/ 4. World Medical Association (WMA): http://www.wma.net/e/			OHCHR: International Covenant on Civil and Political Rights, Article 7 (1976) UNAIDS: Ethical Considerations in HIV Preventive Vaccine Research (2000) CIOMS: International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) WMA: Declaration of Helsinki (2004)
Drugs	1. World Health Organization, Health Technology and Pharmaceuticals (WHO): http://www.who.int/en/ 2. International Conference on Harmonization (ICH): http://www.ich.org/			WHO: Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products (1995) ICH: E6 Good Clinical Practice: Consolidated Guidance (1996)
Privacy/Data Protection	World Medical Association: http://www.wma.net/e/index.htm			Declaration on Ethical Considerations Regarding Health Databases (2002)
Human Biological Materials	World Health Organization: http://www.who.int/en/			Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research (2003)
Genetic Research	1. UNESCO Bioethics Program: http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html 2. WHO Human Genetics Program (WHO): http://www.who.int/genomics/en/ 3. Human Genome Organization (HUGO): http://www.hugo-international.org/			UNESCO: 1. Universal Declaration on the Human Genome and Human Rights (1997) 2. International Declaration on Human Genetic Data (2003) WHO: Proposed International Guidelines on Ethical Issues in Medical Genetics and

				Genetic Services (1998) HUGO: 1. Statement on DNA Sampling: Control and Access (1998) 2. Statement on Gene Therapy Research (2001) 3. Statement on Human Genomic Databases (2002)

Country	Key Organizations	Legislation	Regulations	Guidelines
NORTH AMERICA				
Canada				
General	*National:*			
	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/english/ 2. National Council on Ethics in Human Research: http://www.ncehr-cnerh.org/english/home.php 3. Canadian Institutes for Health Research: http://www.cihr-irsc.gc.ca 4. Association of Canadian Universities for Northern Studies (ACUNS): http://www.acuns.ca/En/acunsEnMain.htm			PRE: 1. Correctional Services Canada: Commissioner's Research Directives: DCOO9 (1987) 2. Royal Commission on Aboriginal People: Ethical Guidelines for Research (1993) 3. National Defence: Research Involving Human Subjects (1998) 4. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2004) ACUNS: Ethical Principles for the Conduct of Research in the North (2003)
	Northwest Territories:			
	Aurora Research Institute: http://www.nwtresearch.com/	Scientist Act (1988): http://www.canlii.org/nt/laws		
	Nunavut:			
	Nunavut Research Institute	Nunavut Scientists Act (1988): http://www.nunavutcourtofjustice.ca/library/consolacts.htm		
	Quebec :			
	1. Quebec Minister of Health and Social Services, Ethics Unit (MSSS) (French): http://ethique.msss.gouv.qc.ca/site/accueil.phtml 2. Fund for Health Research of Quebec (FRSQ): http://www.frsq.gouv.qc.ca/en/ethique/ethique.shtml 3. Fund for Research on Society and Culture (FQRSC) (French):	1. Quebec Civil Code, Section 21 : Articles 11, 20, 21, 35, and 37 : http://www.canlii.org/qc/laws 2. An Act Respecting Health Services and Social Services, RSQ, Chapter S-4.2: Articles 19.1 and 19.2: http://www.canlii.org/qc/laws/sta/s-4.2/20050211/whole.html	MSSS: 1.Terms of Reference for the Designated or Instituted Research Ethics Boards (1998) 2. Ministerial Action Plan on the Ethics of Research and Scientific Integrity (1998) Code of Ethics of Physicians, R.Q., c. M-9, r. 4.1: Sections 28, 29, 30, 31, 45, 48,	MSSS: Contribution of Private Companies within the Framework of Research Activities Derived from Research Grants (2003) FRSQ: Research Ethics and Scientific Integrity Guidelines (2003)

	http://www.fqrsc.gouv.qc.ca/comm_publ/pdf/ethique190902.pdf		61, and 78 (2005): http://www.canlii.org/qc/laws/regu/m-9r.4.1/20050211/whole.html	
	Yukon Territory:			
	Government of Yukon, Department of Tourism and Culture	Yukon Scientists and Explorers Act (2000): http://www.canlii.org/yk/laws/sta/200/20041124/whole.html		
Drugs	Health Canada, Therapeutic Products Directorate: http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_e.html		1. Good Clinical Practice Consolidated Guideline (1997) 2. Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials) (2004)	
Privacy/Data Protection	*National:*			
	1. Office of the Privacy Commissioner of Canada (OPC): http://www.privcom.gc.ca/index_e.asp 2. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/english/	1. Privacy Act, Sections 7-8 (1983): http://www.privcom.gc.ca/legislation/02_07_01_e.asp 2. Personal Information Protection and Electronic Documents Act, Articles 5 and 7 (2001): http://www.privcom.gc.ca/legislation/02_06_01_e.asp Note: Each of the Canadian provinces and territories has enacted privacy legislation, which can be found at http://www.privcom.gc.ca/information/comms_e.asp	OPC: SOR/2001-6, SOR/2001-7, and SOR/2001-8 (December 13, 2000)	PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 3: Privacy and Confidentiality (2004)
Human Biological Materials	Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/english/			Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 10: Human Tissue (2004)
Genetic Research	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/english/ 2. Canadian Biotechnology Advisory Committee (CBAC): http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/Home 3. Biologics and Genetic Therapies Directorate: http://www.hc-sc.gc.ca/hpfb-			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 8: Human Genetic Research (2004) CBAC: Genetic Research and Privacy (2004)

	dgpsa/bgtd-dpbtg/aboutus_e.html			
United States				
General	Department of Health and Human Services, Office for Human Research Protections (OHRP): www.hhs.gov/ohrp/	1. National Research Act (1974): http://www.hhs.gov/ohrp/humansubjects/guidance/statute.htm 2. National Institutes of Health Revitalization Act (1993): http://www.hhs.gov/ohrp/humansubjects/guidance/statute.htm	45 CFR 46, subparts A (2005), B (2001), C (1978), and D (1991) Note: The following other federal departments and agencies also follow subpart A, often referred to as the "Common Rule": Agency for International Development, Central Intelligence Agency, Consumer Product Safety Commission, Department of Agriculture, Department of Commerce, Department of Defense, Department of Education, Department of Energy, Department of Housing and Urban Development, Department of Justice, Department of Veterans Affairs, Department of Transportation, Environmental Protection Agency, National Aeronautics and Space Administration, and National Science Foundation.	Various: www.hhs.gov/ohrp/policy/index.html#topics
Drugs	Food and Drug Administration: www.fda.gov	1. Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (2004): http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm 2. Public Health Service Act, 42 USC Section 262 (1944): http://www.fda.gov/opacom/laws/phsvcact/phsvcact.htm	1. 21 CFR 50 (1980) 2. 21 CFR 312 (1987) 3. 21 CFR 56 (2001)	Various: www.fda.gov/oc/ohrt/irbs/default.htm Guidances and Information Sheets on Good Clinical Practice in FDA-Regulated Clinical Trials: www.fda.gov/oc/gcp/guidance.html
Privacy/Data Protection	1. Department of Health and Human Services, Office for Civil Rights (OCR): http://www.hhs.gov/ocr/hipaa/ 2. Department of Health and Human Services, National Institutes of Health (NIH):	Health Insurance Portability and Accountability Act (1996): http://www.hhs.gov/ocr/hipaa/privrulepd.pdf	OCR: Privacy Rule (2002)	OCR: Standards for Privacy of Individually Identifiable Health Information (2003) NIH: Health Services Research and the HIPAA Privacy Rule (2005)

	http://privacyruleandresearch.nih.gov/			
Human Biological Materials	Department of Health and Human Services, Office for Human Research Protections (OHRP): 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 (2004)
Genetic Research	National Institutes of Health, Office of Biotechnology Activities: http://www4.od.nih.gov/oba/			NIH Guidelines for Research Involving Recombinant DNA Molecules (2002)

EUROPE				
	Key Organizations	**Legislation**	**Regulations**	**Guidelines**
European Union				
General	1. Council of Europe, Bioethics Department (COE): http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/ 2. European Group on Ethics in Science and New Technologies (EGE): http://europa.eu.int/comm/european_group_ethics/index_en.htm			COE: 1. Recommendation No. R (89) 4 on Collection of Epidemiological Data on Primary Health Care (1989) 2. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18 (1999) 3. Additional Protocol on Biomedical Research (2005) EGE: Ethical Aspects of Clinical Research in Developing Countries (2003)
Drugs	1. European Commission, Enterprise Directorate-General, Pharmaceuticals Unit (EC): http://pharmacos.eudra.org/F2/home.html 2. European Medicines Agency (EMEA): http://www.emea.eu.int Note: Directives of the European Commission take effect when the EU member countries enact implementing laws or regulations.	EC: 1. Directive 2001/20/EC (2001): http://pharmacos.eudra.org/F2/eudralex/vol-1/DIR_2001_20/DIR_2001_20_EN.pdf 2. Directive 2005/28/EC (2005): http://pharmacos.eudra.org/F2/eudralex/vol-1/DIR_2005_28/DIR_2005_28_EN.pdf	EC: 1. Detailed Guidance on the European Clinical Trials Database (EUDRACT Database) (2004) 2. Detailed Guidance on the Application Format and Documentation to be Submitted in an Application for an Ethics Committee Opinion on the Clinical Trial on Medicinal Products for Human Use (2004) 3. Detailed Guidance for the Request for Authorisation of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authorities, Notification of Substantial Amendments and Declaration of the End of the Trial (2004)	EMEA: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997) EC: Notice to Applicants: Questions & Answers, Clinical Trial Documents (2005)
Privacy/Data Protection	1. Council of Europe (COE): http://www.coe.int/ 2. European Commission (EC): http://europa.eu.int/	EC: Data Protection Directive 95/46/EC of the European Parliament and of the Council (1995):		COE: 1. Recommendation No. R (83) 10 on the Protection of Personal Data Used for Scientific Research and Statistics (1983) 2. Convention for the Protection of

		http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31995L0046&model=guichett		Individuals with Regard to Automatic Processing of Personal Data (1985) 3. Recommendation No. R (97) 5 on the Protection of Medical Data (1997)
Human Biological Samples	1. European Commission (EC): http://europa.eu.int/ 2. European Group on Ethics in Science and New Technologies (EGE): http://europa.eu.int/comm/european_group_ethics/index_en.htm 3. Council of Europe (COE): http://www.coe.int/ 4. European Medicines Agency (EMEA): http://www.emea.eu.int	EC: 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 (2004): http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_102/l_10220040407en00480058.pdf		EGE: Ethical Aspects of Human Tissue Banking (1998) COE: Draft Instrument on the Use of Archived Human Biological Materials in Biomedical Research (2002) EMEA: Concept Paper on the Development of a Guideline on Biobanks Issues Relevant to Pharmacogenetics (2005)
Genetic Research	Council of Europe: http://www.coe.int/			Recommendation No. R (92) on Genetic Testing and Screening for Health Care Purposes (1992)
Austria				
General	1. Austrian Ethics Commissions (German): http://www.ethikkommissionen.at 2. Ministry of Health (German): http://www.bmgf.gv.at	1. University Act (2002): http://www.ris.bka.gv.at/erv/erv_2002_1_120.pdf 2. Hospitals Act (2002) (German): http://ris.bka.intra.gv.at/bundesrecht/		
Drugs	Ministry of Health (German): http://www.bmgf.gv.at	Austrian Drug Law (2004) (German): http://www.ris.bka.gv.at/	Notice on How to Conduct Clinical Trials	
Privacy/Data Protection	Austrian Data Protection Commission: http://www.dsk.gv.at/indexe.htm	Federal Act Concerning the Protection of Persons (DSG) (2000): http://www.dsk.gv.at/indexe.htm See also: http://www.dsk.gv.at/landes.htm		
Genetic Research	1. Gene Technology Commission (German): http://www.bmgf.gv.at/cms/site/them	Gene Technology Act No. 510 (1994) (German): http://www.bmgf.gv.at/cms/site/		

	en.htm?channel=CH0252 2. Austrian Bioethics Commission: http://www.bundeskanzleramt.at/DesktopDefault.aspx?TabID=3557&Alias=english	detail.htm?thema=CH0264&doc=CMS1085735125660		
Belgium				
General	Consultative Bioethics Committee (French and Flemish): http://www.health.fgov.be/bioeth	Law on Human Experimentation (2004) (French and Flemish): http://www.ulb.ac.be/erasme/fr/visiteguidee/organisation/organigramme/conseilscomites/ethique/essai/loi180504/moniteur180504.pdf		1. Opinion No. 13: Regarding Experimentation on Man (2001) 2. Opinion No. 31: Regarding Experimentation Involving Pregnant and Breastfeeding Women (2004)
Drugs	Directorate-General for Medicinal Products (French and Flemish): http://www.afigp.fgov.be/		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)	
Privacy/Data Protection	Commission for the Protection of Privacy (French and Flemish): http://www.privacy.fgov.be/	Law of December 8, 1992 on Privacy Protection in Relation to the Processing of Personal Data	Decree of February 13, 2001 Implementing the Law of December 8, 1999 (French and	

		as Modified by the Law of December 11, 1998 Implementing Directive 95/46/EC (French and Flemish): http://www.law.kuleuven.ac.be/icri/itl/12privacylaw.php	Flemish): http://www.privacy.fgov.be/normatieve_teksten/AR%20KB%2013%20fév%202001.pdf	
Bosnia				
Drugs	Ministry of Health	Law on Drugs and Pharmacies, Art. 28		
Privacy/Data Protection		Law on the Protection of Personal Data in Bosnia and Herzegovina (2001): http://www.privacyinternational.org/article.shtml?cmd[347]=x-347-63545		
Bulgaria				
General	Ministry of Health	Law for Drugs and Pharmacies in Human Medicine (1997)		
Drugs	1. Ministry of Health (MOH) 2. Bulgarian Drug Agency (BDA): www.bda.bg/	Law for Drugs and Pharmacies in Human Medicine (1997)	MOH: Regulation No. 14 on the Conditions and Order for Conducting Clinical Trials of Drugs on Human Subjects (2000)	BDA: Guidelines of Good Clinical Practice (1997)
Privacy/Data Protection	Commission for Protection of Personal Data: http://xdata.gateway.bg/htmls/en/home.htm	Law for Protection of Personal Data (2002)		
Czech Republic				
General	1. Ministry of Health, Central Ethics Committee (Czech): http://www.mzcr.cz 2. Research and Development Council, Bioethics Committee: http://www.vyzkum.cz/FrontClanek.aspx?idsekce=1018			
Drugs	1. Ministry of Health (MOH) (Czech): http://www.mzcr.cz 2. State Institute for Drug Control (SUKL): http://www.sukl.cz/enindex.htm	Drug Act No. 79 Coll. on Pharmaceuticals and on Amendments to Some Related Acts (1997)	MOH: Ministerial Decree on Good Clinical Practice and Detailed Conditions of Clinical Trials in Pharmaceuticals 301/2003 (2003): http://www.sukl.cz/en08/en0804.htm	SUKL: Reporting of Adverse Reactions for Human Medicinal Products in Clinical Trials (2005)

Privacy/Data Protection	Office for Personal Data Protection: http://www.uoou.cz/eng/index.php3	Personal Data Protection Act No. 101 (2000): http://www.uoou.cz/eng/101_2000.php3		
Denmark				
General	1. Danish Central Scientific Ethical Committee (CVK): http://www.cvk.im.dk/visArtikel.asp?artikelID=1537 2. Danish Council of Ethics (DCE): http://www.etiskraad.dk/sw293.asp	Act on the Biomedical Research Ethics Committee System (2003): http://www.cvk.im.dk/visArtikel.asp?artikelID=1606	CVK: Ministerial Order of October 12, 2000	CVK: Guidelines on Biomedical Experiments (2000)
Drugs	Danish Medicines Agency: http://www.dkma.dk	Medicinal Product Act No. 382 (2003)	1. Executive Order No. 935 on Informed Consent from Patients in Biomedical Trials (2000) 2. Executive Order on Clinical Trials on Medicinal Products, Human Use (2004) 3. Danish Guideline on Notification of Clinical Trials of Medicinal Products in Humans (2004)	Guideline on Informed Consent from Patients in Biomedical Trials (2000)
Privacy/Data Protection	1. Danish Data Protection Agency (DPA): http://www.datatilsynet.dk/eng/index.html 2. Danish Council of Ethics (DCE): http://www.etiskraad.dk/sw293.asp 3. Ministry of Science Technology and Research (VTU) (Danish): http://www.videnskabsministeriet.dk/cgi-bin/news-archive-list.cgi	Act No. 429/2000 on Processing of Personal Data (2000): http://www.datatilsynet.dk/eng/index.html	VTU: Ministerial Order on the Giving of Information to, and the Obtaining of Consent from, Trial Subjects in Biomedical Research Projects (2000)	DCE: Protection of Sensitive Personal Information Other guidelines can be accessed at: http://www.privireal.group.shef.ac.uk/content/dp/denmark.php
Human Biological Materials		1. Act on the Biomedical Research Ethics Committee System (2003): http://www.cvk.im.dk/visArtikel.asp?artikelID=1606 2. Law on Biobanks No. 312 (2003): http://www.etiskraad.dk/sw2296.asp		
Estonia				
Drugs	State Agency of Medicines: http://www.sam.ee/	Medicinal Products Act (2005): http://www.sam.ee/627		

Privacy/Data Protection		1. Personal Data Protection Act (1996) 2. Databases Act (1997)		
Genetic Research	Estonian Genome Project Foundation: http://www.geenivaramu.ee/index.php?show=main&lang=eng	Human Genes Research Act RT I 2000, 104, 685 (2000): http://www.geenivaramu.ee/index.php?lang=eng&sub=18&eetika=1		
Finland				
General	1. Ministry of Social Affairs and Health (MSAH) 2. ETENE Sub-Committee on Medical Research Ethics (TUKIJA): http://www.etene.org/e/tukija/index.shtml/ 3. National Advisory Board on Research Ethics (TENK): http://pro.tsv.fi/tenk/english1.htm	Medical Research Act No. 295/2004 (2004) English: http://www.finlex.fi/en/laki/kaannokset/1999/en19990488 Finish: http://www.finlex.fi/fi/	MSAH: 1. Decree on the National Advisory Board on Health Care Ethics No. 494/1998 (1998) 2. Decree on Medical Research and Subsidiary Regulations Issued in Pursuance Hereof, No. 986/1999 (1999) 3. Decree on the National Research Ethics Council of Finland No. 1347/2002 (2002)	TUKIJA: Checklist for Researchers and Members of Ethics Committees (2001)
Drugs	National Agency for Medicines: http://www.nam.fi/english/index.html	Medicines Act and Decree No. 296/2004 (2004): http://www.nam.fi/uploads/english/Legislation/Medicines_act_and_decree_04-12-10.pdf	Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2004 (2004)	
Privacy/Data Protection	Office of the Data Protection Ombudsman: http://www.tietosuoja.fi/1560.htm	1. Personal Data Act No. 523/1999 (1999): http://www.tietosuoja.fi/uploads/hopxtvf.HTM 2. Act on the Amendment of the Personal Data Act No. 986/2000 (2000): http://www.tietosuoja.fi/uploads/p9qzq7zr3xxmm9j.rtf		
Human Biological Samples		Act on the Medical Use of Human Organs and Tissues No. 101/2001 (2001): http://www.finlex.fi/pdf/saadkaan/E0010101.PDF		
France				
General	1. General Health Administration (GHA) (French):	Note: Unless otherwise specified, all French laws that	GHA: 1. Protection of Persons who	CCNE: Note: Only guidelines issued since 1992

	http://www.sante.gouv.fr 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	govern human subjects research can be found at the following web site (French): http://www.legifrance.gouv.fr/. From there, go to "Les Codes," then to "Code de la Santé Publique" (Public Health Code), then to "Nouvelle Partie Législative" (New Legislative Part), and then scroll down to the indicated Article. 1. Biomedical Research (Loi Huriet-Sérusclat), Articles L1121-1 to L1126-7 (2004) (French): http://www.legifrance.gouv.fr/ 2. Decree No. 97-555 Concerning the National Consultative Ethics Committee for Health and Life Sciences (1997): http://www.ccne-ethique.fr/english/start.htm	Participate in Biomedical Research (Public Health Code, Regulatory Section, Additional Book II, Articles R.2001 to R.2053) 2. Decision of August 20, 2002	are listed here. The complete list can be found at: http://www.ccne-ethique.fr/english/start.htm, then go to List of Opinions. 1. Opinion on Ethics Committees (1992) 2. Cooperation in the Field of Biomedical Research between French Teams and Teams from Economically Developing Countries. Report (1993) 3. Opinion on the Ethics of Research in the Sciences of Human Behaviour. Report (1993) 4. Informed Consent of and Information to Persons Accepting Care or Research Procedures (1998) 5. Opinion on the Preliminary Draft Revision of the Laws on Bioethics (2001) 6. Disparity in Access to Health Care and Participation in Research on a Global Level – Ethical Issues (2003)
Drugs	1. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr 2. French Health Products Safety Agency (AFSSAPS): http://agmed.sante.gouv.fr/ang/indang.htm	Medications for Human Use, Articles L5121-11, L5124-1, and L5126-1) (2004): http://www.legifrance.gouv.fr/.		CCNE: 1. Phase I Trials in Cancer (2002) 2. Transposition into French Law of the European Directive Relating to Clinical Trials on Medicinal Products: A New Ethical Framework for Human Research (2003)
Privacy/Data Protection	1. National Commission of Information and Liberty: http://www.cnil.fr/index.php?id=4 2. National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr	Law 2004-801 of August 6, 2004 Modifying Law 78-17 of January 6, 1978 Relating to the Protection of Data Subjects as Regards the Processing of Personal Data (2004) (French): http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=JUSX0100026L%20		CCNE: Ethical Questions Arising from the Transmission of Scientific Information Concerning Research in Biology and Medicine (1995)
Human Biological Materials	National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-	Donation and Use of the Components and Products of the Human Body, Articles L1211-1		1. Umbilical Cord Blood Banks for Autologous Use for Research (2002) 2. Ethical Issues Raised by Collections of

	ethique.fr	to L1274-3 (2004) (French): http://www.legifrance.gouv.fr/		Biological Material and Associated Information Data: "Biobanks," "Biolibraries" (2003)
Genetic Research	National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr			1. Opinion on Gene Therapy (1990) 2. Opinion regarding the Application of Genetic Testing to Individual Studies, Family Studies and Population Studies. (Problems related to DNA "Banks," Cell "Banks," and Computerization) (1991) 3. Opinion that the Human Genome should not be used for Commercial Purposes. Report. Thoughts Relating to Ethical Problems of Human Genome Research (1991) 4. Opinion on the Use of Somatic Gene Therapy Procedures. Report (1993)
Germany				
General	1. National Ethics Council (NEC) (German): http://www.ethikrat.org 2. Working Group of the Medical Ethics Committees in Germany (German): http://www.ak-med-ethik-komm.de/ 3. Robert Koch Institute (RKI): http://www.rki.de/cln_011/nn_226928/EN/Home/homepage__node.html__nnn=true		NEC: Decree Establishing a National Ethics Council (2001)	
Drugs	1. Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/en/index.php/ 2. Federal Ministry of Education and Research (BMBF): http://www.bmbf.de/en/index.php	Drug Law of the Federal Republic of Germany (AMG), Sections 40-42 (2000): http://www.bmgs.bund.de/downloads/AMG-englische_Fassung.pdf 12th Amendment to the AMG (2004) (German): http://www.ethik-kommission.uniklinik-freiburg.de/pdf/12_amg_novelle.pdf	BfArM : 1. Promulgation on the Principles of the Conduct of Clinical Trials of Drugs According to the Rules (1987) 2. Second Promulgation on the Clinical Trial of Drugs in Human (1997) 3. Regulation for the Application of Good Clinical Practice of Clinical Medications for Human Use (2004) BMBF: Principles and Responsibilities	

			Related to Clinical Studies (2003)	
Privacy/Data Protection	Federal Data Protection Commissioner: http://www.bfd.bund.de/information/infos_engl.html	Federal Data Protection Act, as Amended (2003): http://www.bfd.bund.de/information/bdsg_eng.pdf The German states have additional laws about data protection (German): http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html		
Human Biological Materials	1. German Institute for Cell and Tissue Replacement (DIZG) (German): http://www.dizg.de 2. National Ethics Council (NEC): http://www.ethikrat.org			DIZG: 1. Ethical Code: (2000) 2. Common Standards: Tissues and Cell Banking (2004) NEC: 1. Biobanks for Research – Opinion (2004) 2. Biobanks for Research – Statement (2004)
Genetic Research	1. German Society of Human Genetics (GFHEV): http://www.gfhev.de/en/gfh/ 2. German National Genome Research Network: http://www.ngfn.de/englisch/index.htm	Law of 20 June 1990 to Regulate Matters Related to Gene Technology (1990)		GFHEV: 1. Position Paper of the German Society of Human Genetics (1996) 2. DNA Banking and Personal Data in Biomedical Research: Technical, Social, and Ethical Questions (2004)
Greece				
Drugs	National Organization for Medicines: http://www.eof.gr/eof_en/enhome.html			
Privacy/Data Protection	Hellenic Data Protection Authority: http://www.dpa.gr	Data Protection Act No. 2472 (1997): http://www.dpa.gr/Documents/Eng/2472engl_all.doc		
Genetic Research	Hellenic Data Protection Authority: http://www.dpa.gr/home_eng.htm			Opinion No. 15/2001 (2001)
Hungary				
General	1. Ministry of Health (EüM): http://www.eum.hu/eum/eum_angol.main.page	1. Parliamentary Act No. CLIV, Chapter VIII (1997) 2. Parliamentary Act No. IV:	EüM: Decree on Biomedical Research on Human Beings 23/2002 (V. 9)	

	2. Medical Research Council, Scientific and Research Ethics Committee	Crimes Against the Order of Medical Interventions and Medical Research, and Against Self-Determination Related to Health Issues (1978) 3. Parliamentary Act No. VI (2002)	(2002)	
Drugs	1. Ministry of Health (EüM): http://www.eum.hu/eum/eum_angol.main.page 2. National Institute of Pharmacy: http://www.ogyi.hu/index.php?lang=en 3. Medical Research Council, Ethics Committee for Clinical Pharmacology	Medicines Act XXV (1998) (Hungarian): http://www.ogyi.hu/index.php?menu=menu&main=main/laws&lang=hu	EüM: Decree on Clinical Trials of Products for Human Use and the Application of Good Clinical Practice 24/2002 (V. 9) (2002)	
Privacy/Data Protection	Parliamentary Commissioner for Data Protection and Freedom of Information	Act LXIII of 1992 on Protection of Personal Data and Disclosure of Data of Public Interest, Amended by the Parliamentary Act No XLVIII of 2003: http://abiweb.obh.hu/dpc/legislation/1992_LXIIIa.htm		
Iceland				
General	Ministry of Health and Social Security: http://ministryofhealth.is	Act on the Rights of Patients No. 74 (1997): http://ministryofhealth.is/laws-and-regulations//nr/34	Regulation on Scientific Research in the Health Sector, No. 552 (1999)	
Drugs	Ministry of Health and Social Security, Medicinal Control Agency: http://ministryofhealth.is	Medical Products Act No. 93 (1994): http://ministryofhealth.is/media/Laws%20in%20english/The_Medicinal_Products_Act_No_93-1994.pdf	Regulation on Clinical Trials of Medicinal Products in Humans No. 443 (2004)	
Privacy/Data Protection	Data Protection Authority: http://www.personuvernd.is/tolvunefnd.nsf/pages/english	1. Health Sector Database Act No. 139 (1998): http://ministryofhealth.is/laws-and-regulations/nr/659 2. Act on the Protection of Privacy as Regards the Processing of Personal Data,	Government Regulation on a Health Sector Database No. 32 (2000)	

		No. 77/2000, as Amended: http://www.personuvernd.is/tolvunefnd.nsf/pages/A6B42A045297151D00256DB40053600B 3. Judgement by the Supreme Court of Iceland Concerning the Health Sector Database (2003): http://www.personuvernd.is/tolvunefnd.nsf/pages/60CD0F820FBD71D700256E4D004B1108		
Human Biological Samples	Ministry of Health and Social Security: http://ministryofhealth.is	Act on Biobanks No. 110 (2000): http://ministryofhealth.is/laws-and-regulations/nr/31	Regulations on the Keeping and Utilization of Biological Samples in Biobanks No. 134 (2001)	
Ireland				
General	1. Irish Council for Bioethics (ICB): http://www.bioethics.ie 2. Irish Medicines Board (IMB): http://www.imb.ie/			ICB: Operational Procedures for Research Ethics Committees: Guidance 2004 IMB: Guide to Clinical Trials (2004)
Drugs	Irish Medicines Board: http://www.imb.ie/	Control of Clinical Trials and Drug Act No. 17 (1990): http://www.irishstatutebook.ie/front.html	Statutory Instrument No. 190: European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations (2004)	
Privacy/Data Protection	Data Protection Commission: http://www.dataprivacy.ie/docs/Home/4.htm	1. Data Protection Act (1988): http://www.dataprivacy.ie/viewdoc.asp?Docid=64&Catid=47&StartDate=1+January+2005&m=l 2. Data Protection (Amendment) Act (2003): http://www.dataprivacy.ie/documents/legal/act2003.pdf	A number of Statutory Instruments have been approved: http://www.dataprivacy.ie/ViewDoc.asp?DocId=-1&CatID=47&m=l	
Human Biological Materials	Irish Council for Bioethics: http://www.bioethics.ie			Human Biological Material: Recommendations for Collection, Use, and Storage in Research (2005)
Italy				
General	1. National Federation of Ethics Committees (FNACE) (Italian): http://www.unich.it/fnace/	Statute on the National Federation of Ethics Committees (1995) (Italian):	FNACE: Regulation Implementing the Statute on the National Federal of	NBC: Opinion of the National Bioethics Committee on the European Protocol on

	2. National Monitoring Center for Clinical Trials (OSS): http://oss-sper-clin.sanita.it/ 3. National Bioethics Committee (NBC): http://www.governo.it/bioetica/eng/index.html 4. Ministry of Health (Italian): http://www.ministerosalute.it	http://www.unich.it/fnace/statuto.htm	Ethics Committees OSS: Ministerial Decree: Terms of Reference for the Establishment and the Functioning of Ethics Committees (March 18, 1998)	Biomedical Research (1999)
Drugs	1. National Monitoring Center for Clinical Trials: http://oss-sper-clin.sanita.it/index_ingl.htm 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): http://oss-sper-clin.sanita.it/normativa/dpr_439_fase_I_21-9-01.pdf 2. Legislative Decree No. 211 (2003): 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 (Italian): http://www.ministerosalute.it/ccm/documenti/D_Lgs24giugno2004_184.pdf Non-official English translation: http://oss-sper-clin.sanita.it/normativa/decreto_24062003_inglese.pdf	Italy has numerous regulations that govern drug research, which can be found at http://oss-sper-clin.sanita.it/normativa_ing.htm (Italian). The following regulations appear to be the most important: 1. Ministerial Decree: Composition and Determination of the Functions of the National Ethics Committee for Clinical Drug Research (Nov. 23, 1999) 2. Ministerial Decree: Controlled Clinical Trials in General Practice and Pediatrics (May 10, 2001) 3. Ministerial Decree: Therapeutic Use of Medicines After Clinical Experiments (May 8, 2003) 4. Ministerial Decree: Non-profit Controlled Clinical Trials with Medicines (Dec. 17, 2004)	
Privacy/Data Protection	Italian Data Protection Commission: http://www2.garanteprivacy.it/garante/frontdoor/1,1003,,00.html?LANG=2	Italian Personal Data Protection Code, Legislative Decree No. 196 of June 30, 2003 (2003): http://www.dataprotection.it/codice_privacy_english.htm	Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000)	
Genetic Research	Italian Society of Human Genetics: http://sigu.univr.it/			Guidelines for Genetic Biobanks (2003)
Latvia				
Drugs	State Agency of Medicines:		1. Cabinet Regulation No. 312 of	

	http://zaale.vza.gov.lv/english/index.html		12 September 2000 and Amendment of the Cabinet Regulation No. 291 (2000) 2. Regulation No. 506, Amendments to the Cabinet Regulations No. 312 of September 12, 2000 (2003) 3. Regulation No. 542, Amendments to the Cabinet Regulations No. 312 of September 12, 2000 (2004)	
Privacy/Data Protection	Ministry of Justice, State Data Inspectorate	Personal Data Protection Law (2000): http://www.privacyexchange.org/legal/nat/omni/latvialaw.html		
Genetic Research		Human Genome Research Act (2003)		
Lithuania				
Drugs	State Medicines Control Agency: http://www.vvkt.lt/engl/			
Privacy/Data Protection	Data Protection Authority	Law on Legal Protection of Personal Data, No. IX-1296 (2003): http://www3.lrs.lt/cgi-bin/preps2?Condition1=208886&Condition2		
Luxembourg				
Drugs	Ministry of Health (French): http://www.ms.etat.lu/			
Privacy/Data Protection	National Commission for Data Protection (French and German): http://www.cnpd.lu/	On the Protection of Persons with Regard to the Processing of Personal Data (2002): http://www.cnpd.lu/loi_langue_anglaise.pdf		
Macedonia				
General	Ministry of Health of Macedonia: www.zdravstvo.gov.mk			
Drugs	Macedonian Drug Agency (Macedonian): http://www.zdravstvo.gov.mk/sector_content.php?code=bl	Drug Law (1998) (Macedonian) http://www.zdravstvo.gov.mk/documents/documents/zakon_za_lekovi.pdf	Regulations on Clinical Trials of Medicinal Products on Human Subjects (1998)	
Genetic Research	Macedonian Academy of Sciences			

	and Arts Research Center for Genetic Engineering and Biotechnology: www.manu.edu.mk			
Malta				
Drugs	Medicines Authority: http://medicinesauthority.gov.mt/	See: http://medicinesauthority.gov.mt/legislation.htm	See: http://medicinesauthority.gov.mt/clinicaltrials.htm	Guidance Notes on Good Clinical Practice (2005)
Privacy/Data Protection	Data Protection Commissioner	Data Protection Act (2001): http://www.privacyinternational.org/countries/malta/Data%20Protection%20Act%20CHAPT440.pdf		
Netherlands				
General	Central Committee for Research Involving Human Subjects (CCMO): http://www.ipfier2.nl/main.asp?pid=1&taal=1	1. Population Screening Act (1996): http://www.gr.nl/wbo.php?phpLang=en 2. Medical Research Involving Human Subjects Act (1998): http://www.ipfier2.nl/hipe/uploads/downloads/WMO-English.doc 3. Medical Research (Human Subjects) Compulsory Insurance Decree (2003): http://www.ccmo.nl/download/verzekeringsbesluit_2003-eng.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)	Manual for the Review of Medical Research Involving Human Subjects (2002)
Drugs	1. Medicines Evaluation Board (MEB): http://www.cbg-meb.nl/uk/overcbg/index.htm 2. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/	Medicines Act, Article 29	MEB: Decree on Manufacturing and Delivering Medicinal Products, Article 55 (BBA)	CCMO: Clinical Research with Medicinal Products in the Netherlands (2004)
Privacy/Data Protection	1. Dutch Data Protection Authority: http://www.dutchdpa.nl/index.stm 2. Federation of Biomedical Scientific Societies (FMWV) (Dutch): http://www.fmwv.nl/	Personal Data Protection Act (2004) (Dutch): http://www.cbpweb.nl/indexen/ind_wetten_wbp_wbp.stm English translation of 2000 version: http://www.cbpweb.nl/indexen/ind_wetten_wbp_wbp.stm		FMWV: Code for Proper Secondary Use of Data (2002)
Human Biological	Federation of Biomedical Scientific	Civil Code, Article 467 (1994)		Code for Proper Secondary Use of Human

Materials	Societies (Dutch): http://www.fmwv.nl/	(Dutch): http://www.healthlaw.nl/wgboeng.html		Tissue in the Netherlands (2002)
Genetic Research	1. Dutch Health Care Inspectorate: http://www.igz.nl/indexie.html 2. Central Committee for Research Involving Human Subjects (CCMO): http://www.ccmo.nl/		Decree on Immunological Pharmaceutical Products (2001)	Guidelines for Researchers on the Evaluation by Official Agencies of Gene Therapy Research (2004) (Dutch): http://213.154.234.72/Documenten/Documenten%20IM/LeidraadGentherapieversie1-10-2004.pdf
Norway				
General	1. Ministry of Education and Research (MER) 2. National Committee for Medical Research Ethics (NEM): http://www.etikkom.no/Engelsk/NEM/nem 3. National Committee for Research Ethics in Science and Technology (NENT): http://www.etikkom.no/Engelsk/NENT/ 4. National Committees for Research Ethics (NCRE): http://www.etikkom.no/Engelsk/ 5. National Committee for Research Ethics in the Social Sciences and the Humanities (NESH): http://www.etikkom.no/Engelsk/NESH		MER: Terms of Reference for the Regional Committees for Medical Research Ethics, Norway (2003)	NEM: 1. Research Ethical Review in Norway (1998) 2. NEM: Standard Operating Procedures for the Regional Committees for Medical Research Ethics (2002) NENT: 1. Research Ethics for Research Councils (1992) 2. NENT: Guide to Research Ethics (1992) NESH: Guidelines for Research Ethics in the Social Sciences, Law, and the Humanities (2001) NCRE: Research Ethics Guidelines for Internet Research (2003)
Drugs	Norwegian Medicines Agency: http://www.legemiddelverket.no/eng/ct/clinicaltrials.htm	Medicines Act (1992): http://www.lovdata.no/info/lawdata.html	Regulations Concerning Clinical Trials of Human Drugs (1999)	Guidelines for the Regulations Concerning Clinical Trials of Human Drugs (1999)
Privacy/Data Protection	1. Data Inspectorate: http://www.datatilsynet.no/templates/Page____194.aspx 2. National Committee for Research Ethics in the Social Sciences and the Humanities (NESH): http://www.etikkom.no/Engelsk/NESH	Personal Data Act No. 31 (2000): http://www.datatilsynet.no.htest.osl.basefarm.net/upload/Dokumenter/regelverk/lov_forskrift/lov-20000414-031-eng.pdf	Regulations on the Processing of Personal Data (2003): http://www.datatilsynet.no.htest.osl.basefarm.net/upload/Dokumenter/regelverk/lov_forskrift/POF_eng.pdf Other regulations are listed here: http://www.privireal.group.shef.a	Research Ethics Guidelines for Internet Research (2003)

			c.uk/content/dp/norway.php	
Human Biological Materials	1. Ministry of Health and Care Services (MHCS) 2. Ministry of Education and Research (MER)	Act on Biobanks (2003) (Norwegian): http://www.lovdata.no/all/nl-20030221-012.html	MHCS: Guidelines for the Norwegian Act on Biobanks (2003) (Norwegian): http://odin.dep.no/hod/norsk/publ/rundskriv/042051-990014/ MER: Terms of Reference for the Regional Committees for Medical Research Ethics, Norway, Chapter 3 (2003)	
Genetic Research	National Committee for Research Ethics in Science and Technology (NENT): http://www.etikkom.no/Engelsk/NENT/	Medical Use of Biotechnology Act No. 56 (1994)		
Poland				
General	1. Ministry of Health, Bioethics Appeals Commission (MOH): http://www.kb.mz.gov.pl/index_en.html 2. Ethics Committee of the Supreme Council of Doctors (SCD)		MOH: Regulation of the Minister of Health (1999)	SCD: Code of Medical Ethics (2003)
Drugs	Ministry of Health, Office for Registration of Medical Products (Polish): http://www.mz.gov.pl	1. Medical Profession Act (1997) 2. Pharmaceutical Law, Act of Sept. 6, 2001 3. Act on Amendment of Pharmaceutical Law (2004)	1. Decree of the Minister of Health on Clinical Trials on Minors (2004) 2. March 11, 2005 Order of the Minister of Health Concerning Detailed Requirements of Good Clinical Practice (2005)	
Privacy/Data Protection	Inspector General for the Protection of Personal Data: http://www.giodo.gov.pl/168/j/en/	Act on the Protection of Personal Data (1997): http://www.giodo.gov.pl/data/filemanager_en/61.doc		
Portugal				
Drugs	National Institute of Pharmacy and Medicines, Clinical Trials: http://www.infarmed.pt/pt/ensaios_clinicos/index.html	Approval of the Applicable Legal Standards for the Conduct of Clinical Trials of Medicines for Human Use, Law No. 46/2004 (2004) (Portuguese): http://www.infarmed.pt/pt/legislacao/leg_farm_comp/ficheiros/l		

		ei_46_2004.pdf 2. Approval of the Composition, Operations, and Financing of the Ethics Committee for Clinical Research, Decree No. 57/2005 (2005) (Portuguese): http://www.infarmed.pt/pt/legislacao/leg_farm_comp/ficheiros/portaria_57-2005.pdf		
Privacy/Data Protection	National Data Protection Commission: http://www.cnpd.pt/english/index_en.htm	1. Constitution, Article 35 (1997) 2. Act No. 10/1995 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	Law 12/2005 (2005)		
Romania				
General	Ministry of Health (MOH) (Romanian): http://www.ms.ro/g_ms/ms.htm		Ordinance No. 57/16.08.2002 (2002)	
Drugs	1. Ministry of Health (MOH) (Romanian): http://www.ms.ro/g_ms/ms.htm 2. National Medicines Agency: http://www.anm.ro/en/home.html		MOH: 1. Order of MOH No. 615/2004 Transposing Directive 2001/20/EC of the European Parliament and of the Council (2004) 2. Order of MOH No. 1300/2004: Detailed Guidance on the Application Format and Documentation to be Submitted in an Application for an Ethics Committee Opinion on the Clinical Trial on Medicinal Products for Human Use (2004) 3. Order of MOH No. 1117/2004: Detailed Guidance for the Request for Authorization of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authorities, Approval of Substantial Amendments and Declaration of the End of the	MOH: Guideline for Clinical Trials in Pediatric Populations (CPMP/ICH/2711/99) (1999)

			Trial (2004)	
Privacy/Data Protection	People's Advocate: http://www.avp.ro/indexen.html	Law No. 677/2001 for the Protection of Persons Concerning the Processing of Personal Data and Free Circulation of Such Data (2001): http://www.avp.ro/leg677en.html		
Russia				
General	National Ethics Committee		National Ethics Committee Regulations (2000)	
Drugs	1. Ministry of Health (MOH) 2. Ethics Committee of the State Department for Control of Drug Quality 3. Scientific Center for Expertise of the Remedies for Medicinal Use (Russian): http://www.regmed.ru/ 4. Federal Supervision Service for Public Health and Social Affairs (Russian): http://www.roszdravnadzor.ru/	1. Federal Drug Law No. 86-OC, 22.06, Article 37 (1998) 2. Rules of the Conduct of Good Clinical Trials in the Russian Federation, Branch Standard OST-42-511-99 (1998) 3. On Medicinal Products, Federal Law No. 86-FZ (2001)	MOH: 1. Ministry of Health Order No. 16 (Jan. 24, 2000) 2. Ministry of Health Order No. 103 (March 24, 2000) 3. Rules of Clinical Practice in the Russian Federation, Minister's Decree #266 (2003)	
Privacy/Data Protection		1. Law of the Russian Federation on Information, Informatization, and Information Protection, No. 24-FZ (1995): http://www.datenschutz-berlin.de/gesetze/internat/fen.htm 2. Participation in International Information Exchange (1996)		
Serbia and Montenegro				
Serbia				
Drugs	1. Ministry of Health (MOH): http://www.zdravlje.sr.gov.yu/default.asp?lang=2&poe=30 2. Serbian Drug Agency: http://www.alims.sr.gov.yu/index_eng.htm	Law for Drugs and Pharmacies of the Republic of Serbia No. 84/2004 (2004)	MOH: 1. Regulation on Conducting Drug Clinical Trials on Human Subjects 2. Regulation for Conducting Clinical Trials	
Montenegro				
Drugs	1. Ministry of Health of Montenegro: www.mz.cg.yu	Law for Drugs and Pharmacies of Montenegro, Articles 37-39		

Slovak Republic				
Drugs	State Institute for Drug Control: http://www.sukl.sk/	Act on Drugs and Medical Devices No. 140/1998, Coll. in the Wording of Act No. 9/2004 (2004): http://www.sukl.sk/clin_trials.doc		
Privacy/Data Protection	Office for Personal Data Protection: http://www.dataprotection.gov.sk/buxus/generate_page.php3?page_id=413	1. Act on Protection of Personal Data in Information Systems (1998): http://www.statistics.sk/webdata/english/acts/act5298/act5298.htm 2. Protection of Personal Data, Act No. 428/2002 Coll. (2002): http://www.dataprotection.gov.sk/buxus/generate_page.php3?page_id=449		
Slovenia				
Drugs	Agency for Medicinal Products and Medical Devices (Slovenian): http://www2.gov.si/mz/mz-splet.nsf/f1?OpenFrameSet&Frame=main&Src=/mz/mz-splet.nsf/0/6A4C3562F6E310A4C1256B1E004D1B8F?OpenDocument			
Privacy/Data Protection	Data Protection Review Commission	1. Personal Data Protection Act No. 59 (1999): http://www.privacyexchange.org/legal/nat/omni/slovenia.html 2. Act Amending the Personal Data Protection Act No. 57/01 (2001)		
Spain				
Drugs	Spanish Agency for Medications and Health Products (Spanish): http://www.agemed.es/Index.htm	1. Medication Law 25/1990, Title III: Clinical Trials (1990) (Spanish): http://www.agemed.es/Index.htm - then go to Legislación, then to España, then to Parte I: General 2. Royal Decree 223/2004: Regulation of Medication	Circular No. 07/2004 (2004)	

		Clinical Trials (2004) (Spanish): http://www.agemed.es/Index.htm - then go to Legislación, then to España, then to Parte I: Ensayos Clínicos		
Privacy/Data Protection	*National:*			
	Spanish Data Protection Authority: https://www.agpd.es/index.php	1. Organic Law 15/1999 of December 13 on the Protection of Personal Data (1999): https://www.agpd.es/upload/Ley%20Org%E1nica%2015-99_ingles.pdf 2. Law 41/2002 of November 14, Regulatory Basis on Patient Autonomy and of the Rights and Obligations in the Area of Information and Clinical Documentation (2002) (Spanish): http://www.unizar.es/fyd/oliverpd/legislaci%F3n/ley41_2002a.html		
	Catalonia:			
	Catalan Agency for Data Protection	Law of the Autonomous Community of Catalonia No. 5/2002 (2002)		
Human Biological Materials		1. Royal Decree 411/1996, of March 1, By Which Activities Regarding the Use of Human Tissues are Regulated (1996) (Spanish): http://europa.eu.int/comm/research/biosociety/pdf/spanish_act411.pdf		
Srpska				
Drugs	1.Ministry of Health (MOH) 2. Drug Agency: http://www.alrs.net/indexen.htm	Law on Drugs and Pharmacies of the Republic of Srpska	Regulation on Conducting Clinical Trials (2005)	Guidelines of Good Clinical Practice
Sweden				
General	1. Central Ethical Review Board (CEPN) (Swedish): http://www.forskningsetikprovning.se/centrala_n.htm	Law No. 460 on the Ethical Review of Research Involving Humans (2003) (Swedish): http://www.notisum.se/rnp/SLS/	CEPN: 1. Ordinance No. 615 on Ethical Review of Research Involving Humans (2003)	SRC: 1. Ethical Guidelines of Epidemiological Research (1994) 2. Guidelines for Good Medical Research

	2. Swedish Research Council (SRC): http://www.vr.se/english/index.asp/	LAG/20030460.HTM	2. Ordinance No. 616 with Instructions for Regional Ethics Boards (2003) 3. Ordinance No. 617 with Instructions for the Central Ethical Review Board (2003)	(1996) 3. Guidelines for the Ethical Evaluation of Medical Research on Humans (2003) 4. Policy Statement Regarding the Assessment of Scientific Studies in which Patients or Healthy Subjects are to Undergo Invasive Operations (2003)
Drugs	Medical Products Agency: http://www.mpa.se/eng/index.shtml/	Pharmaceuticals Act No. 1992: 859 (1992) (Swedish): http://www.notisum.se/rnp/SLS/LAG/19920859.HTM	1. Medical Products Agency's Provisions and Guidelines on the Clinical Trials of Medicinal Products (1999) 2. Medical Product Agency's Provisions and Guidelines on Clinical Trials of Medicinal Products for Human Use, Code of Statutes No. 6 (2003)	
Privacy/Data Protection	Swedish Data Inspection Board: http://www.datainspektionen.se/in_english/start.shtml	Personal Data Act No. 204 (1998): http://www.datainspektionen.se/pdf/ovrigt/pul-eng.pdf		
Human Biological Materials	1. National Board of Health and Welfare (SOS): http://www.sos.se/sosmenye.htm 2. Swedish Research Council (SRC): http://www.vr.se/english/ 3. Swedish National Biobank Program: http://www.biobanks.se/	Biobanks in Medical Care Act No. 297 (2002): http://www.sweden.gov.se/content/1/c6/02/31/26/f69e36fd.pdf	SOS: 1. Regulation No. 746 (2002) 2. SOSFS No. 11 (2002) 3. SOSFS No. 2 (2004)	SRC: Research Ethics Guidelines for Using Biobanks (2003) For more information see: http://www.codex.uu.se/codex_eng/codex/oversikter/ovrigt/biobank.html
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.sos.se/sosmenye.htm	Act Concerning the Use of Certain Genetic Technology in Medical Screening (1991): http://europa.eu.int/comm/research/biosociety/pdf/bioethics-annexes2106.pdf , pages 175-176.		Genetics and Gene Technology in the Health Care: State of the Art and Guidelines for Ethical Considerations (1999)
Switzerland				
General	1. Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/ 2. Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE): http://www.nek-cne.ch/en/		Many of the Swiss cantons have implemented regulations regarding human subject research: http://www.swissethics.ch/fileadmin/user_upload/Dokumente/f_RegelungenKant.doc	SAMS: Guidelines on Human Research (1997)

Drugs	1. Swiss National Advisory Commission on Biomedical Ethics (CNE): http://www.nek-cne.ch/en/ 2. Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/?lang=2	Law on Medicinal Products and Medical Devices (2002): http://www.bag.admin.ch/heilmitt/gesetz/HMG_Engl.pdf/	CNE: Ordinance on Clinical Trials of Therapeutic Products, RS 812.214.2 (2004)	
Privacy/Data Protection	Swiss Federal Data Protection Commissioner: http://www.edsb.ch/e/aktuell/index.htm	1. Federal Law on Data Protection (1992): http://www.edsb.ch/e/gesetz/schweiz/dsge.pdf 2. Regulation of June 14, 1993 Regarding the Release of Professional Secrets in the Area of Medical Research, RS 235.154 (1993) (French): http://www.admin.ch/ch/f/rs/235_154/index.html Note: Many Swiss cantons have enacted similar legislation that governs data collection and processing in the public sector.		
Genetic Research	Swiss Academy of Medical Sciences: http://www.samw.ch/	Swiss Federal Constitution, Article 119 (1992)		Medical-Ethical Guidelines for Genetic Investigations in Humans (1993)
Ukraine				
Drugs	State Pharmacological Center: http://www.pharma-center.kiev.ua/index_a.html	On Medicines, Articles 7 and 8 (1999): http://www.pharma-center.kiev.ua/zakon_lzu_a.html	Ministry of Health of Ukraine Order No. 347 (2000)	
Privacy/Data Protection		Information Act (1992)		
United Kingdom				
General	*England:*			
	1. Department of Health (DH): http://www.dh.gov.uk 2. Central Office for Research Ethics Committees (COREC): http://www.corec.org.uk			DH: Research Governance Framework for Health and Social Care (2001) COREC:

	3. Medical Research Council (MRC): http://www.mrc.ac.uk			1. Guidelines for Good Clinical Practice in Clinical Trials (1998) 2. Interim Guidelines for Research Involving Human Participants in Developing Societies, Ethical Guidelines for MRC-Sponsored Studies (1999) 3. Governance Arrangements for NHS Research Ethics Committees (2001) 4. Standard Operating Procedures for Research Ethics Committees in the United Kingdom (2005) 5. New Operational Procedures for NHS Research Ethics Committees (2004) MRC: 1. Good Research Practice (2000) 2. Personal Information in Medical Research (2000) 3. Research Involving Human Participants in Developing Societies (2004) 4. Medical Research Involving Children (2004)
	Scotland:			
	NHSScotland, Chief Scientist Office: http://www.show.scot.nhs.uk/cso/		Adults with Incapacity Regulations (2002): http://www.scotland-legislation.hmso.gov.uk/legislation/scotland/ssi2002/20020190.htm	Research Governance Framework for Health and Community Care (2001)
	Wales:			
	Wales Office of Research and Development for Health and Social Care: http://www.word.wales.gov.uk/			Research Governance Framework for Health and Social Care in Wales (2001)
Drugs	1. Medicines and Healthcare Products Regulatory Agency (MHRA): http://www.mhra.gov.uk 2. Medical Research Council (MRC): http://www.mrc.ac.uk	Medicines Act (1968)	MHRA: The Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004)	MHRA: Consultation Letter on the Medicines for Human Use (Clinical Trials) Regulations (2003) MRC: 1. MRC Guidelines for Good Clinical Practice in Clinical Trials (1998) 2. MRC Policy on Antiretroviral Therapy for People Infected with HIV and Involved in AIDS Research in Developing Countries (2003)

Privacy/Data Collection	*England:*			
	1. Information Commissioner Office: http://www.informationcommissioner.gov.uk/ 2. Medical Research Council (MRC): http://www.mrc.ac.uk	Data Protection Act (1998): http://www.opsi.gov.uk/acts/acts1998/19980029.htm	A number of Statutory Instruments have been developed to implement the Data Protection Act: http://www.dca.gov.uk/ccpd/dpsubleg.htm	MRC: Personal Information in Medical Research (2003)
	Scotland:			
	NHSScotland: http://www.show.scot.nhs.uk/			Protecting Patient Confidentiality (2002)
Human Biological Materials	1. Royal College of Physicians (RCP): http://www.rcplondon.ac.uk/index.asp 2. Medical Research Council (MRC): http://www.mrc.ac.uk 3. Department of Health (DH): http://www.dh.gov.uk 4. Human Tissue Authority	Human Tissue Act (2004): http://www.opsi.gov.uk/acts/acts2004/20040030.htm		RCP: Research Based on Archived Information and Samples (1999) MRC: Human Tissue and Biological Samples for Use in Research (2001) DH: The Use of Human Organs and Tissue: An Interim Statement (2003)
Genetics Research	1. Advisory Committee on Genetic Testing (ACGT): http://www.advisorybodies.doh.gov.uk/genetics/acgt/ 2. Public Health Genetics Unit: http://www.phgu.org.uk/index.php			ACGT: Advice to Research Ethics Committees (1998)

ASIA/PACIFIC/MIDDLE EAST				
Country	**Key Organizations**	**Legislation**	**Regulations**	**Guidelines**
Australia				
General	National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/ethics/human/ahec/index.htm	National Health and Medical Research Council Act (1992): http://scaleplus.law.gov.au/html/pasteact/0/379/top.htm		1. Joint NHMRC/AVCC Statement and Guidelines on Research Practice (1997) 2. National Statement on Ethical Conduct in Research Involving Humans (1999) 3. Human Research Ethics Handbook – Commentary on the National Statement on Ethical Conduct in Research Involving Humans (2001) 4. Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) 5. Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004)
Drugs	Therapeutic Goods Administration: http://www.tga.gov.au/	Therapeutic Goods Act (1989): http://www.comlaw.gov.au/comlaw/Legislation/ActCompilation1.nsf/0/697A52AA408416B4CA256FBF000F43EC?OpenDocument	Therapeutic Goods Regulations (1991)	Human Research Ethics Committees and the Therapeutic Goods Administration (2001)
Privacy/Data Protection	*Federal:*			
	Office of the Privacy Commissioner: http://www.privacy.gov.au/	Privacy Act No. 119 (1998), Incorporating Amendments up to Act No. 49 (2004): http://www.privacy.gov.au/publications/privacy88_030504.doc	See: http://www.privacy.gov.au/act/guidelines/index.html	
	New South Wales:			
		Privacy and Personal Information Protection Act (2005): http://www.austlii.edu.au/au/legis/nsw/consol_act/papipa1998464/index.html		
	Victoria:			
		Information Privacy Act No. 98 (2000):		

		http://www.dms.dpc.vic.gov.au/Domino/Web_Notes/LDMS/PubLawToday.nsf?OpenDatabase		
Human Biological Materials	National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/ethics/human/ahec/index.htm			National Statement on Ethical Conduct in Research Involving Humans, Chapter 15: Use of Human Tissue Samples (1999)
Genetic Research	National Health and Medical Research Council, Australian Health Ethics Committee: http://www.nhmrc.gov.au/ethics/human/ahec/index.htm	Genetic Privacy and Non-Discrimination Act (1998): http://www.aph.gov.au/parlinfo/billsnet/98021.pdf		1. National Statement on Ethical Conduct in Research Involving Humans, Chapter 16: Human Genetic Research (1999) 2. Essentially Yours: The Protection of Human Genetic Information in Australia (2003)
Bangladesh				
General	Ministry of Health and Family Welfare, Bangladesh Medical Research Council: http://www.bmrc.net			
Drugs	Bangladesh Directorate of Drug Administration: http://www.ddabd.org	1. The Drugs Act (1964) http://www.ddabd.org/drug_rules.htm 2. Drugs (Control) Ordinance 1982, Ordinance No. VIII (1982): http://www.ddabd.org/ordinance_1982.htm		
China				
General	1. Ministry of Health (MOH) (Mandarin): http://www.moh.gov.cn/ 2. Ministry of Science and Technology	Law on Practicing Doctors (1999), Articles 8 and 9		MOH: Guidelines on Ethical Review of Medical Research (1998)
Drugs	State Drug Administration (Mandarin): http://www.moh.gov.cn/	Drug Administration Law (2001)	1. Good Clinical Practice (1999) 2. Drug Clinical Trial Administration Norms (1999)	
Privacy/Data Protection	*Hong Kong:*			
	Privacy Commissioner for Personal Data: www.pco.org.hk	Personal Data (Privacy) Ordinance (1996): http://www.pco.org.hk/english/ordinance/ordfull.html		
Human Biological Materials	Ministry of Health (Mandarin): http://www.moh.gov.cn/		See: Procedures for Exporting Human and Animal Specimens from China (2003):	

			http://www.usembassy-china.org.cn/sandt/Specimen-Export.htm	
India				
General	Indian Council of Medical Research, Central Ethics Committee on Human Research: http://www.icmr.nic.in/bioethics.htm			Ethical Guidelines for Biomedical Research on Human Subjects (2000)
Drugs	1. Drugs Controller General, India, Central Drugs Standard Control Organization (DCG): http://cdsco.nic.in 2. Indian Council of Medical Research, Central Ethics Committee on Human Research (ICMR): http://www.icmr.nic.in/bioethics.htm	Drugs and Cosmetics Act, Schedule Y (1988): http://cdsco.nic.in/html/GCP.htm - Appendix II	DCG: Good Clinical Practices for Clinical Research in India (2001)	ICMR: Ethical Guidelines for Biomedical Research on Human Subjects: Statement of Specific Principles for Clinical Evaluation of Drugs/Devices/Diagnostics/ Vaccines/Herbal Remedies (2000)
Genetic Research	Indian Council of Medical Research, Central Ethics Committee on Human Research: http://www.icmr.nic.in/bioethics.htm			Ethical Guidelines for Biomedical Research on Human Subjects: Statement of Specific Principles for Human Genetics Research (2000)
Indonesia				
Drugs	Ministry of Health, National Institute of Health Research and Development	Indonesian Health Act No. 23 (1992)	Regulation No. 39/19 on Health Research and Development (1995)	Guidelines for Ethics in Health Research and Development (2002)
Israel				
General	Ministry of Health: http://www.health.gov.il/english/		Medical Experiments Involving Human Subjects (1999)	
Drugs	Ministry of Health, Pharmaceutical Administration: http://www.health.gov.il/english/Pages_E/default.asp?maincat=10		Guidelines for Clinical Trials in Human Subjects (1999)	
Privacy/Data Protection	Registrar of Databases, Ministry of Justice	Protection of Privacy Law No. 5741 (1981), as Amended by Law No. 5745 (1985)		
Genetic Research	Israel Academy of Sciences and Humanities (Hebrew): http://www.academy.ac.il/	Genetic Information Law (2000)		Population-Based Large-Scale Collections of DNA Samples and Databases of Genetic Information (2002)
Japan				
General	1. Ministry of Education, Culture,			MECSST and MHLW:

	Sports, Science, and Technology (MECSST) 2. Ministry of Health, Labor, and Welfare (MHLW)			Ethics Guidelines for Epidemiological Research (2002) MHLW: Ethical Guidelines for Clinical Research (2003)
Drugs	1. Ministry of Health, Labor, and Welfare (MHLW) 2. Pharmaceuticals and Medical Devices Agency: http://www.pmda.go.jp/index-e.html	Pharmaceutical Affairs Law, Article 80-2 (1996)	MHLW: Good Clinical Practice Guidelines (1997)	
Privacy/Data Protection	Ministry of Internal Affairs and Communications	Personal Information Protection Act (2003)		
Genetic Research	1. Ministry of Education, Culture, Sports, Science, and Technology (MECSST) 2. Ministry of Health, Labor, and Welfare (MHLW) 3. Ministry of Economy, Trade, and Industry (METI)			MECSST, MHLW, and METI: Ethics Guidelines for Human Genome/Gene Analysis Research (2001) MECSST and MHLW: Guidelines for Clinical Research in Gene Therapy (2002)
Jordan				
Drugs	Jordan Food and Drug Administration: http://www.jordan.jo/en/index.html	1. Narcotic and Psychotropic Law No. 11 (1988) 2. Clinical Trial Law No. 67 (2001) 3. Pharmacy and Drug Law No. 80 (2001)		
Korea				
Drugs	Korea Food and Drug Administration	Pharmaceutical Affairs Law (1999)	Regulation for Evaluation on Safety and Efficacy of Drugs (1999)	
Privacy/Data Protection	Ministry of Government Administration and Home Affairs	Act on the Protection of Personal Information Maintained by Public Agencies No. 4734 (1994)		
Nepal				
General	Nepal Health Research Council: http://www.nhrc.org.np/			National Ethical Guidelines for Health Research in Nepal (2001)
New Zealand				
General	1. Ministry of Health (MOH), National Ethics Advisory Committee:	1. Health Research Council Act, Sections 24 and 25 (1990):	MOH: Operational Standards for Ethics	MOH: 1. Guidelines – Compensation for Injuries

	http://www.newhealth.govt.nz/neac.htm 2. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/root/Ethics/Ethics%20Overview/HRC_Ethics_Committee.html	http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes 2. New Zealand Public Health and Disability Act, Section 16 (2000): http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes	Committees (2002)	Caused as a Result of Participation in a Clinical Trial and the Role of Ethics Committees (1993) 2. Operational Standards for Ethics Committees (2002) HRC: 1. Guidelines for Researchers on Health Research Involving Maori (1998) 2. Guidelines on Ethics in Health Research (2002)
Drugs	1. Health Research Council (HRC), Standing Committee on Therapeutic Trials: http://www.hrc.govt.nz/root/pages_regulatory/Standing_Committee_on_Therapeutic_Trials.html 2. New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz 3. Researched Medicines Industry (RMI): http://www.rmianz.co.nz	Medicines Act (2005): http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes	Medsafe: New Zealand Regulatory Guidelines for Medicines, Vol. 3: Interim Good Clinical Research Practice Guidelines (1998)	RMI: Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial (1997)
Privacy/Data Protection	Office of the Privacy Commissioner: http://www.privacy.org.nz/top.html	Privacy Act (2002): http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes		
Human Biological Materials	1. Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/root/Ethics/Ethics%20Overview/HRC_Ethics_Committee.html 2. Office of the Health and Disability Commissioner (HDC): www.hdc.org.nz	1. Human Tissue Act (1989): http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes 2. Health and Disability Commissioner Act (2003): http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes		Use, Storage, and Disposal: Report to the New Zealand Department of Health (1992)
Genetic Research	Health Research Council (HRC), Gene Technology Advisory Committee: http://www.hrc.govt.nz/root/pages_regulatory/Gene_Technology_Advisory_Committee.html			

Philippines				
General	1. Philippine Council for Health Research and Development, National Ethics Committee (PCHRD): http://www.pchrd.dost.gov.ph/PCHRD/ethics/index.htm 2. Department of Science and Technology: http://www.dost.gov.ph/			PCHRD: 1. National Guidelines on the Conduct of Biomedical Research (2000) 2. Guidelines on the Rights of Human Participants in Biomedical Research (2000) 3. Guidelines for Clinical Trials (2000) 4. Guidelines for Organ Transplantation Research (2000) 5. Guidelines on HIV/AIDS Research (2000)
Drugs	Bureau of Food and Drugs: http://www.bfad.gov.ph/		Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products (Administrative Order No. 47-a) (2001)	
Genetic Research	Philippine Council for Health Research and Development, National Ethics Committee (PCHRD): http://www.pchrd.dost.gov.ph/PCHRD/ethics/index.htm			Guidelines on Genetic Engineering Research (2000)
Singapore				
General	1. Ministry of Health (MOH): http://www.moh.gov.sg/ 2. National Medical Ethics Committee (NMEC) 3. Bioethics Advisory Committee (BAC): http://www.bioethics-singapore.org		MOH: Directive of June 25, 1998: Hospital Ethics Committees NMEC: Ethical Guidelines on Research Involving Human Subjects (1997)	BAC: Research Involving Human Subjects: Guidelines for IRBs (2004)
Drugs	1. Health Sciences Authority of Singapore (HSA), Center for Drug Administration (CDA): http://www.hsa.gov.sg 2. Ministry of Health National Medical Ethics Committee (NMEC)	1. Medicines Act Section 74 (Cap. 176) (1975): http://statutes.agc.gov.sg 2. Medicines (Clinical Trials) Regulations (2000)	CDA: Singapore Guideline for Good Clinical Practice (1998)	HSA - Various: http://www.hsa.gov.sg/html/business/cda_trials_guide_appl.html NMEC: Good Clinical Practice Guidelines (1997)

Taiwan				
General	Forum for Independent Review System in Taiwan: http://www.jirb.org.tw/English_Version/eng-index.asp	Medical Services Act, Articles 7, 56, and 57 (2004)		Standards of Composition and Operations of Medical Institution Human Experiments Committee (2003)
Drugs	Department of Health: http://www.doh.gov.tw/EN/Webpage/index.aspx/		Guideline for Good Clinical Practice (2004)	Operational Guideline for Drug Clinical Trials (2002)
Privacy/Data Protection	Ministry of Justice	Computer-Processed Personal Data Protection Law (1995): http://www.privacyexchange.org/legal/nat/omni/taiwan.html		
Thailand				
General	1. National Research Council of Thailand (NCRT): http://www.nrct.net/eng 2. Medical Council of Thailand (MCT) (Thai): http://www.tmc.or.th		NCRT: Regulation on the Permission of Foreign Researchers (1982) MCT: Rule of the Medical Council on the Observance of Medical Ethics (2002)	
Drugs	Food and Drug Administration, Drug Control Division: http://www.fda.moph.go.th/eng/index.stm/		Thailand Good Clinical Practice Guidelines (2000)	
Privacy/Data Protection		Official Information Act, B.E. 2540 (1997): http://www.oic.thaigov.go.th/eng/statue/Statutedata.htm		

LATIN AMERICA/CARIBBEAN				
Country	**Key Organizations**	**Legislation**	**Regulations**	**Guidelines**
Argentina				
Drugs	*National:*			
	National Administration of Medications, Foods, and Medical Technology (ANMAT) (Spanish): http://www.anmat.gov.ar/principal.html		1. Provision 5330/97 on General Guidelines for the Conduct of Clinical Trials (1997) (Spanish): http://infoleg.mecon.gov.ar/infolegInternet/anexos/45000-49999/46745/norma.htm	
	Buenos Aires Province:			
		Requirements for Health Research, Law 11.044 (1991)		
Privacy/Data Protection		Personal Data Protection Act No. 25, 326 (2000) (Spanish): http://www.ulpiano.com/Dataprotection_argentina.htm		
Bolivia				
General	Ministry of Public Health			Research Ethics and Guidelines for Clinical Trials (2003)
Brazil				
General	1. National Health Council (CNS) (Portuguese): http://conselho.saude.gov.br/comissao/doc_ref_eticpesq.htm/ 2. National Commission on Research Ethics (CONEP) (Portuguese): http://conselho.saude.gov.br/comissao/eticapesq.htm	CNS: Decree 98 830: Collection by Foreigners of Data and Scientific Materials in Brazil (1990)	CONEP: 1. Resolution 196/96: Rules on Research Involving Human Subjects (1996) 2. Resolution 292/1999: On Research with Foreign Cooperation (1999) 3. Resolution 304/2000: On Complimentary Rules for Research Involving Indigenous People (2000) 4. Internal CONEP Regulation (2001) 5. Regulation of Resolution CNS 292/99 on Research with Foreign Cooperation (2002)	
Drugs	1. National Health Council (CNS) (Portuguese):		CNS: Resolution 251/1997: On	

	http://conselho.saude.gov.br/comissao/doc_ref_eticpesq.htm 2. National Healthcare Surveillance Agency (Portuguese): http://www.anvisa.gov.br		Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests (1997)	
Human Biological Materials	National Commission on Research Ethics (Portuguese): http://conselho.saude.gov.br/comissao/eticapesq.htm			Approval Guidelines for Ethical Analysis of Research Projects Involving Storage of Materials or Use of Materials Stored by Previous Research: Resolution 347/05 (2005)
Genetic Research	National Commission on Research Ethics (Portuguese): http://conselho.saude.gov.br/comissao/eticapesq.htm			Approval Guidelines for Ethical Analysis and Conduct of Research Projects in the Special Thematic Area of Human Genetics: Resolution 340/04 (2004)
Chile				
General	Ministry of Health (Spanish): http://www.minsal.cl		1. Supreme Decree No. 42 (1986) 2. Supreme Decree No. 1.935 (1993) 3. General Technical Rule No. 2 of the Ministry of Health (1993) 4. Exemption Resolution No. 134 (1994) 5. Supreme Decree No. 494 (1999) 6. Exemption Resolution No. 1.856 (1999) 7. Resolution No. 2.085 of the Ministry of Health (2001)	
Drugs	Ministry of Health (Spanish): http://www.minsal.cl		Technical Rule No. 57: Regulation of the Conduct of Clinical Trials that Use Pharmaceutical Products in Human Beings (2001)	Ethical Guidelines for Clinical Trials with Pharmaceutical and Biological Products (2001)
Privacy/Data Protection		Law for the Protection of Private Life No. 19.628 (1999)		
Colombia				
General	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430 (1993)	
Drugs	National Institute of Drug and Food Surveillance (Spanish):			

	http://www.invima.gov.co/			
Privacy/Data Protection		Constitution, Article 15 (2003)		
Human Biological Materials	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter VI (1993)	
Genetic Research	Ministry of Health, National Institute of Health (Spanish): http://www.ins.gov.co/		Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapter II (1993)	
Costa Rica				
General	1. National Council on Health Research (CONIS) Network of Scientific Ethics Committees (Spanish): http://www.netsalud.sa.cr/conis/index.htm 2. Social Security Fund (CCSS), Research and Bioethics Subarea (Spanish): http://www.cendeisss.sa.cr/etica/01-PRESEN.html 3. Ministry of Health: www.netsalud.sa.cr/ms/ministe.htm	General Health Law, Articles 64-68 (1973) (Spanish): http://www.ministeriodesalud.go.cr/dirasjud/Ley%20General%20de%20Salud.doc	CONIS: Executive Decree No. 31078-S (2003) CCSS: Regulation of Clinical Investigation in the Assistance Services of the Social Security Fund (2003)	CONIS: 1. Ethical and Legal Principles 2. Duties and Responsibilities of the National Council on Health Research, of Investigators, and of the Sponsor 3. Structure and Functioning of the Committee Network 4. Design of the Research Protocol 5. Requirements for the Submission of a Research Protocol 6. Informed Consent 7. Approval and Follow-up of a Research Project 8. Sanctions
Drugs	1. National Council on Health Research (CONIS) Network of Scientific Ethics Committees (Spanish): http://www.netsalud.sa.cr/conis/index.htm 2. Ministry of Health (Spanish): http://www.ministeriodesalud.go.cr/dirregis			CONIS: 1. Guidelines for Good Clinical Practice (1996) 2. Protocol for Clinical Trials
Human Biological Materials	National Council on Health Research Network of Scientific Ethics Committees (Spanish): http://www.netsalud.sa.cr/conis/index.htm			Informed Consent, Research that Requires Biobanks

Jamaica				
General	Ministry of Health: http://www.moh.gov.jm			Ministry of Health Guidelines for the Conduct of Research on Human Subjects (2002)
Mexico				
General	Secretariat of Health (Spanish): http://www.salud.gob.mx/	General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2005) (Spanish): http://www.cddhcu.gob.mx/leyinfo/pdf/142.pdf	Regulation of the General Health Law in the Area of Health Research (1986)	
Drugs	General Directorship of Medicines and Health Technologies		Regulation of the General Health Law in the Area of Health Research, Title Three (1986)	
Privacy/Data Protection		See listing at: http://profesor.uia.mx/aveleyra/comunica/privacidad/leyes2.htm (Spanish)		
Human Biological Materials	Secretariat of Health (Spanish): http://www.salud.gob.mx/	General Health Law, Title XIV, Articles 313-350 (2005) (Spanish): http://www.cddhcu.gob.mx/leyinfo/pdf/142.pdf	Regulation of the General Health Law in the Area of Health Research, Title II, Chapter VI (1986)	
Genetic Research	Secretariat of Health (Spanish): http://www.salud.gob.mx/		Regulation of the General Health Law in the Area of Health Research, Title III, Chapter II (1986)	
Panama				
General	Commemorative Gorgas Institute on Health Studies (Spanish): http://www.gorgas.gob.pa/	Law No. 78 that Restructures and Organizes the Commemorative Gorgas Institute on Health Studies (2003)		
Peru				
General	National Institute of Health (Spanish): http://www.ins.gob.pe/	General Health Law No. 26842, Article 28 (1997) (Spanish): http://www.minsa.gob.pe/infodigemid/normatividad/LEY2684202.HTM		
Drugs	National Institute of Health (Spanish): http://www.ins.gob.pe/		Ministerial Resolution No. 0212-81-SA/DVM: Rules for the Use of Drugs in Clinical Trials (1981)	

Uruguay				
Human Biological Materials	Ministry of Public Health (Spanish): http://www.msp.gub.uy/		Circular No. 40/95 Establishing Rules Regarding the Donation of Organs and Tissues for Scientific and Therapeutic Purposes (1995) (Spanish): http://www.msp.gub.uy/normas/i-normas.html - pages 97-98	
Venezuela				
General	1. National Fund on Science and Technology, Commission on Bioethics and Biosecurity (FONACIT) (Spanish): http://www.fonacit.gov.ve/bioetica.asp 2. Venezuelan Research Institute, Bioethics Commission (IVIC) (Spanish): http://www.ivic.ve/bioetica/	Constitution, Article 46 (Spanish): http://www.venezuela-oas.org/Constitucion%20de%20Venezuela.htm	Resolution No. 48 (1998)	FONACIT: Code on Bioethics and Biosecurity (2002) IVIC: 1. Annex 1: General Ethical Issues in Research Involving Living Persons 2. Annex 2: Necessity of Establishing a Clear and Precise Study Protocol Before Starting Research 3. Informed Consent
Drugs	National Institute of Hygiene "Rafael Rangel" (Spanish): http://www.inhrr.gov.ve	Medicines Act, Articles 72 and 73		
Genetic Research	Venezuelan Research Institute, Bioethics Commission (Spanish): http://www.ivic.ve/bioetica/			Contract for Accessing Genetic Resources (2003)

AFRICA				
Country	**Key Organizations**	**Legislation**	**Regulations**	**Guidelines**
Botswana				
General	Ministry of Health Research and Development Committee: http://www.gov.bw/government/ministry_of_health	Anthropological Research Act 45 (1967)		
Drugs	Ministry of Health, Drug Regulatory Unit: http://www.gov.bw/government/ministry_of_health.html#dru_section		Drugs and Related Substances Regulations (1993)	
Ethiopia				
General	Ethiopian Science and Technology Commission, Health Department: http://www.telecom.net.et/~estc/			National Health Research Ethics Review Guidelines (2004)
Human Biological Materials	Ethiopian Science and Technology Commission, Health Department: http://www.telecom.net.et/~estc/			National Health Research Ethics Review Guidelines, Section 8 (2004)
Kenya				
General	1. National Council for Science and Technology (NCST) 2. Ministry of Health (MOH): http://www.health.go.ke/index.html	Science and Technology Act (2001)	NCST: Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (2004) MOH: Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005)	
Drugs	Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/	Pharmacy and Poisons Act, Chapter 244 (2001): http://www.pharmacyboardkenya.org/legislation.htm		
South Africa				
General	1. Medical Research Council of South Africa (MRC): http://www.mrc.ac.za 2. National Health Research Ethics Council 3. Department of Health (DH): http://www.doh.gov.za	National Health Act No. 61, Chapter 9 (2003): http://www.doh.gov.za/docs/legislation-f.html		MRC: 1. Guidelines on Ethics for Medical Research (2002) 2. Guidelines on Ethics for Medical Research: HIV Preventive Vaccine Research (2003)

				DH: Ethics in Health Research: Principles, Structures, and Processes (2004)
Drugs	Medicines Control Council: http://www.mccza.com		Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2000)	
Tanzania				
General	1. National Institute for Medical Research, National Health Research Ethics Committee: http://www.nimr.or.tz/Pages/About_us.html 2. Tanzania Commission for AIDS, National Research and Ethics Committee			Guidelines on Ethics for Health Research in Tanzania (2001)
Drugs	Tanzania Food and Drugs Authority: http://www.tfda.or.tz/	Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003)		
Uganda				
General	Uganda National Council on Science and Technology (UNCST): http://www.uncst.co.ug/			UNCST: Guidelines for the Conduct of Health Research Involving Human Subjects in Uganda (1997)
Drugs	National Drug Authority: http://www.health.go.ug/National_drug.htm	National Drug Authority Statute (1993)		
Zimbabwe				
General	Medical Research Council of Zimbabwe: http://www.mrcz.org.zw	1. Government Notice Act (1974) 2. Research Act (1986)		Guidelines for Researchers and Ethics Review Committees in Zimbabwe (2004)
Drugs	Medical Control Authority of Zimbabwe: mcaz@africaonline.co.zw	Medicines and Allied Substances Control Act, Chapter 15:03 (1997)		

The following countries were researched, and no laws, regulations, or guidelines pertaining to human subject protections could be located:

Asia/Pacific/Middle East:
Afghanistan, Bhutan, Cambodia, Djibouti, Egypt, Iraq, Kazakhstan, Laos, Maldives, Pakistan, Palau, Papua New Guinea, Sudan, Tunisia, Vietnam, Yemen.

Latin America/Caribbean:
Belize, Bermuda, Ecuador, El Salvador, Guyana, Haiti, Paraguay, Suriname.

Africa:
Cameroon, Madagascar, Malawi, Morocco, Mozambique, Sudan, Zambia.