



GENINFO

Newsletter on the Ethical, Legal and Social
Issues in Human Genetics

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March-April 2007



Dear reader,

I am pleased to introduce to you Ms. Thu Minh Nguyen, the next GenInfo newsletter Editor-in-chief. Ms. Nguyen will be in charge of this function during my maternity leave and will also be coordinating the HumGen internet site for the next year.

Having worked with the HumGen team for several years, Ms. Nguyen has already collaborated in the preparation of the GenInfo newsletter.

I am certain that you will appreciate her rigour and her continued commitment to ensure that the HumGen website evolves to meet your needs.

Emmanuelle Lévesque, Editor-in-chief

EDITORIAL



Whither Pediatric Research and Predisposition Genetic Testing?

Patenaude A.F., Sénécal K., Avaré D.

Abstract: Research in which children undergo genetic testing for predisposition to adult-onset diseases or disorders could lead to a better understanding of these conditions. It could also possibly help encourage early detection and the development of clinical and preventive interventions for those found to be at increased risk. Increasingly, predisposition testing is becoming part of pediatric genetic research. However, the paucity of normative texts about the conduct of pediatric research using predisposition genetic testing generates complex legal and ethical issues. Drawing on the current texts that govern predisposition genetic testing in research and the norms of pediatric research generally, we outline points of consensus and divergence as well as recommendations regarding predisposition genetic testing in pediatric research.

(2006) 4:2 *GenEdit*, 1-9

INTERNATIONAL / REGIONAL

United Nations (UN) - General Assembly: *Convention relative aux droits des personnes handicapées*

New York - December 13, 2006

Link: [URL](#)

Key Words: Autonomy - Confidentiality - Disability - Discrimination - Education - Employer/Employment - Integrity - Minor/Child - Privacy - Research

United Nations (UN) - General Assembly: *Convention on the Rights of Persons with Disabilities*

New York - December 13, 2006

Link: [URL](#)

Key Words: Autonomy - Confidentiality - Disability - Discrimination - Education - Employer/Employment - Integrity - Minor/Child - Privacy - Research

Council of the European Union: *Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006 on Medicinal Products for Paediatric Use and Amending Regulation (EEC) no. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) no. 726/2004*

Strasbourg - December 12, 2006

Link: [URL](#)

Key Words: Access Info/Material - Beneficence - Community/Population - Conflict of Interest - Equity - Ethical Review - Intellectual Property - Minor/Child - Patient/Participant/Individual - Professional - Public Health - Research - Researcher

Council of the European Union: *Regulation (EC) No. 1902/2006 of the European Parliament and the Council of 20 December 2006 Amending Regulation 1901/2006 on Medicinal Products for Paediatric Use*

Brussels - December 20, 2006

Link: [URL](#)

Key Words: Minor/Child - Research

European Agency for the Evaluation of Medicinal Products (EMA): *Guideline on Conduct of Pharmacovigilance for Medicines Used by the Paediatric Population*

London - January 26, 2007

Link: [URL](#)

Key Words: Access Info/Material - Beneficence - Biobank - Community/Population - Consent - Data - Databases - DNA - Education - Family - Follow-up - Man/Paternity - Minor/Child - Pharmacogenomics - Professional - Research - Storage - Woman/Maternity

NATIONAL

American College of Obstetricians and Gynecologists (The) (ACOG): *Screening for Fetal Chromosomal Abnormalities*

Washington - January 1, 2007

(2007) 109:1 *Obstetrics & Gynecology*, 217

Key Words: Access Info/Material - Autonomy - Communication of Results - Consent - Counseling (general) - Disability - Genetic Screening - Genetic Testing - Minor/Child - Patient/Participant/Individual - Prenatal - Psychosocial Aspects - Woman/Maternity

EuroGentest Network of Excellence: *Draft Recommendations of the Minimal Criteria for Genetic Counselling Related to Genetic Testing*

Leuven - January 1, 2007

Link: [URL](#)

Key Words: Carrier Status - Communication of Results - Community/Population - Consent - Counseling (general) - Counseling (Post-test) - Counseling (Pre-test) - Disability - Education - Employer/Employment - Family - Follow-up - Genetic Screening - Genetic Services - Genetic Testing - Incompetent Adult - Insurer/Insurance - Patient/Participant/Individual - Pre-implantation - Prenatal - Professional - Psychosocial Aspects

Life Insurance Association: *Genetics and Life Insurance*

Singapore - April 1, 2006

Link: [URL](#)

Key Words: Access Info/Material - Genetic Testing - Insurer/Insurance

Society of Obstetricians and Gynaecologists of Canada (SOGC): *Statement on Access to Genetic Screening*

Ottawa - January 17, 2007

Key Words: Access Info/Material - Autonomy - Beneficence - Communication of Results - Family - Genetic Screening - Minor/Child - Prenatal - Professional - Woman/Maternity

United States - Department of Health and Human Services (DHHS): *Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors*

Rockville - November 1, 2006

Link: [URL](#)

Key Words: Follow-up - Gene Therapy - Patient/Participant/Individual - Research - Somatic Therapy - Storage

United States/House of Representatives: *An Act to Prohibit Discrimination on the Basis of Genetic Information with Respect to Health Insurance and Employment (H.R. 493, S. 358)*

Washington - April 25, 2007

Link: [URL](#)

Key Words: Confidentiality - Data - Discrimination - Employer/Employment - Family - Genetic Testing - Insurer/Insurance - Patient/Participant/Individual - Privacy

Comité d'éthique de la recherche - Hôtel-Dieu de Lévis: *La recherche en génétique humaine - Formulaire de consentement - Guide du chercheur (version révisée)*

Lévis - October 1, 2006

Link: [URL](#)

Key Words: Biobank - Cancer - Commercialization - Communication of Results - Compensation for Participation - Confidentiality - Databases - DNA - Research - Right of Withdrawal - Socio-Economic Aspects - Third Party

Fonds de la Recherche en Santé du Québec (FRSQ): *Modes opératoires normalisés (MON) pour assurer les bonnes pratiques de recherche clinique*

Montréal - January 1, 2007

Link: [URL](#)

Key Words: Commercialization - Confidentiality - Conflict of Interest - Consent - Data - Ethical Review - Ethics Review Board - Follow-up - Incompetent Adult - Minor/Child - Recruitment - Research - Researcher - Tissue

SPECIALIZED MODULES

StemGen

For a comprehensive database of international, regional and national legislation and policies on stem cell research and related therapies, visit [StemGen](#). A unique feature of StemGen is the [STEM CELL WORLD MAP](#), which describes the policy approaches adopted in over 50 countries.

UPCOMING EVENTS

SARS, Avian Influenza and the Precautionary Principle (Conférencier: Dr. Richard Schabas)

Organized by: Chaire de Recherche du Canada en Droit et Médecine

Date: March 7, 2007

Location: Montréal, Québec, Canada

Information:

The 8th Asian Bioethics Conference : Biotechnology, Culture, and Human Values in Asia and Beyond

Organized by: Asian Bioethics Association

Date: March 19-23, 2007

Location: Bangkok, Thaïlande

Information:

Governing the Globalization of Public Health (Conférencière: Allyn L. Taylor)

Organized by: Chaire de Recherche du Canada en Droit et Médecine

Date: April 4, 2007

Location: Montréal, Québec, Canada

Information:

Biobanking and Biorepositories 2007 Conference

Organized by: IBC Life Sciences

Date: April 26-27, 2007

Location: Amsterdam, Pays-Bas

Information:

The 20th Anniversary of the DMD Gene Discovery : Impact on Muscle Biology, Disease and Therapy

Organized by: Institut de recherche en santé d'Ottawa (IRSO)

Date: May 3-5, 2007

Location: Ottawa, Ontario, Canada

Information:

12th Human Genome Meeting

Organized by: Human Genome Organisation (HUGO)

Date: May 21-24, 2007

Location: Montréal, Québec, Canada

Information:

2007 Annual Meeting - International Biobanking Standards

Organized by: International Society for Biological and Environmental Repositories (ISBER)

Date: May 30-June 2, 2007

Location: Singapour, Singapour

Information:

2007 Joint Ethics Conference : 18ème conférence annuelle de la Société canadienne de bioéthique et 3ème conférence internationale sur l'éthique clinique et la consultation

Organized by: Société canadienne de bioéthique

Date: May 30-June 3, 2007

Location: Toronto, Ontario, Canada

Information:

Integrative Systems Biology for Health - From First Principles to Medical Applications

Organized by: Systemoscope Consortium

Date: June 25-28, 2007

Location: Paris, France

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., "**Research and Public Health Surveillance Using Newborn Bloodspots in Canada**", in Knoppers B.M. (ed.), *Genomics and Public Health: Legal and Socio-Ethical Perspectives* (Leiden/Boston: Brill/Martinus Nijhoff, 2006)

Abstract: Newborn screening programmes are highly effective public health programmes that exist on all continents. The essential goal of newborn screening is to test early for disorders which can be prevented or for disorders whose severity can be

reduced by timely intervention. While newborn screening programmes provide considerable health benefits for children, the blood samples collected as part of routine newborn screening programmes have acquired a new and significant value as a result of the development of genomics. Generally, after newborn screening is completed, the dried blood spots are stored in public health laboratories, for variable periods of time, in order to permit confirmatory diagnosis, re-testing if needed, and quality control. The storage of dried blood spots for these purposes is not particularly controversial since these uses are related to the primary purpose of the initial collection: namely, screening for various disorders. These blood samples are considered valuable resources for health research and possible tools to help answer important public health questions

Avard D., Vallance H., Greenberg C., Laberge C., Kharaboyan L., Plant M., "**Variability in the Storage and Use of Newborn Dried Bloodspots in Canada: Is it Time for National Standards?**", (2006) 2:3 *Genomics, Society and Policy*, 80

Abstract: Storage and secondary use of bloodspots collected for newborn screening raises controversies because of the particularly sensitive nature of the information that can be derived from them and the lack of national standards and consistent provincial policies that can serve to guide storage facilities. This report, derived through a review of Canadian and provincial policy statements, a survey of provincial newborn screening laboratory directors and program directors, as well as through a consultative workshop, illustrates the social, ethical and legal issues regarding the storage, access and further uses of newborn bloodspots. The report indicates that there is a need for heightened transparency and clear recommendations concerning the criteria for storage, the duration of storage, and permissible secondary uses of dried bloodspots in Canada.

Health Canada, External Working Group on the Registration and Disclosure of Clinical Trial Information (EWG-CT)(McGillivray B., Alessi-Severini S., Armstrong P., Belisle J.-P., Binder C., Clark A.F., Downie J., Grimshaw J., Joly Y. et al.), "**Options for Improving Public Access to Information on Clinical Trials of Health Products in Canada**", Ottawa, 2006, online: [URL](#)

Abstract: This report provides the final recommendations of the EWG-CT on options for improving public access to information about clinical trials in Canada.

Joly Y., "**Wind of Change: In re Fisher and the Evolution of the American Biotechnology Patent Law**", (2006) 24:1 *Law in Context*, 67

Abstract: This article discusses the sources and the evolution of the judicial and administrative changes in the American application of the patent law to the biotechnology sector. It also provides an in-depth analysis of the landmark case, *In re Fisher*, which constituted a major step towards this new approach to biotechnology patenting. Other recent cases reflecting this repositioning will be commented on as well. It is the contention of the author that the American patent law has evolved toward a less permissive yet more rational approach toward patenting gene sequences. The modern patent system, in this case, has once again shown its capacity to adapt. The biotechnology sector, since the beginning of its mass development, has generated a number of complex challenges for the patent system and several controversial issues remain to this day. Will the system, in time, also be successful at meeting these other important challenges raised by the biotechnology revolution?

Knoppers B.M., "**Introduction: Of Genomics and Public Health: Building Public Goods?**", in Knoppers B.M. (ed.), *Genomics and Public Health: Legal and Socio-Ethical Perspectives* (Leiden/Boston: Brill/Martinus Nijhoff, 2006)

Abstract: All signs point to the potential for the Human Genome Project to provide tools for the translation of genomic knowledge to clinical diagnosis, with implications for every level of the health care system. Indeed, "[g]enomics is inspiring the development of very large longitudinal cohort studies and even studies of entire populations to establish repositories of biological materials ('biobanks') for discovery and characterization of genes associated with common diseases." With these "biobanks", an important advance in human genetics will be the identification and characterization of numerous common genetic variants at specific loci that increase or decrease the risks for various diseases singly and in combination with other genes and with various chemical, physical, infectious, pharmacologic and social factors. Yet, when applied to such population studies and to the ensuing accompanying genomic databases, current consent and

privacy mechanisms may limit the use of these biobanks for public health research.

Knoppers B.M. (ed.), "**Genomics and Public Health: Legal and Socio-Ethical Perspectives**", (Leiden/Boston: Martinus Nijhoff Publishers, 2006)

Abstract: When genomics and public health are integrated into society, it will create as many responsibilities as rights for citizens, researchers, and decision makers. Indeed, the expression of genetic risk factors in both common and infectious diseases is of great interest to public health. Policy development in this area then needs to tackle crucial themes such as: research and its application to public health and genomic medicine, the authority of the state, the right to privacy, and the roles and responsibilities of citizens and the State. Considering the current fears of a world-wide pandemic, this book is a timely and insightful exploration of both research possibilities and the role of the state. It will help to understand the limits of possible state access to biobanks and data. It examines the issue of the possible use of newborn screening programmes by public health authorities. It also attempts to understand the protection of individual privacy and the public interest in the promotion of health and the prevention of disease. Moreover, do citizens have a say? Will public attitudes be different towards research in public health genomics compared to genetic testing?

Lévesque E., "**Enjeux éthiques et légaux soulevés par la recherche en génétique: l'encadrement québécois et le pistes de solution des normes internationales (résumé de présentation)**", (2006) 43:3 *Annales de biologie clinique du Québec*, 11, online: [URL](#)

Abstract: [French version only]

 EDITORIAL TEAM

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