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# GENINFO

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

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January-February 2009



Happy New Year to all our readers!

With the arrival of the New Year, there have also been important developments in the regulation of genetic testing and research.

In this edition of *GenInfo*, we would like to draw your attention to several documents. First, is the adoption of the Additional Protocol to the Convention of Human Rights and Biomedicine by the Council of Europe. This additional protocol concerns genetic

testing for health purposes.

See also the Statement adopted by the Vatican entitled *Instruction Dignitatis Personae on Certain Bioethical Questions*. The Vatican stresses the need to preserve and protect the dignity of all persons from the moment of conception. Therefore, medical procedures such as embryonic stem cell research, cloning or in-vitro fertilization should be banned. This is the first time in 20 years that the Vatican has published authoritative instructions on biomedical issues.

A third important document to note is the Draft 2nd Edition of the Canadian Tri-Council *Policy Statement: Ethical Conduct for Research Involving Humans* published by the Interagency Advisory Panel on Research Ethics. The draft document is currently available for public consultation and commentary.

Finally, the National Human Genome Research Institute of the United States has embarked on a long-range planning process focused on the future of human genome research. To kick-start a conversation among the community, NHGRI has posted three white papers on its website to start the conversation on: 1) Applying Genomics to Clinical Problems - Diagnostics, Preventive Medicine, Pharmacogenomics; 2) Applying Genomics to Clinical Problems - Therapeutics; 3) A Vision for the Future of Genomics: Education and Community Engagement. These white papers are available for viewing and comment at <http://www.genome.gov/About/Planning>

Happy Reading!

Karine Sénécal and Thu Minh Nguyen (Co-Editors)



### Biobanks and Longitudinal Studies: Where Are the Children?

Julie Samuël, Nola M. Ries, David Malkin and Bartha Maria Knoppers

**Abstract:** The inclusion of children in longitudinal research using biobanks raises specific ethical and legal issues. This article analyzes ethical frameworks concerning participation in biobanks and suggests that such frameworks, developed in the context of competent adults as research subjects, are not adapted for research involving children. It concludes that there is a need to elaborate guidelines specific to biobanks and longitudinal studies involving children and provides recommendations regarding parental authorization, the child's assent and consent, and on the return of results in this context.

(2008) 6:3 *GenEdit*, 1-8

[Full Text](#)

#### INTERNATIONAL / REGIONAL

The Innovation Partnership: *Toward an Era of Intellectual Property: From Confrontation to Negotiation*

Montreal - September 1, 2008

Link: [URL](#)

Key Words: Commercialization - Common Heritage - Intellectual Property - Ownership - Patents

Council of Europe: *Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Genetic Testing for Health Purposes*

Strasbourg - November 27, 2008

Link: [URL](#)

Key Words: Access Info/Material - Assent/Dissent - Beneficence - Carrier Status - Consent - Consumer - Counseling (general) - Data - Deceased - Dignity - Discrimination - DNA - Equity - Family - Genetic Information - Genetic Screening - Genetic Testing - Incompetent Adult - Minor/Child - Patient/Participant/Individual - Predictive Testing - Privacy - Public Health - Right not to Know - Storage - Tissue

Council of Europe: *Explanatory Report of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Genetic Testing for Health Purposes (CETS No. 203)*

Strasbourg - November 27, 2008

Link: [URL](#)

Key Words: Access Info/Material - Assent/Dissent - Beneficence - Confidentiality - Consent - Consumer - Counseling (general) - Data - Deceased - Dignity - Discrimination - DNA - Family - Follow-up - Genetic Screening - Genetic Testing - Incompetent Adult - Minor/Child - Newborn - Privacy - Public Health - Tissue

#### NATIONAL

American College of Medical Genetics (ACMG): *Statement on Guidance for Genetic Counseling in Advanced Paternal Age*

Bethesda - June 1, 2008

(2008) 10:6 *Genetics in Medicine*, 457

Link: [URL](#)

Key Words: Counseling (general) - Counseling (Pre-test) - Foetus - Genetic Testing - Man/Paternity -

## Prenatal

American College of Medical Genetics (ACMG): *First Trimester Diagnosis and Screening for Fetal Aneuploidy*

Bethesda - January 1, 2008

(2008) 10:1 Genetics in Medicine, 73

Link: [URL](#)

Key Words: Confidentiality - Foetus - Follow-up - Genetic Screening - Genetic Testing - Professional - Right not to Know - Socio-Economic Aspects - Woman/Maternity

American College of Medical Genetics (ACMG): *Carrier Screening for Spinal Muscular Atrophy*

Bethesda - January 1, 2008

(2008) 10:11 Genetics in Medicine, 1

Link: [URL](#)

Key Words: Carrier Status - Confidentiality - Consent - Counseling (general) - Counseling (Post-test) - Discrimination - Education - Foetus - Follow-up - Genetic Screening - Genetic Testing - Man/Paternity - Pre-implantation - Preconception - Prenatal - Socio-Economic Aspects - Woman/Maternity

American College of Obstetricians and Gynecologists (The) (ACOG): *Committee Opinion No. 409 - Direct-to-consumer Marketing of Genetic Testing*

Washington - June 1, 2008

Link: [URL](#)

Key Words: Carrier Status - Conflict of Interest - Consumer - Counseling (general) - Counseling (Post-test) - Counseling (Pre-test) - DNA - Genetic Testing - Insurer/Insurance - Patient/Participant/Individual - Privacy - Professional

American College of Obstetricians and Gynecologists (The) (ACOG): *Committee Opinion No. 410 - Ethical Issues in Genetic Testing*

Washington - June 1, 2008

Link: [URL](#)

Key Words: Access Info/Material - Assent/Dissent - Beneficence - Cancer - Communication of Results - Confidentiality - Consent - Counseling (general) - Data - Discrimination - DNA - Education - Employer/Employment - Family - Follow-up - Genetic Screening - Genetic Testing - Insurer/Insurance - Minor/Child - Patient/Participant/Individual - Preconception - Predictive Testing - Prenatal - Privacy - Professional - Psychosocial Aspects - Woman/Maternity

American Society of Human Genetics (ASHG): *Ancestry Testing Statement*

Boston - November 13, 2008

Link: [URL](#)

Key Words: Access Info/Material - Beneficence - Community/Population - Consumer - Counseling (general) - Data - Education - Family - Genetic Testing - Liability - Patient/Participant/Individual - Privacy - Research

Canadian Paediatric Society (CPS): *Ethical Issues in Health Research in Children*

Ottawa - October 1, 2008

(2008) 13:8 Paediatr Child Health, 707

Link: [URL](#)

Key Words: Assent/Dissent - Beneficence - Communication of Results - Consent - Ethics Review Board - Liability - Minor/Child - Research - Researcher

Interagency Advisory Panel on Research Ethics (PRE): *Draft 2nd Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*

Ottawa - December 4, 2008

Link: [URL](#)

Key Words: Access Info/Material - Adult - Assent/Dissent - Autonomy - Beneficence - Biobank - Communication of Results - Compensation for Participation - Confidentiality - Conflict of Interest - Consent - Consultation/Collaboration - Counseling (general) - Criteria - Data - Databases - Deceased - Dignity - Discrimination - DNA - Duty to recontact - Duty to Warn - Equity - Ethical Review - Ethics Review Board - Follow-up - Genetic Information - Governance - Incompetent Adult - Integrity - Justice - Minor/Child - Patient/Participant/Individual - Privacy - Recruitment - Research - Researcher - Right not to Know - Right of Withdrawal - Storage - Tissue - Waiver of Consent

National Cancer Institute (NCI): *Towards a Data Sharing Culture: Recommendations for Leadership from Academic Health Centers*

Bethesda - September 1, 2008

Link: [URL](#)

Key Words: Data - Intellectual Property - Open Source

National Council of Ethics for the Life Sciences (CNECV) - Portugal: *Opinion on Direct Marketing of Genetic Tests to the Public (Opinion No. 56)*

Lisbon - July 8, 2008

Link: [URL](#)

Key Words: Access Info/Material - Beneficence - Carrier Status - Commercialization - Community/Population - Confidentiality - Consumer - Counseling (general) - Counseling (Post-test) - Counseling (Pre-test) - Education - Family - Genetic Screening - Genetic Testing - Man/Paternity - Patient/Participant/Individual - Pre-implantation - Prenatal - Privacy - Professional - Psychosocial Aspects

The President's Council on Bioethics: *The Changing Moral Focus of Newborn Screening: An Ethical Analysis*  
Washington - December 1, 2008

Link: [URL](#)

Key Words: Access Info/Material - Biobank - Carrier Status - Consent - Counseling (general) - Discrimination - Education - Eugenics - Follow-up - Genetic Screening - Genetic Testing - Governance - Man/Paternity - Newborn - Ownership - Psychosocial Aspects - Public Health - Socio-Economic Aspects - State - Storage - Waiver of Consent - Woman/Maternity

Vatican - The Holy See: *Instruction Dignitatis Personae on Certain Bioethical Questions*  
Rome - December 8, 2008

Link: [URL](#)

Key Words: Consent - Criteria - Dignity - Disability - Discrimination - Embryo - Embryos (created for research) - Ethical Review - Eugenics - Family - Foetus - Gene Therapy - Genetic Engineering - Genetic Testing - Germline Therapy - Integrity - Justice - Man/Paternity - Pre-implantation - Preconception - Prenatal - Professional - Reproductive Cloning - Research - Researcher - Respect for Human Life - Socio-Economic Aspects - Somatic Therapy - Stem Cell - Surplus Embryos - Therapeutic Cloning - Tissue - Umbilical Cord Blood - Woman/Maternity

Quebec/Government - Ministry of Health and Social Services: *Politique de périnatalité - Un projet porteur de vie 2008-2018*  
Quebec - January 1, 2008

Link: [URL](#)

Key Words: Access Info/Material - Counseling (general) - Education - Genetic Screening - Genetic Testing - Man/Paternity - Newborn - Prenatal - Woman/Maternity

## UPCOMING EVENTS

Conference on pharmacogenomics research - Mes gènes sont uniques  
Organized by: Centre de recherche en droit public (CRDP), Université de Montréal  
Date: January 13, 2009  
Location: Ryatt Regency Hotel, Montreal (Qc) Canada  
Information: <http://www.pharmacogenomique.ca>

ENGAGE Consortium Meeting  
Organized by: European Network of Genomic and Genetic Epidemiology (ENGAGE)  
Date: January 14-16, 2009  
Location: Barcelona, Spain  
Information: <http://www.euengage.org/>

**77e Congrès de l'Acfas - La science en français : une affaire capitale**  
Organized by: Association francophone pour le savoir  
Date: May 11-15, 2009  
Location: Ottawa, Ontario, Canada  
Information: <http://www.acfas.ca/congres/2009/pages/appel.html>

## TEAM PUBLICATIONS

Joly Y., "The Transfer of Technologies: Towards a Personalized Approach", *Discover* (Genome Quebec, 2008)  
Abstract: Over the past three decades, developing the commercial potential of academic research has gradually become a priority for political decision-makers in Québec and the rest of Canada. For the population, an adequate return on investment is essential. The commercialization of research also raises numerous social, ethical and economic questions. Even though controversial, the systematic application of intellectual property rights to new discoveries in biotechnology remains fundamental. The accumulation of patents in certain sectors obliges the scientists to negotiate multiple agreements for licensing and the transfer of material involving considerable costs in time and money. Until now, very few universities have successfully managed to make any profit from their scientists' biotech innovations. Rather than encouraging a single approach, would it not be more appropriate to personalize

our strategy to better face the challenges raised by the technology transfer? In recent years, numerous alternative approaches to promote technology transfer have been proposed, from the open source model to patent pools, public data banks, and so on. While continuing to favour commercialization as the central approach, to obtain optimal technology transfer it may be more appropriate to integrate these new models and to utilize them strategically.

Samuël J., "Les médecins et le sport : les affres du dopage sportif", dans Duguet, A.-M., Filippi I. et Herveg J., dir., *Évolution récente des actions en responsabilité médicale en France : comparaison avec l'étranger*, (Bordeaux: Les Études hospitalières, 2008)

Abstract: [Available in French only] La responsabilité médicale suscite toujours un large intérêt tant pour les juristes que pour les professionnels de santé. La création en France d'un système d'indemnisation des accidents médicaux conduit à s'interroger sur l'impact de ce nouveau dispositif sur des actions en responsabilité. C'est le thème choisi pour le onzième Séminaire d'actualité de droit médical dont cet ouvrage réunit la majorité des présentations. Plusieurs interventions ont cerné, pour la France, l'évolution de la jurisprudence, le choix procédural, le bilan de l'activité de l'ONIAM et des CRCI. Ensuite, des orateurs étrangers ont présenté la situation en Europe : Allemagne, Belgique, Italie, Portugal, aux États-Unis et dans d'autres pays tels le Brésil, le Pérou et la Tunisie. Enfin, le Forum des jeunes chercheurs s'est élargi, accueillant des présentations non seulement sur la responsabilité médicale, mais aussi sur le droit de la santé, les droits des patients, l'éthique médicale et l'accès aux soins. Le réseau s'est enrichi de participants venus du Magrheb, d'Afrique, de Chine, du Canada et des USA qui ont fait partager l'expérience de leurs pays et ont présenté des études comparatives. Cet ouvrage témoigne du dynamisme de la recherche en droit médical en France et l'intégration du Séminaire d'actualité de droit médical dans une Université européenne d'été de droit de la santé et éthique biomédicale, soutenue par le ministère de l'Enseignement supérieur, est une reconnaissance de la qualité des intervenants et des programmes proposés.

Samuël J., "Les médecins et le dopage sportif", (Montréal: Les Éditions Thémis - Collection Droit, biotechnologie et société, 2008)

Abstract: [Not available]

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 EDITORIAL TEAM

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