第5回臨床研究専門委員会	資料 3
平成20年 1月16日	

各国・地域の臨床研究に関する法制について

International Compilation of Human Research Protections

2008 Edition

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

PURPOSE

This Compilation lists the approximately 900 laws, regulations, and guidelines that govern human subjects research in 84 countries, as well as from a number of international and regional organizations. This Compilation was developed for IRBs/Ethics Committees, researchers, sponsors, and others who are involved in international research. Its purpose is to help these groups familiarize themselves with the laws, regulations, and guidelines where the research will be conducted, to assure those standards are followed appropriately.

This year's Compilation features a new section on research standards for Embryos, Stem Cells, and Cloning. The 2008 Edition includes the laws, regulations, and/or guidelines for four new countries: Georgia, Kazakhstan, Kuwait, and Turkey. In addition, Montenegro declared its independence from Serbia in 2006, so that country is now listed separately. Finally, the Compilation includes numerous updates to the 2007 Edition.

ORGANIZATION

The Table of Contents is found on page 3. Under each country, the rows categorize the standards as:

1. General, i.e., applicable to most or all types of human subjects research
2. Drugs
3. Privacy/Data Protection
4. Human Biological Materials
5. Genetic
6. Embryos, Stem Cells, and Cloning

These six categories overlap, so it is necessary to review all standards to obtain a complete understanding of the country's requirements.

The standards are then organized into four columns:

1. Key Organizations – include those groups that issue regulations or guidelines, or serve in a national oversight role for human subjects research
2. Legislation – includes statutes, statutory instruments, 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.
4. Guidelines – refer to non-binding instruments.

The year of the document's initial approval or most recent modification is indicated in parenthesis (when that information is available), unless the date is part of the document's actual title. For example, Law 46/2006 indicates the law was enacted in 2006.

HOW TO ACCESS A DESIRED DOCUMENT

Documents can be accessed in several ways:

1. For laws, the web address (URL) is listed whenever available.
2. For regulations and guidelines, desired documents can be accessed in several ways:
    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.
    d. For non-English language standards, the URL is listed if available.
3. The local research ethics committee also should be able to provide information about applicable laws, regulations, and guidelines.

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

TOPICS NOT COVERED

In order to focus its scope, the Compilation does not include:

1. Laws that represent enabling legislation, i.e., authorize an agency to promulgate human subjects regulations, but do not direct the content of those regulations.
2. Laws, regulations, or guidelines specific to clinical bioethics, medical devices, adverse event reporting, insurance requirements, clinical trial inspection procedures, assisted reproduction, human tissue engineering, or informed consent in clinical practice.
3. Ethics codes of academic, medical, or other professional organizations.
4. Working papers, drafts, or discussion papers.

Updates and Broken Links
Updates and broken links should be reported to the attention of Edward E. Bartlett, PhD, Office for Human Research Protections, International Activities Program, at: edward.bartlett@hhs.gov .

Disclaimer
Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new 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 human subject 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.

TABLE OF CONTENTS

Region:

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/ 5. United Nations Educational, Scientific, and Cultural Organization (UNESCO): http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html			OHCHR: International Covenant on Civil and Political Rights, Article 7 (1976) UNAIDS: Ethical Considerations in HIV Preventive Vaccine Research (2000) CIOMS: 1. International Guidelines for Ethical Review of Epidemiological Studies (1991) 2. International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) WMA: Declaration of Helsinki (2004) UNESCO: Universal Declaration on Bioethics and Human Rights (2005)
Drugs	1. World Health Organization (WHO): http://www.who.int/en/ 2. International Conference on Harmonization (ICH): http://www.ich.org/			WHO: 1. Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation (2002) 2. Operational Guidance: Information Needed to Support Clinical Trials of Herbal Products (2005) 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	1. World Health Organization: http://www.who.int/en/ 2. International Air Transport Association (IATA): http://www.iata.org/ 3. International Society for Biological and Environmental Repositories (ISBER): http://www.isber.org			WHO: Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research (2003) IATA:

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				Infectious Substances and Diagnostic Specimens Shipping Guidelines (2005) ISBER: Best Practices for Repositories I: Collection, Storage and Retrieval of Human Biological Materials for Research (2005)
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. 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) 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. Royal Commission on Aboriginal People (RCAP) 2. National Defence 3. Correctional Service of Canada 4. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/english/ 5. National Council on Ethics in Human Research: http://www.ncehr-cnerh.org/english/home.php			RCAP: Ethical Guidelines for Research (1993): http://www.pre.ethics.gc.ca/english/pdf/RCAP_Guidelines_1993.pdf National Defence: Research Involving Human Subjects (1998): http://www.admfincs.forces.gc.ca/admfincs/subjects/daod/5061/0_e.asp Correctional Service of Canada: Commissioner's Directive - Research: DCOO9 (2004): http://www.csc-scc.gc.ca/text/plcy/cdshtm/009-cde_e.shtml PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2005)
	Newfoundland and Labrador:			
	Health Research Ethics Authority: http://www.hrea.ca/	Bill 23: An Act to Establish a Health Research Ethics Authority for the Province of Newfoundland and Labrador (2006): http://www.hoa.gov.nl.ca/hoa/bills/Bill0623.htm		
	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)		
	Quebec:			
	1. Quebec Minister of Health and Social Services, Ethics Unit (MSSS) (French):	1. Civil Code of Quebec, S.Q., c. 64: Articles 11, 20, 21, 22, 24, and 25 (1991):	MSSS: 1.Terms of Reference for the Research Ethics Boards	FRSQ: Research Ethics and Scientific Integrity Guidelines (2003)

Country	Key Organizations	Legislation	Regulations	Guidelines
	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): http://www.fqrsc.gouv.qc.ca/fonds/ethique/index.html 4. Commission de l'éthique de la Science et de la Technologie (CEST): http://www.ethique.gouv.qc.ca 5. Comité d'éthique de Santé Publique : http://msssa4.msss.gouv.qc.ca/fr/sujets/ethiqSP.nsf/vsite?OpenView	http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/CCQ/CCQ_A.html 2. An Act Respecting Health Services and Social Services, R.S.Q., c. S-4.2: Articles 19.1 and 19.2: http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/S_4_2/S4_2_A.html	Designated or Instituted in Accordance to Article 21 of the Civil Code of Quebec (1998) (French): http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml 2. Ministerial Action Plan on Research Ethics and Scientific Integrity (1998) (French): http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml 3. Contribution of Private Companies within the Framework of Research Activities Derived from Research Grants (2003) (French): http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml 4. Ethics Review and Continuous Ethics Review of Multi-center Projects Mechanism (2007) (French) 5. Memorandum 1: Clarification Regarding Subject-Matter and Territorial Jurisdictions of Research Ethics Boards (2007) (French) http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml 6. Memorandum 2: Clarification Regarding the Concept of Continuous Monitoring of Project Ethics (2007) (French) http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml 7. Memorandum 3: Clarification Regarding the REB Review of Relevant Parts of the Budget and the Sponsor-Institution-Researcher Agreement (2007) (French) http://ethique.msss.gouv.qc.ca/site/130.0.0.1.0.0.phtml	

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	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.	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/			PRE: 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-cceb.ca/epic/internet/incbac-cceb.nsf/en/Home 3. Biologics and Genetic Therapies Directorate: http://www.hc-sc.gc.ca/hpfb-dgpsa/bgtd-dpbtg/aboutus_e.html			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 8: Human Genetic Research (2004) CBAC: Genetic Research and Privacy (2004)
	Quebec:			
	RMGA Network of Applied Genetic Medicine			1. Statement of Principles: Human Genome Research (2000) http://www.rmga.qc.ca/en/index.htm

Country	Key Organizations	Legislation	Regulations	Guidelines
				2. Statement of Principles on the Ethical Conduct of Human Research Involving Populations (2003) http://www.rmga.qc.ca/en/index.htm
Embryos, Stem Cells, and Cloning	1. Interagency Advisory Panel on Research Ethics (PRE): http://www.pre.ethics.gc.ca/english/ 2. Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html			PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 9: Research Involving Human Gametes, Embryos, or Foetuses (2004) CIHR: Updated Guidelines for Human Pluripotent Stem Cell Research (2007): http://www.cihr-irsc.gc.ca/e/34460.html
United States				
General	The U.S. Federal Policy for the Protection of Human Subjects consists of four subparts. All of the Common Rule departments and agencies subscribe to subpart A (2005). Some of the departments and agencies also subscribe to additional subparts: 1. Subpart B: Additional Protections for Pregnant Women, Human Fetuses, and Neonates (2001) 2. Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (1978) 3. Subpart D: Additional Protections for Children Involved as Subjects in Research (1991) Each department's or agency's participation in the various subparts is indicated below in parenthesis: • Agency for International Development: www.usaid.gov/ (Subpart A) • Central Intelligence Agency: www.odci.gov/ (Subparts A, B, C, and D) • Consumer Product Safety	Department of Defense: United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects Department of Education: 1. Protection of Pupil Rights Amendment (1974) 2. Family Educational Rights and Privacy Act (1974) Department of Health and Human Services: Public Health Service Act (1993): http://www.hhs.gov/ohrp/humansubjects/guidance/statute.htm	Agency for International Development: • 22 CFR 225 Central Intelligence Agency: • Executive Order 12333 Consumer Product Safety Commission: • 16 CFR 1028 Department of Agriculture: • 7 CFR 1c Department of Commerce: • 15 CFR 27 Department of Defense: • 32 CFR 219 • DoD Directive 3216.02 (2002) *Army:* • AR 70-25 • AR 40-38 *Navy:* • SECNAVINST 3900.39 series • BUMED Instruction 3900.6 series *Air Force:* • AFI 40-402 (2000) *OUSD(P&R):* • USUHS Instruction 3201	Office for Human Research Protections: http://www.hhs.gov/ohrp/policy/index.html#topics

Country	Key Organizations	Legislation	Regulations	Guidelines
	Commission: www.cpsc.gov/ (Subpart A) • Department of Agriculture: www.usda.gov/wps/portal/usdahome/ (Subpart A) • Department of Commerce: www.commerce.gov/ (Subpart A) • Department of Defense: www.dtic.mil/biosys/org/regulatory.html (Subpart A) • Department of Education: www.ed.gov/ (Subparts A and D) • Department of Energy: www.energy.gov/engine/content.do/ (Subpart A) • Department of Health and Human Services: www.hhs.gov/ohrp/ (Subparts A, B, C, and D) • Department of Homeland Security: www.dhs.gov/ (Subpart A) • Department of Housing and Urban Development: www.hud.gov/ (Subpart A) • Department of Justice: www.usdoj.gov/ (Subpart A) • Department of Transportation: www.dot.gov/ (Subpart A) • Department of Veterans Affairs (Subpart A) 1. Office of Research Oversight (ORO): www1.va.gov/oro/ 2. Office of Research and Development: www.research.va.gov • Environmental Protection Agency: www.epa.gov/ (Subpart A) • National Aeronautics and Space Administration:		*DTRA:* • DTRA Directive 3216.1 • DTRA Instruction 3216.2 Department of Education: • 34 CFR 97 subparts A (1991) and D (1997) • 34 CFR 98 (1984) • 34 CFR 99 (2000) • 34 CFR 350.4(c) (1991) • 34 CFR 356.3(c) (1991) Department of Energy: • 10 CFR 745 (1991) • Order 1300.3 • Order 481.1 Department of Health and Human Services: • 45 CFR 46 Department of Homeland Security: • Public Law 108-458, Section 8306 Department of Housing and Urban Development: • 24 CFR 60 Department of Justice: • 28 CFR 22 (1976) • 28 CFR 46 (1991) • 28 CFR 512 (1994) Department of Transportation: 49 CFR 11 Department of Veterans Affairs: • 38 CFR 16 (1991) • 38 CFR 17.85 (1998) Environmental Protection Agency: • 40 CFR 26 National Aeronautics and Space Administration: • 14 CFR 1230 National Science Foundation: • 45 CFR 690	

Country	Key Organizations	Legislation	Regulations	Guidelines
	www.nasa.gov/home/index.html?skipIntro=1 (Subpart A) • National Science Foundation: www.nsf.gov (Subpart A)			
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
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): http://privacyruleandresearch.nih.gov/	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)
Human Biological Materials	Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/			1. Issues to Consider in the Research Use of Stored Data or Tissues (1997) 2. Guidance on Research Involving Coded Private Information or Biological Specimens (2004)
Genetic Research	National Institutes of Health, Office of Biotechnology Activities: http://www4.od.nih.gov/oba/	Research on Transplantation of Fetal Tissue, Public Law 103-43		NIH Guidelines for Research Involving Recombinant DNA Molecules (2002)
Embryos, Stem Cells, and Cloning	1. National Institutes of Health 2. Food and Drug Administration, Center for Biologics Evaluation and Research: http://www.fda.gov/cber/index.html 3. Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/ 4. National Research Council: http://www.nationalacademies.org/nrc/	Research on Transplantation of Fetal Tissue. Public Law 103-43	NIH: Approval Process for the Use of Human Pluripotent Stem Cells in NIH-Supported Research (2000)	FDA: Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products. October 14, 1993. 58 FR 53248. OHRP: Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles (2002) NRC: 1. Guidelines for Human Embryonic Stem

Country	Key Organizations	Legislation	Regulations	Guidelines
				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

Country	Key Organizations	Legislation	Regulations	Guidelines
EUROPE				
European-wide				
General	1. Council of Europe, Bioethics Division (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. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=1&DF=10/24/2007&CL=ENG 2. Additional Protocol on Biomedical Research (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG		EGE: Ethical Aspects of Clinical Research in Developing Countries (2003): http://ec.europa.eu/european_group_ethics/docs/avis17_en.pdf
Drugs	1. European Commission, Enterprise Directorate-General, Pharmaceuticals Unit (EC): http://europa.eu.int/comm/enterprise/pharmaceuticals/index_en.htm 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: http://europa.eu/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf 2. Directive 2005/28/EC: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_091/l_09120050409en00130019.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. European Commission (EC): http://europa.eu.int/ 2. Council of Europe, Bioethics Division (CoE): http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/	EC: Data Protection Directive 95/46/EC of the European Parliament and of the Council (1995): http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&num		

Country	Key Organizations	Legislation	Regulations	Guidelines
		doc=31995L0046&model=guichett CoE: 1. Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1985) 2. Recommendation No. R (97) 5 on the Protection of Medical Data (1997)		
Human Biological Samples	1. European Commission (EC): http://europa.eu.int/ 2. Council of Europe, Bioethics Division (CoE): http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/ 3. European Group on Ethics in Science and New Technologies (EGE): http://europa.eu.int/comm/european_group_ethics/index_en.htm 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: http://europa.eu/eur-lex/pri/en/oj/dat/2004/l_102/l_102220040407en00480058.pdf CoE: 1. Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=1&DF=10/24/2007&CL=ENG 2. Recommendation Rec (2006)4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin (2006)		EGE: Ethical Aspects of Human Tissue Banking (1998) 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/T/E/Legal_affairs/Legal_co-operation/Bioethics/	Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14 (1999): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=1&DF=10/24/2007&CL=ENG		Recommendation No. R (92) on Genetic Testing and Screening for Health Care Purposes (1992)