

WELCOME

Stem cells have generated much interest for researchers because of their ability to replace and repair damaged tissues. This potential raises the prospect of stem cell use for reversing and treating diseases and injuries. However, many publicized scientific studies in this field have been refuted because of the ethical and legal controversies surrounding stem cell research, particularly with respect to the derivation of stem cells from embryonic sources.

In this month's GenInfo, I invite you to consult the *Updated Guidelines for Human Pluripotent Stem Cell Research* (updated and published by the Canadian Institutes of Health Research in June 2007), the National Consultative Ethics Committee for Health and Life Sciences (CCNE) *Opinion on the Commercialisation of Human Stem Cells and Other Cell Lines* (2006) and the *Recommendations on the Ethical Review of hESC FP7 Research Projects* (2007), adopted by the European Group on Ethics in Science and New Technologies .

For a comprehensive listing of policies, laws and regulations on stem cell research adopted by different countries around the world, please visit the *Stem Cell World Map* found on our recently revamped *StemGen* website: www.stemgen.org

Thu Minh Nguyen, Editor-in-chief

EDITORIAL

Consent in Pharmacogenomic Research

Phillips M.S., Joly Y., Silverstein T., Avard D.

This article analyzes the emerging ethical and legal requirements for informed consent in pharmacogenomic research. It reviews how policies at the international, regional and national levels have responded to new ethical challenges raised by genetics. It concludes that the policy framework in the field of pharmacogenomics is still in its infancy and needs to be further developed to answer the challenges raised by this important discipline.

(2007) 5:2 *GenEdit*, 1-9

LAWS AND POLICIES - NEW DOCUMENTS

INTERNATIONAL / REGIONAL

Council for International Organization of Medical Sciences (CIOMS) : *Special Ethical Considerations for Epidemiological Research [Draft]*

Geneva, June 1, 2006

<http://www.cioms.ch/>

Keywords: **Biobank - Community/Population - Confidentiality - Consent - Databases - Ethics Review Board - Psychosocial Aspects - Research**

Organisation for Economic Co-operation and Development (OECD) : *Draft Guidelines for Quality Assurance in Molecular Genetic Testing*

Paris, July 1, 2006

<http://www.oecd.org/dataoecd/43/26/37103271.pdf>

Keywords: **Confidentiality - Counseling (Post-test) - Counseling (Pre-test) - DNA - Genetic Services - Genetic Testing - Privacy**

World Health Organization (WHO) : *Sickle-Cell Anaemia (Report by the Secretariat)*

Geneva, April 24, 2006

http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_9-en.pdf

Keywords: **Access Info/Material - Autonomy - Beneficence - Carrier Status - Community/Population - Confidentiality - Counseling (general) - Developing Countries - Diversity - Duty to Warn - Education - Equity - Family - Follow-up - Gene Therapy - Genetic Screening - Genetic Testing - Male/Paternity - Minor/Child - Newborn - Patient/Participant/Individual - Preconception - Prenatal - Public Health - Research - Woman/Maternity**

European Commission : *Europeans and Biotechnology in 2005: Patterns and Trends*

Brussels, July 1, 2006

http://www.ec.europa.eu/research/press/2006/pdf/pr1906_eb_64_3_final_report-may2006_en.pdf

Keywords: **Community/Population - Data - DNA - Gene Therapy - Governance - Nanotechnology - Pharmacogenomics - Research - Respect for Human Life - Stem Cell**

NATIONAL

Association of Genetic Nurses and Counsellors, Clinical Genetics Society (CGS) : *Professional Roles in the Multidisciplinary Team in Genetics - A Framework for Practice*

Birmingham, April 1, 2006

http://www.clingensoc.org/Docs/WP_AGNC_CGS.pdf

Keywords: **Counseling (general) - Patient/Participant/Individual - Professional - Standard of Care**

Vlaams Instituut voor Wetenschappelijk en Technologisch Aspectenonderzoek (viWTA), EuroGentest Network of Excellence : *Ethical and Social Aspects of Genetic Testing Services: Issues and Possible Actions - A Technology Assessment Contribution to the Eurogentest Network of Excellence*

Brussels, October 1, 2005

<http://www.viwt.be/files/FinaleVolledigeDefinitieveEindrapportEurogentest.pdf>

Keywords: **Communication of Results - Community/Population - Consent - Counseling (Pre-test) - Discrimination - Ethics Review Board - Genetic Screening - Genetic Services - Genetic Testing - Incompetent Adult - Patient/Participant/Individual - Pre-implantation - Public Health**

Human Genetics Society of Australasia (HGSA) : *HGSA Position Statement on Parental Consent to*

the Paternity Testing of Children for Non-Clinical Purposes

Sydney, August 1, 2006

<http://hgsa.com.au/images/UserFiles/Attachments/nonconsensualtestingfinala050806.pdf>

Keywords: **Beneficence - Consent - Genetic Testing - Male/Paternity - Minor/Child**

National Cancer Institute (NCI), National Institutes of Health (NIH) : *First-Generation Guidelines for NCI-Supported Biorepositories*

Bethesda, December 5, 2005

<http://72.14.205.104/search?q=cache:OiglUjrjKO4J:biospecimens.cancer.gov/biorepositories/First%2520Generation%2520Guidelines%2520042006.pdf+First-Generation+Guidelines+for+NCI-Supported+Biorepositories&hl=fr&ct=clnk&cd=1&gl=ca>

Keywords: **Access Info/Material - Cancer - Community/Population - Confidentiality - Consent - Databases - Intellectual Property - Ownership - Patient/Participant/Individual - Research - Storage**

Nuffield Council on Bioethics : *Genetic Screening - A Supplement to the 1993 Report by the Nuffield Council on Bioethics*

London, July 1, 2006

[http://www.nuffieldbioethics.org/fileLibrary/pdf/Genetic_Screening_-_a_Supplement_to_the_1993_Report_\(2006\).pdf](http://www.nuffieldbioethics.org/fileLibrary/pdf/Genetic_Screening_-_a_Supplement_to_the_1993_Report_(2006).pdf)

Keywords: **Biobank - Carrier Status - Communication of Results - Community/Population - Confidentiality - Consent - Consultation/Collaboration - Counseling (general) - Education - Employer/Employment - Family - Genetic Screening - Genetic Services - Genetic Testing - Insurer/Insurance - Patient/Participant/Individual - Pharmacogenomics - Population Genetics - Predictive Testing - Professional - Researcher - Socio-Economic Aspects**

Society of Obstetricians and Gynaecologists of Canada (SOGC) : *Carrier Screening for Genetic Disorders in Individuals of Ashkenazi Jewish Descent*

Ottawa, April 1, 2006

(2006) 177 *Journal of Obstetrics and Gynaecology Canada*, 324

<http://www.sogc.org/guidelines/public/177E-CPG-April2006.pdf>

Keywords: **Access Info/Material - Beneficence - Carrier Status - Community/Population - Confidentiality - Consent - Counseling (general) - Education - Family - Genetic Screening - Genetic Testing - Male/Paternity - Minor/Child - Preconception - Prenatal - Professional - Psychosocial Aspects - Woman/Maternity**

The Royal Pharmaceutical Society of Great Britain (RPSGB) : *Realising the Potential of Genomic Medicine*

London, July 1, 2006

<http://www.rpsgb.org.uk/pdfs/genommedsrept.pdf#search=%22realising%20the%20potential%20of%20genomic%20medicine%22>

Keywords: **DNA - Embryo - Embryos (created for research) - Ethical Review - Gene Therapy - Genetic Testing - Liability - Pharmacogenomics - Professional - Research - Researcher - Stem Cell - Surplus Embryos - Therapeutic Cloning**

United States - Department of Health and Human Services (DHHS) - Food and Drug Administration (FDA) : *Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are not Individually Identifiable*

Rockville, April 25, 2006

<http://www.fda.gov/cdrh/oivd/guidance/1588.pdf>

Keywords: **Access Info/Material - Biobank - Conflict of Interest - Consent - Ethics Review Board - Patient/Participant/Individual - Research - Tissue - Waiver of Consent**

United States/Senate : *Genomics and Personalized Medicine Act of 2006, Bill S. 3822*

Washington, August 3, 2006

<http://www.theorator.com/bills109/s3822.html>

Keywords: **Community/Population - Data - Discrimination - Genetic Testing - Patient/Participant/Individual - Pharmacogenomics - Privacy - Research**

Washington State Department of Health : *Genetic Counselor Sunrise Review*

Olympia, January 1, 2006

http://www.doh.wa.gov/hsqa/sunrise/2006/gen_couns_ofm_approved.pdf

Keywords: **Competence - Counseling (general) - Family - Liability - Patient/Participant/Individual - Professional - Standard of Care**

Washington State Department of Health : *Newborn Screening Tests & Your Baby*

Tumwater, August 1, 2006

http://www.doh.wa.gov/EHSPHL/PHL/Newborn/pubs/2007_en_brochure.pdf

Keywords: **Access Info/Material - Communication of Results - Genetic Screening - Minor/Child - Newborn - Patient/Participant/Individual - Privacy**

Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) : *Outil d'aide à la décision pour l'introduction de programmes de dépistage populationnel génétique [ébauche]*

Québec, June 1, 2006

http://www.aetmis.gouv.qc.ca/site/index.php?fr_ds_depistage_genetique

Keywords: **Community/Population - Genetic Screening - Genetic Testing**

Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) : *Decision Aid for the Introduction of Population-Based Genetic Screening Programs [draft]*

Québec, June 1, 2006

http://www.aetmis.gouv.qc.ca/site/index.php?en_ds_genetic_screening

Keywords: **Community/Population - Genetic Screening - Genetic Testing**

Fonds de la Recherche en Santé du Québec (FRSQ) : *Rapport préliminaire: groupe-conseil sur l'encadrement des banques de données et de matériel biologique à des fins de recherche en santé*

Québec, May 1, 2006

Keywords: **Access Info/Material - Confidentiality - Consent - Data - Databases - DNA - Education - Ethical Review - Governance - Patient/Participant/Individual - Research - Storage - Tissue**

Québec/Assemblée nationale et gouvernement : *Loi modifiant la Loi sur l'accès aux documents des organismes publics et sur la protection des renseignements personnels et d'autres dispositions législatives*

Québec, June 14, 2006

L.Q. 2006, c. 22.

<http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=5&file=2006C22F.PDF>

Keywords: **Access Info/Material - Confidentiality - Data - Databases**

UPCOMING EVENTS

31st Annual Meeting organized by International Association for the Philosophy of Sport

Date: **September 18 - 21, 2006**

Location : **Cheltenham, United Kingdom**

Information:

Bien commun et mondialisation: historique et perspectives organized by Canada Research Chair in Law and Medicine

Date: **September 20, 2006**

Location : **Montréal, Québec, Canada**

Information:

4ème colloque annuel des programmes de bioéthique de l'Université de Montréal : La technologie en santé: fascination et fragilité organized by Programmes de bioéthique de l'Université de Montréal

Date: **September 28 - 29, 2006**

Location : **Montréal, Québec, Canada**

Information:

Training in Research Ethics: Social and Behavioural Sciences and Humanities Program

organized by National Council on Ethics in Human Research (NCEHR)

Date: **September 29, 2006**

Location : **Charlottetown, Prince Edward Island, Canada**

Information:

L'intérêt général et les notions voisines organized by Canada Research Chair in Law and Medicine

Date: **October 4, 2006**

Location : **Montréal, Québec, Canada**

Information:

27ème congrès annuel: La génétique, le pari de la vie organized by Société québécoise de biologie clinique (SQBC)

Date: **October 4 - 7, 2006**

Location : **La Malbaie, Québec, Canada**

Information:

International Conference: 2020 Vision-Variation and Function in the Genome organized by Genome Canada

Date: **October 25 - 27, 2006**

Location : **Quebec City, Quebec, Canada**

Information:

Évolution d'une notion nouvelle: le patrimoine commun de l'humanité organized by Canada
Research Chair in Law and Medicine
Date: **November 1, 2006**
Location : **Montréal, Québec, Canada**
Information:

Training in Research Ethics: Social and Behavioural Sciences and Humanities Program
organized by National Council on Ethics in Human Research (NCEHR)
Date: **November 18, 2006**
Location : **Calgary, Alberta, Canada**
Information:

Frontiers in Biomedical Research, HKU 2006 organized by The University of Hong Kong Li Ka
Shing Faculty of Medicine
Date: **December 8, 2006**
Location : **Hong Kong, China**
Information:

10th Annual Meeting: Pharmacogenomics organized by National Coalition for Health Professionals
Education in Genetics (NCHPEG)
Date: **February 1 - 2, 2007**
Location : **Bethesda, Maryland, USA**
Information:

**One Origin, One Race, One Earth: Genetics, Human Rights and the Next Phase of Human
Evolution** organized by Alberta Civil Liberties Research Centre
Date: **November 15 - 17, 2007**
Location : **Calgary, Alberta, Canada**
Information:

TEAM PUBLICATIONS

Avard D., Kharaboyan L., Knoppers B.M., "**Newborn Screening for Sickle Cell Disease: Socio-Ethical Implications**", *First Do No Harm: Law, Ethics and Healthcare* (Aldershot: Ashgate Publishing Limited, 2006) .

Abstract : Neonatal screening for SCD allows early diagnosis and therefore early treatment and education. However, such a screening programme must take into consideration a number of socio-ethical concerns. Three main socio-ethical concerns with respect to SCD neonatal screening are presented. First, the need to address the difficulties raised by revealing carrier status; second, whether neonatal screening should be selective or universal; and third, the need to address the role of consumer groups if screening is to reach its promise of predictive and preventive aspects.

Isasi R.M., Knoppers B.M., "**Beyond the Permissibility of Embryonic and Stem Cell Research: Substantive Requirements and Procedural Safeguards**", (2006) 21: 10 *Human Reproduction*, 2474 , online: <http://humrep.oxfordjournals.org/cgi/content/abstract/del235v1>

Abstract : This report provides a comparative analysis of the regulation of embryonic stem cells and cloning research in 50 countries. The development of international stem cell consortia involving the

exchange of materials, data and knowledge presumes 'policy know-how' on the varying positions and governing regulations of the various partners; knowledge is essential for the feasibility of such international collaborative projects.

Knoppers B.M., "**Biobanks: New Challenges for Bioethics and Biolaw**", (2006) *Iustitia*, 47.

Abstract : It is important to remember that a biobank is not a fridge with specimens in it or a pathology lab, and it is not a study that some geneticist has done. A biobank is a database that can be searched, and it is organized in a systematic way. To understand why biobanks are attracting the attention of policymakers, first definitions of genetic data, personal data, and medical data will be presented in order to determine whether these terms refer to different things. Then, a more theoretical portion will be addressed and will look at whether we can use biobanks, and huge projects that cover whole countries, as in Iceland, Estonia and the United Kingdom, for public health purposes.

Knoppers B.M., Bordet S., Isasi R.M., "**Preimplantation Genetic Diagnosis: An Overview of Socio-Ethical and Legal Considerations**", (2006) *7 Annu. Rev. Genomics Hum. Genet.*, 201 .

Abstract : Preimplantation genetic diagnosis (PGD) permits the selection of embryos of a particular genotype prior to implantation. As a reproductive technology involving embryo selection, PGD has become associated with considerable controversy. This review examines some of the ethical, legal, and social issues raised by PGD. Relevant ethical considerations include the status of the embryo and the interests and duties of the parents. On a social policy level, considerations of access as well as the impact of this technology on families, women, and physician's duties also warrant consideration. An analysis of these issues in the context of using PGD for selecting embryos unaffected by a serious disorder and for sex selection is presented. We also present a brief survey of PGD-related regulatory schemes in several countries, including the United Kingdom and the United States.

Knoppers B.M., Joly Y., Simard J., Durocher F., "**The Emergence of an Ethical Duty to Disclose Genetic Research Results: International Perspectives**", (2006) *Eur. J. Hum. Genet.* (advanced publication) , online: <http://www.nature.com/uidfinder/10.1038/sj.ejhg.5201690>

Abstract : The last decade has witnessed the emergence of international ethics guidelines discussing the importance of disclosing global and also, in certain circumstances, specific genetic research results to participants. This discussion is all the more important considering the advent of pharmacogenomics and the increasing incidence of 'translational' genetic research in the post-genomic era. We surveyed both the literature and the ethical guidelines using selective keywords. We then analyzed our data using a qualitative method approach and singled out countries or policies that were representative of certain positions. From our findings, we conclude that at the international level, there now exists an ethical duty to return individual genetic research results subject to the existence of proof of validity, significance and benefit.

Sillon G., Joly Y., "**Regard éthico-juridique sur la pharmacogénomique : Perspectives et enjeux**", *16ème congrès mondial de droit médical; Actes du congrès* (Bordeaux : Association mondiale de droit médical, 2006), vol. 1, 241 .

[French version only]

Simard J. et al., "**Evaluation of BRCA1 and BRCA2 Mutation Prevalence, Risk Prediction Models and a Multi-Step Testing Approach in French-Canadian High-Risk Breast and Ovarian Cancer Families**", (2006) *J. Med. Genet.* (advanced publication) , online: <http://jmg.bmjournals.com/cgi/rapidpdf/jmg.2006.044388v1>

Abstract : Here we report the results of multi-step genetic testing for mutations in BRCA1 or BRCA2 in a large series of breast cancer families in the French-Canadian population of Quebec. A total of 256 high-risk families were ascertained from regional familial cancer clinics throughout the province of

Quebec. Eight of the fifteen distinct mutations found in 62 positive families had never been previously reported in this population, whereas 82% carried one of the four mutations currently observed in 2 or more families. In this population, a testing strategy employing an initial test using a panel of reported recurrent mutations, followed by full sequencing in families with Manchester scores higher than or equal to 18 represents an efficient test in terms of overall cost and sensitivity.

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