

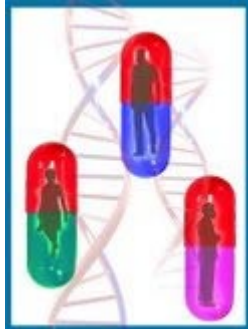


# GENINFO

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

EDITORIAL | LAWS AND POLICIES | EVENTS | TEAM PUBLICATIONS

November-December 2007



Ethics in the field of genetics is in a state of constant evolution. This evolution is a result of scientific advances in genetics, some of which are progressing rapidly and/or appear to offer particular medical promise. One such field is pharmacogenomics. This area of research has the primary goal of personalising and improving pharmacological treatments by studying the relationship between genetics and drug response.

When applied to emerging fields in genetics like pharmacogenomics, novel ethics questions that are not raised in other fields of genetics, often emerge. This month, we invite you to read our new editorial that examines such questions in the context of pharmacogenomic research.

Happy Reading!  
Guillaume Sillon, editor, GenInfo

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

**World Intellectual Property Organization (WIPO):** *Bandung Declaration on the Protection of Traditional Cultural Expressions, Traditional Knowledge, and Genetic*

## Resources

Geneva - June 28, 2007

WIPO/GRTKF/IC/11/12

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

**Key Words:** Community/Population - Consultation/Collaboration - Data - Developing Country - Diversity - Equity - Intellectual Property - Ownership

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**European Commission/Data Protection Working Party: *Opinion 4/2007 on the Concept of Personal Data***

Brussels - June 20, 2007

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

**Key Words:** Adult - Biobank - Data - Databases - Deceased - DNA - Employer/Employment - Foetus - Insurer/Insurance - Privacy - Tissue

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**European Federation of Pharmaceutical Industries and Associations (EFPIA), Royal College of Physicians (RCP): *Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants***

London - September 1, 2007

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

**Key Words:** Ethical Review - Ethics Review Board - Research - Tissue

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## NATIONAL

**American Society of Human Genetics (ASHG): *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States***

Boston - September 1, 2007

(2007) 81:3 Am. J. Hum. Genet., 635

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

**Key Words:** Commercialization - Communication of Results - Counseling (general) - Follow-up - Genetic Testing - Patient/Participant/Individual - Standard of Care

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**General Medical Council (GMC): *0-18 years: Guidance for All Doctors***

London - October 1, 2007

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

**Key Words:** Minor/Child

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**German National Ethics Council (Geschäftsselle des Nationalen Ethikrates):**

*Predictive Health Information in the Conclusion of Insurance Contracts*

Berlin - February 1, 2007

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

**Key Words:** Confidentiality - Discrimination - Genetic Screening - Genetic Testing - Insurer/Insurance - Predictive Testing - State

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**Greece - National Bioethics Commission: *Opinion on Umbilical Cord Blood Banking***

Athens - February 1, 2007

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

**Key Words:** Ethical Review - Storage - Umbilical Cord Blood

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**National Council of Ethics for the Life Sciences (CNECV) - Portugal: *Opinion N. 52 on the Legal System for DNA Profile Databases***

Lisbon - June 12, 2007

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

**Key Words:** Adult - Community/Population - Consent - Data - Databases - DNA - Minor/Child - Privacy - Tissue

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**The American Medical Informatics Association (AMIA): *Toward a National Framework for the Secondary Use of Health Data: An American Medical Informatics Association White Paper***

Orlando - January 1, 2007

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

**Key Words:** Access Info/Material - Communication of Results - Data - Databases - Patient/Participant/Individual - Public Health - Research - Researcher - Storage

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**United States - Department of Health and Human Services (DHHS) - Food and Drug Administration (FDA): *Guidance for Industry on Gene Therapy Clinical Trials - Observing Subjects for Delayed Adverse Events***

Rockville - November 28, 2006

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

**Key Words:** Consent - Data - Gene Therapy - Patient/Participant/Individual - Tissue

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**United States - State of Arizona (Government):** *An Act Amending Title 20, Chapter 4, Article 3, Arizona Revised Statutes, by Adding Section 20-826.04; Amending Title 20, Chapter 4, Article 9, Arizona Revised Statutes, by Adding Section 20-1057.11; Amending Title 20, Chapter 6, Article 4, Arizona Revised Statutes, by Adding Section 20-1342.06; Amending Title 20, Chapter 6, Article 5, Arizona Revised Statutes, by Adding Sections 20-1402.03 and 20-1404.03; Relating to Health Insurance Policies*

Phoenix - June 2, 2007

U.S., HB 2629, 1st session

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

**Key Words:** Discrimination - Genetic Testing - Insurer/Insurance - Woman/Maternity

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**United States/House of Representatives:** *Federal Government Policy on Genetic Discrimination in Insurance or Employment*

Washington - April 30, 2007

Calendar No. 125, 110th Congress, 1st Session, H.R. 493

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

**Key Words:** Discrimination - Employer/Employment - Genetic Screening - Genetic Testing - Insurer/Insurance

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**United States/House of Representatives:** *S. 1505 Affordable Biologics for Consumers Act (Introduced in Senate), To Amend the Public Health Service Act to Provide for the Approval of Biosimilars, and for Other Purposes.*

Washington - May 24, 2007

U.S., Bill S. 1505, 110th Cong., s.1.

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

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

### **Visions National Health Law Conference**

**Organized by:** Health Law Institute, Université d'Alberta

**Date:** November 8-10, 2007

**Location:** Banff, Alberta, Canada

**Information:**

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### **Première table ronde sur l'éthique en santé publique: explorons les bases**

**Organized by:** Agence de la santé publique du Canada (Facilitateur)

**Date:** November 8-9, 2007

**Location:** Montréal, Québec, Canada

**Information:**

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### **1st Congress of the International Society of Nutrigenetics/Nutrigenomics**

**Organized by:** International Society of Nutrigenetics/Nutrigenomics

**Date:** November 11-13, 2007

**Location:** Athènes, Grèce

**Information:**

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### **CCGM Réunion Annuelle 2007**

**Organized by:** Collège Canadien de Généticiens Médicaux

**Date:** November 14-18, 2007  
**Location:** Vancouver, Colombie-Britannique, Canada  
**Information:**

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**Conférence Mondiale sur le Dopage dans le Sport**

**Organized by:** Agence mondiale antidopage  
**Date:** November 15-17, 2007  
**Location:** Madrid, Espagne  
**Information:**

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**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:**

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**Conférence bilingue sur le diabète de type II - Génétique du diabète : regard sur les dernières avancées scientifiques**

**Organized by:** Diabetes Genes Discovery Group  
**Date:** November 20, 2007  
**Location:** Montréal, Québec, Canada  
**Information:**

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**Le 7e séminaire d'experts de l'IIREB: «Généticisation» et responsabilités**

**Organized by:** Institut International de Recherche en Éthique Biomédicale  
**Date:** December 5-6, 2007  
**Location:** Paris, France  
**Information:**

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**Symposium international : «Translational Medicine and Public Health Policy: Lessons from Biobanks Ethical, Legal, Social Issues (ELSI)»**

**Organized by:** Fondation Brocher  
**Date:** December 6-7, 2007  
**Location:** Genève, Suisse  
**Information:**

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**Les enjeux éthiques et juridiques en recherche populationnelle**

**Organized by:** Regroupement des organismes de santé publique de la région de Québec (DMSP, DSP-CHUQ, DRSP, FSI, INSPQ, URESP, URSP, CSSS)  
**Date:** February 18, 2008  
**Location:** Québec, Québec, Canada  
**Information:**

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**International Stem Cell Forum 2008**

**Organized by:** International Stem Cell Forum  
**Date:** February 26-27, 2008  
**Location:** San Francisco, Californie, États-Unis  
**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:**

 **TEAM PUBLICATIONS**

Avard D., Vallance H., Greenberg C., Potter B., "Newborn Screening by Tandem Mass Spectrometry", (2007) 98:4, *Revue canadienne de santé publique*, 284-286

**Abstract:** Emerging technologies like Tandem Mass Spectrometry (TMS) enable multiple tests on a single blood sample and allow the expansion of Newborn Screening

(NBS) to include various metabolic diseases. Introducing TMS for NBS raises important social and ethical questions: what are the criteria for adding disorders to screening panels? What evidence justifies expansion of screening? How can equity in NBS access and standards be ensured? How can policy standards be set, given the multiplicity of stakeholders? This article outlines five key recommendations for advancing the NBS agenda: national public health leadership; transparency; increased national consistency in NBS strategy. The latter includes: minimum standards; collaboration between the federal and provincial/territorial governments and diverse stakeholders; and supporting research and/or programs based on effectiveness that integrate ethical and social issues into assessment.

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Lévesque E., "L'accès aux informations de santé à des fins de recherche sans le consentement des patients : mise en parallèle des modèles québécois et français", in Duguet A.-M., Herveg J., Filippi I. (eds.), *Séminaire d'actualité du droit médical - Dossier médical et données médicales de santé - Protection de la confidentialité, conditions d'accès, échanges pour les soins et les recherches* (Bordeaux: Les Études Hospitalières, 2007), 207

**Abstract:** [French version only]

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Samuël J., Alemdjrodo, R., Knoppers B.M., "Les droits de l'enfant et la thérapie génique : les enjeux éthiques et les particularités de l'article 21 du Code civil du Québec", (2006) 66: Printemps, *Revue du Barreau*, 181-210, online: [URL](#)

**Abstract:** [French version only]

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 EDITORIAL TEAM

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