



# GENINFO

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

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March-April 2008

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As many of our readers know, part of our work at HumGen is to track the publication of new ethical and legal documents in the field of human genetics, and to make this collection freely available to all with an interest in this area. HumGen has become a well-established tool for people involved in human genetics the world over, including: legal practitioners and jurists, ethicists, health professionals, scientists, students, and more.

If you agree that the HumGen website and the GenInfo newsletter are useful tools, and you have colleagues and friends who you think should be aware of them, we invite you to click on the "Share your resources" button on the left! We thank you for helping us to spread the word about HumGen and GenInfo and we are certain your colleagues will thank you for sharing us as a resource.

Enjoy the newest edition of GenInfo!

Guillaume Sillon, editor-in-chief

EDITORIAL



## Consent in Pharmacogenomic Research

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

**Abstract:** 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

**International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): Definitions for Genomic Biomarkers. Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories**

Geneva - November 1, 2007

Approved by CHMP in November 2007, issued as [EMA/CHMP/ICH/437986/2006](#), date for coming into operation : May 2008

**Link:** [URL](#)

**Key Words:** Confidentiality - DNA - Pharmacogenomics - Privacy - Storage

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**NATIONAL**

**American Academy of Actuaries: Comment Letter on the Actuarial Implications of Restricting Insurers' Use of Genetic Information**

Washington - February 16, 2007

**Link:** [URL](#)

**Key Words:** Genetic Information - Genetic Screening - Genetic Testing - Insurer/Insurance

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**Australia/Government - Parliament of Australia: Gene Technology Amendment Act 2007**

Canberra - June 28, 2007

**Link:** [URL](#)

**Key Words:** Genetic Engineering - Intellectual Property - Liability - Patents - Research

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**Australia/Government - Parliament of Australia: Gene Technology Amendment Regulations 2007 (No. 1)**

Canberra - May 23, 2007

**Link:** [URL](#)

**Key Words:** Genetic Engineering - Intellectual Property - Patents

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**Australia/Government - Parliament of Australia: Privacy (Data Security Breach Notification) Amendment Bill 2007: Explanatory Memorandum**

Canberra - January 1, 2008

**Link:** [URL](#)

**Key Words:** Access Info/Material - Confidentiality - Employer/Employment - Privacy

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**Canadian Invitational Workshop: Final Workshop Report on the Health Technology Assessment in Newborn and Prenatal Screening: Ethical, Legal, and Social Issues**

Ottawa - February 1, 2008

**Link:** [URL](#)

**Key Words:** Genetic Screening - Newborn - Population Genetics - Prenatal - Research - Researcher

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**EuroGentest Network of Excellence: Definitions of Genetic Testing**

Leuven - January 4, 2007

**Link:** [URL](#)

**Key Words:** Counseling (general) - Genetic Screening - Genetic Testing - Pharmacogenomics

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**National Academy of Clinical Biochemistry (NACB): Guidelines and Recommendations for Laboratory Analysis and Application of Pharmacogenomics in Clinical Practice**

Washington - December 1, 2007

**Link:** [URL](#)

**Key Words:** Genetic Testing - Patient/Participant/Individual - Pharmacogenomics - Population Genetics - Research

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**National Health Policy Forum: Pharmacogenomics: A Policy Primer**

Washington - January 28, 2008

**Link:** [URL](#)

**Key Words:** Commercialization - Communication of Results - Confidentiality - Consent - Education - Insurer/Insurance - Intellectual Property - Patents - Pharmacogenomics - Privacy - Psychosocial Aspects - Right not to Know - Socio-Economic Aspects - State - Storage

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**Society of Obstetricians and Gynaecologists of Canada (SOGC): Prenatal Screening for Fetal Aneuploidy**

Ottawa - February 1, 2007

2007 *Journal of Obstetrics and Gynaecology Canada* 162-179

**Link:** [URL](#)

**Key Words:** Counseling (general) - Foetus - Genetic Screening - Genetic Services - Genetic Testing - Prenatal - Woman/Maternity

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**Quebec/Government - Ministry of Health and Social Services:** *Recueil de textes normatifs relatifs à l'éthique en recherche*

Québec - January 22, 2008

**Link:** [URL](#)

**Key Words:** Research

## 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

### **Conférence Canadienne sur la génétique humaine**

**Organized by:** Fondation Canadienne Gène Cure avec les Instituts de recherche en santé du Canada

**Date:** April 9-12, 2008

**Location:** St. Sauveur, Québec, Canada

**Information:**

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### **International GE3LS Symposium 2008: Navigating the Changing Landscape**

**Organized by:** Genome Canada

**Date:** April 28-30, 2008

**Location:** Calgary, Alberta, Canada

**Information:**

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### **Translating ELSI: Global Perspectives on the Ethical, Legal and Social Implications of Human Genome Research**

**Organized by:** Center for Genetic Research Ethics and Law du Département de bioéthique de l'Université Case Western Reserve

**Date:** May 1-3, 2008

**Location:** Cleveland, Ohio, États-Unis

**Information:**

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### **Journées Génétiques**

**Organized by:** Réseau de Médecine Génétique Appliquée

**Date:** May 14-17, 2008

**Location:** Québec, Québec, Canada

**Information:**

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### **XX International Congress of Genetics: Genetics - Understanding Living Systems**

**Organized by:** International Federation of Genetics et la German Genetics Society

**Date:** July 12-17, 2008

**Location:** Berlin, Allemagne

**Information:**

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### **Illes Rencontres internationales francophones de bioéthique. La bioéthique : un nouvel espace de gouvernance, de diversité et de partage dans les pays de la Francophonie**

**Organized by:** Organisation internationale de la francophonie

**Date:** October 20-22, 2008

**Location:** Québec, Québec, Canada

**Information:**

Avard D., Simard J., Horsman D., Wilson B.J., Meschino W.S., Kim Sing C., Plante M., Eisen A., Howley H.E., "**Variations in rates: why we need clinical management recommendations**", (2007) 1:2 *Open Medicine*, Letter

**Abstract:** This piece is a rapid response to the article "Variation in Rates of Uptake of Preventive Options in BRCA1 and BRCA2 Mutation Carriers Across Canada". The identification of BRCA1 and BRCA2 genes for hereditary breast and ovarian cancer (HBOC) has increased the use of predictive genetic testing. This capability has spurred the development of clinical services in most Canadian provinces that provide cancer genetic services (including surveillance or interventions) to those affected and their family members. Metcalfe and colleagues recently reported that the uptake of preventive measures (such as mastectomy, oophorectomy, treatment with Tamoxifen or Raloxifene, and MRI screening) varied across Canada, with the lowest uptake in Montreal. One reason for these variations, they speculate, may be differences in health care professionals' acceptance and recommendation of such preventive procedures. They indicate that future research is needed to explain these differences. This raises questions of whether the lack of consistent national recommendations for clinical management of individuals carrying a deleterious BRCA1 and BRCA2 mutation contributes to these differences.

Day B., Langlois R., Tremblay M., Knoppers B.M., "**Canadian Health Measures Survey: Ethical, Legal and Social Issues**", (2007) 18 *Statistics Canada, Supplement to Health Reports*, 37

**Abstract:** This article describes how the Canadian Health Measures Survey (CHMS) of Statistics Canada has addressed the ethical, legal and social issues (ELSI) arising from the survey. The development of appropriate procedures and the rationale behind them are discussed in detail for some specific ELSI. Health Canada's Research Ethics Board, the Office of the Privacy Commissioner of Canada, and the Data Access and Control Services Division at Statistics Canada, provided advice to the CHMS on ELSI. Statistics Canada's legal obligation to protect confidentiality, the oath of office, and security measures at Statistics Canada are explained. Additional information on safeguards specific to the CHMS is presented. The ELSI discussed include communication and consent, privacy and confidentiality, reporting results to survey respondents, inclusiveness, and storage of biospecimens. Common to all ELSI is the need for respondents' awareness and acceptance of their role in the survey process, and the obligation of the CHMS to respect respondents and the data they provide.

Horsman D., Wilson B.J., Avard D., Meschino W.S., Kim Sing C., Plante M., Eisen A., Howley H.E., Simard J., "**Clinical Management Recommendations for Surveillance and Risk-Reduction Strategies for Hereditary Breast and Ovarian Cancer Among Individuals Carrying a Deleterious BRCA1 or BRCA2 Mutation**", (2007) 29:1 *Journal of the Society of Obstetricians and Gynecologists of Canada*, 45

**Abstract:** In Canada, there are wide variations in services for patients at risk for hereditary breast and ovarian cancer (HBOC), and clinical interventions and recommendations differ between regions and/or provinces. The National Hereditary Cancer Task Force developed recommendations to address the clinical management of patients at high risk of HBOC and related cancers. These recommendations are based on current practice in high-risk cancer clinics that provide care for individuals with known BRCA1 or BRCA2 mutations. These recommendations pertain to (1) surveillance options including breast self-examination, clinical breast examination, breast surveillance by imaging, ovarian cancer surveillance, and surveillance for men; (2) risk-reduction strategies including prophylactic mastectomy, prophylactic salpingo-oophorectomy, and pharmacoprevention; and (3) the use of exogenous hormones. Regular updates should occur as new evidence becomes available.

Knoppers B.M., Saginur M., "**Bio-Banking**", in *The Cambridge Textbook of Bioethics* (Cambridge: Cambridge University Press, 2008)

**Abstract:** For many years, physicians at a cancer clinic have been storing biological samples left over after being used for diagnosis in clinical testing. Prior to 2000, no consent for storage or research was obtained. In 2000, the clinic changed its policy and began to systematically request consent for the use and storage of leftover biological samples "for future cancer research." From that point on, the clinic has been storing samples only when the patient consented. It discards samples when the patient does not consent. Many of the sample donors are still alive (some are still patients at the clinic),

while others have died. The clinic now has over 4000 samples, with comprehensive clinical data. Two groups of geneticists would like to use the samples for research, one examining the genetic basis of certain cancers, and the other examining the genetic basis of ethnicity and drug response in a randomized, heterogeneous population study.

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