

**GenInfo**

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# GENINFO

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

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September-October 2009



Dear Readers,

We would like to take this opportunity to announce the appointment of Ma'n H. Abdul-Rahman as the new co-editor-in-chief of GenInfo since our colleague, Karine Sénécal, has left on maternity leave. Mr. Abdul-Rahman will assume this role alongside Thu Minh Nguyen, our current co-editor-in-chief.

We would also like to draw your attention to the publication of a new book entitled, "Pediatric Research in Canada," which explores the ethical and legal issues in pediatric research. This book, the result of a two-year project, presents a critical analysis of international and Canadian policies on pediatric research.

Furthermore, for those who are interested, we would like to remind you that registration is still open for the *5<sup>th</sup> International DNA Sampling Conference: The Age of Personalized Genomics*. This conference will give participants the opportunity to engage in discussion and debate on the ethical, legal and social controversies of personalized genomics. It is organized by the Health Law Institute of Alberta together with our team, the Centre of Genomics and Policy. It will be held between September 16-18<sup>th</sup>, 2009, in Banff, Alberta. For more information, please visit: <http://www.genomealberta.ca/APG>.

Co-Editors-in-Chief

Thu Minh Nguyen & Ma'n H. Abdul-Rahman

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**EDITORIAL**

GENEDITORIAL



## Direct to Consumer Genetic Tests. An Overview of Guidelines and Position Papers

Karine Sénécal, Pascal Borry, Heidi C. Howard, Denise Avard

**Abstract:** A growing number of private companies are offering, via the Internet, genetic tests "directly to consumers". These types of genetic "services" raise a number of ethical concerns, in particular, the validity and clinical utility of these tests and the fact that they are conducted without a system in place to ensure that consumers understand the scope, limits and the basic meaning of the results. This GenEdit analyzes existing normative documents which address genetic tests offered directly to consumers. It identifies three broad approaches regarding the normative framework that should govern such testing. The first approach generally advocates for the ban of these services, while the second appears to allow them, provided that certain conditions are met. The third approach falls somewhere in the middle. These normative documents were also studied for specific information related to the roles and responsibilities of healthcare professionals, pre-test information, consent and communication of results, as well as the importance of educating the public and healthcare professionals. It concludes by stressing the scientific, social and moral necessity for a consistent and adapted normative framework, and the need to initiate activities for public education and public consultation.

(2009) 7:1 GenEdit, 1-14

[Full Text](#)

### LAWS AND POLICIES NEW DOCUMENTS

#### INTERNATIONAL / REGIONAL

Industry Pharmacogenomics Working Group: *Pharmacogenomics Informational Brochure for IRBs/ IECs & Investigational Site Staff*

Kenilworth - January 2, 2009

Link: [URL](#)

Key Words: Biobank - Communication of Results - Confidentiality - Consent - Databases - DNA - Pharmacogenomics - Research - Right of Withdrawal

UNESCO - World Commission on the Ethics of Scientific Knowledge and Technology (COMEST): *Summary Report on Recommendations Adopted at the Sixth Ordinary Session*

Kuala Lumpur - June 16, 2009

Link: [URL](#)

Key Words: Employer/Employment - Ethical Review - Professional - Research - Researcher

The European Association for Bioindustries (EuropaBio): *Core Ethical Values*

Brussels - August 11, 2009

Link: [URL](#)

Key Words: Community/Population - Compensation for Participation - Confidentiality - Conflict of Interest - Consent - Consumer - Counseling (general) - Developing Country - Dignity - Discrimination - Donor - Embryo - Gene Therapy - Genetic Engineering - Genetic Information - Genetic Testing - Germline Therapy - Justice - Patient/Participant/Individual - Privacy - Professional - Public Health - Reproductive Cloning - Respect for Human Life - Stem Cell - Therapeutic Cloning

#### NATIONAL

Canadian General Standards Board (CGSB): *Research ethics boards reviewing biomedical clinical trials*

Ottawa - June 15, 2009

Link: [URL](#)

Key Words: Confidentiality - Consent - Education - Ethical Review - Ethics Review Board - Governance -

Patient/Participant/Individual - Professional - Recruitment - Research - Researcher

Federal Republic of Germany: *Human Genetic Examination Act (Genetic Diagnosis Act - GenDG)*

Berlin - April 24, 2009

Link: [URL](#)

Key Words: Community/Population - Consent - Consultation/Collaboration - Disability - Discrimination - Duty to Warn - Embryo - Employer/Employment - Foetus - Genetic Screening - Genetic Testing - Incompetent Adult - Insurer/Insurance - Patient/Participant/Individual - Prenatal - Professional

France/Government: *Arrêté du 23 juin 2009 relatif à l'information, à la demande et au consentement de la femme enceinte à la réalisation d'une analyse portant sur les marqueurs sériques maternels et à la réalisation du prélèvement et des analyses en vue d'un diagnostic prénatal in utero prévues à l'article R.2131-1 du code de la santé publique*

Paris - June 23, 2009

Link: [URL](#)

Key Words: Confidentiality - Consent - Foetus - Genetic Testing - Prenatal - Professional - Public Health - Waiver of Consent - Woman/Maternity

Genetic Alliance: *Considerations and Recommendations for a National Policy Regarding the Retention and Use of Dried Blood Spot Specimens after Newborn Screening*

Washington - August 21, 2009

Link: [URL](#)

Key Words: Assent/Dissent - Biobank - Confidentiality - Consent - Consumer - Education - Genetic Information - Genetic Screening - Man/Paternity - Newborn - Ownership - Prenatal - Privacy - Public Health - Research - Storage - Woman/Maternity

Health Canada: *Draft Guidance for Health Canada: Biobanking of Human Biological Material*

Ottawa - January 1, 2009

Key Words: Access Info/Material - Benefit Sharing - Biobank - Commercialization - Communication of Results - Compensation for Participation - Confidentiality - Consent - Data - Databases - DNA - Duty to recontact - Ethics Review Board - Genetic Information - Governance - Ownership - Population Genetics - Privacy - Recruitment - Research - Researcher - Right of Withdrawal - Standard of Care - Storage - Tissue - Waiver of Consent

House of Lords Science and Technology Committee: *Genomic Medicine*

London - July 7, 2009

Link: [URL](#)

Key Words: Benefit Sharing - Consultation/Collaboration - Consumer - Data - Genetic Testing - Insurer/Insurance - Patents - Patient/Participant/Individual - Pharmacogenomics - Privacy - Socio-Economic Aspects

National Cancer Research Institute: *Samples and Data for Research: Template for Access Policy Development*

London - June 19, 2009

Link: [URL](#)

Key Words: Access Info/Material - Biobank - Cancer - Communication of Results - Confidentiality - Consent - Data - Databases - DNA - Ethical Review - Ethics Review Board - Genetic Information - Governance - Research - Right of Withdrawal - Tissue

Swedish National Council on Medical Ethics (SMER): *Consultation response on the final report of the Committee on patent protection of biotechnological inventions (SOU 2008:20)*

Stockholm - October 9, 2008

Link: [URL](#)

Key Words: Consent - DNA - Genetic Testing - Intellectual Property - Patents - Patient/Participant/Individual - Stem Cell - Tissue

#### UPCOMING EVENTS

ENGAGE General Assembly 2009

Organized by: European Network for Genetic and Genomic Epidemiology (ENGAGE)

Date: September 18, 2009

Location: Amsterdam, The Netherlands

Information: <http://www.euengage.org/>

The 50th Annual Meeting of the European Society for Paediatric Research (ESPR)

Organized by: European Society for Paediatric Research (ESPR)

Date: October 9-12, 2009  
 Location: Hamburg, Germany  
 Information: <http://www2.kenes.com/Paediatic-Research/pages/home.aspx>

Third International Symposium on Hereditary Breast and Ovarian Cancer  
 Organized by: Hereditary Breast and Ovarian Cancer Foundation and McGill University  
 Date: October 14-16, 2009  
 Location: Montréal, (Québec), Canada  
 Information: [http://www.odon.ca/brca/home\\_e.htm](http://www.odon.ca/brca/home_e.htm)

The American Society of Human Genetics - 59th Annual Meeting  
 Organized by: The American Society of Human Genetics  
 Date: October 20-24, 2009  
 Location: Honolulu, (Hawaii), United-States  
 Information: <http://www.ashg.org/2009meeting/>

HUGO Symposium on Genomics and Ethics, Law and Society  
 Organized by: The Human Genome Organisation  
 Date: November 1-3, 2009  
 Location: Geneva, Switzerland  
 Information: <http://www.hugoevents.org/gels/index.php>

Beyond the Embryo: Transnational, Transdisciplinary and Translational Perspectives on Stem Cell Research  
 Organized by: The Canadian Stem Cell Network and the Brocher Foundation  
 Date: November 14-15, 2009  
 Location: Hermance (Lake of Geneva), Switzerland  
 Information:

#### ▶ TERM PUBLICATIONS

Avard D., Samuël J., Knoppers B.M. (eds.), "", *Paediatic Research in Canada* (Montreal: Les Éditions Thémis, 2009) 270pp  
 Abstract: [None available]

Borry P., Howard H.C., Sénécal K., Avard D., "Health-related direct-to-consumer genetic testing: a review of companies' policies with regard to genetic testing in minors", (2009) *Familial Cancer*, doi:10.1007/s10689-009-9253-9  
 Abstract: More and more companies are advertising and selling genetic tests directly to consumers. Considering the ethical, legal, and psychological concerns surrounding genetic testing in minors, a study of companies' websites was performed in order to describe and analyze their policies with respect to this issue. Of the 29 companies analyzed, 13 did not provide any information about this matter, eight companies allowed genetic testing upon parental request, four companies stated that their website is not directed to children under 18 years, and four companies suggested that in order to be tested, applicants should have reached the age of legal majority. If private companies offer genetic tests which are also offered in a clinical setting, can they be expected to adhere to the existing clinical guidelines with regard to these tests? If so, a certain ambiguity exists. Many companies are emphasizing in their disclaimers that their services are not medical services and should not be used as a basis for making medical decisions. Nonetheless, it remains debatable whether genetic testing in minors would be appropriate in this context. In line with the Advisory Committee on Genetic Testing, the Human Genetics Commission addressed the problem of non-consensual testing and recommended not to supply genetic testing services directly to those under the age of 16 or to those not able to make a competent decision regarding testing.

Bouffard C., Viville S., Knoppers B.M., "Genetic diagnosis of embryos: Clear explanation, not rhetoric, is needed",  
 Abstract: Embryonic research and genetic testing continue to raise concerns. With controversy comes debate and, sometimes, distortion of facts through the use of loaded terms and concepts that call to mind both historical events and science fiction. Achieving greater public understanding of genetic diagnosis of embryos, known generally as preimplantation genetic diagnosis, has implications for the development of regulations and health policies for a broad field that includes genomics, reproductive genetics and embryonic research. We examine the debate about genetic testing and embryonic research with particular reference to the use of words and concepts that have distorted public and scientific discourse in ways that could have a negative influence of laws and regulations for new reproductive technologies generally.

Bucci L.M., Stanton-Jean M., "Toward a Policy Framework on Nanomedicine: A Canadian Perspective", *Novelty or Disguise? Regulation and Policy-making in Nanotechnology* (Italy: Neos Edizioni s.r.l., 2009)

Abstract: Nanomedicine (NM) is changing the way we understand healthcare and health services by bringing new drug delivery systems, real time diagnostic testing, in vivo medical imaging, and maybe in the near future, regenerative medicine. Meanwhile, the NM industry is expanding without any restrictions. In Canada, initiatives toward a broader policy framework for NM are still in their infancy but have so far paid little attention to the analysis of models and how they could provide insight into developing a conceptual framework for analyzing NM issues. This paper addresses this gap and identifies as well as examines three health services models- the medical model, the public health model and the fundamental rights model- that could inform a future NM policy framework in Canada. The overall aim of this paper is to discuss the relevant risks associated with NM within the Canadian context, explore the three models and discuss their appropriateness to Canada.

Caulfield T., Zarzeczny A., McCormick J., Bubela T., Joly Y., Isasi R. et al, "International stem cell environments: A world of difference", (2009) *Nature Reports Stem Cells*, doi:10.1038/stemcells.2009.61

Abstract: [None available]

Caulfield T., Zarzeczny A., McCormick J., Joly Y., Isasi R. et al, "The Stem Cell Research Environment: A Patchwork of Patchworks", (2009) *5 Stem Cell Rev and Rep*, 82

Abstract: Few areas of recent research have received as much focus or generated as much excitement and debate as stem cell research. Hope for the therapeutic promise of this field has been matched by social concern associated largely with the sources of stem cells and their uses. This interplay between promise and controversy has contributed to the important as we enter this new era of stem cell research. The current progression towards translational and clinical research among international collaborators serves as a catalyst for identifying potential policy conflict and makes it imperative to address jurisdictional variability in stem cell research environments. The existing patchworks seen in contemporary stem cell research environments provide a valuable opportunity to consider how variations in regulations and policies across and within jurisdictions influence research efficiencies and directions. In one sense, the stem cell research context can be viewed as a living experiment occurring across the globe. The lessons to be gleaned from examining this field have great potential for broad-ranging general science policy application.

Grégoire G., Alemdjrodo R., Chagnon A., "La discrimination génétique et l'assurance-vie : les mesures de protection actuelles suffisent-elles?", (2009) 14:1 *Lex Electronica*, 1

Abstract: [Available in French only]

Isasi R.M., Knoppers B.M., "Governing stem cell banks and registries: Emerging issues", *Stem Cell Res.* 2009 Sep-Nov;3(2-3):96-105., online: [URL](#)

Abstract: The expansion of national and international research efforts in stem cell research is increasingly paired with the trend of establishing stem cell banks and registries. In jurisdictions crossing the spectrum of restrictive to liberal stem cell policies, banks and registries are emerging as an essential resource for transnational access to quality-controlled and ethically sourced stem cell lines. In this study, we report the preliminary findings of a survey of stem cell banks participating in the International Stem Cell Forum's International Stem Cell Banking Initiative (ISCBI). The questionnaire circulated to all ISCBI members addressed both general issues surrounding research policies (e.g., national policies regulating the permissibility of conducting embryonic stem cell research (hESCR)) and, more specifically, issues relating to the governance of stem cell banking projects. The results of the questionnaire were complemented by scholarly research conducted by the authors. This article provides an overview of the current international hESC banking landscape (I). For this purpose, the policy and governance approaches adopted in the surveyed stem cell banks at the national level will be analyzed and areas of convergence and variance will be identified (II). Finally, while our analysis is focused on research grade hESCs, the lessons to be gleaned from this examination will encourage further thought, analysis, and research into the issues raised in the banking and governance of other sources of stem cell lines (e.g., SCNT, parthenogenesis, iP) (IV).

Knoppers B.M., Laberge C., "Return of Accurate and Actionable Results: Yes", (2009) 9:6-7: *AJOB*, 107

Abstract: [None available]

Nycum G., Knoppers B.M., Avar D., "Intra-familial Obligations to Communicate Genetic Risk Information: What Foundations? What Forms?", (2009) 3 *McGill Journal of Law and Health*, 21

Abstract: Genetic information is not only personal information, it is also familial as well as universal. Although most individuals who undergo genetic testing report feeling some

obligation to communicate their results with family members, such communication is highly context specific and will be shaped by many factors, including the type of genetic condition at issue (i.e., a single-gene or multifactorial genetic condition), familial relationships, individual personalities and perceptions of what is in the family's best interest. Moreover, the foundation and forms for such an obligation are not clear. How would such an obligation be grounded? Is it a moral obligation? Is it a legal obligation? This article explores the possible foundations and forms for an intra-familial obligation to communicate genetic information. Such an obligation is not created in any legislative regime worldwide and, moreover, it would be difficult to make out a claim for civil liability under Canadian common law and Quebec civil law rules. It is therefore important for policy makers to address this issue and clarify whether there is or is not a legal obligation to communicate genetic information within families.

Rothstein M.A., Joly Y., "Genetic Information and Insurance Underwriting: Contemporary Issues and Approaches in the Global Economy", in Atkinson P., Glasner P. & Lock M., eds., *The Handbook of Genetics & Society: Mapping the New Genomic Era* (London and New York: Routledge, 2009), Chapter 10, pp. 127-144  
Abstract: [None available]

Tassé A.M., Petit É., Godard B., "Differences in Regulatory Frameworks Governing Genetic Laboratories in Four Countries", (2009) 37 *Journal of Law, Medicine & Ethics*, 351  
Abstract: [None available]

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