



GENINFO

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

EDITORIAL | LAWS AND POLICIES | EVENTS | TEAM PUBLICATIONS

September-October 2008



Knowledge transfer is an important component of the work of researchers. Over the summer months, the HumGen team has been hard at work updating the content and the format of our Frequently Asked Questions (FAQs) section on the HumGen website. With this issue of GenInfo, we are proud to launch our new FAQs. In the newly updated FAQs you will find new questions and answers, newly updated content, and a new design, layout, and navigation. If you have suggestions for questions you would like to see added to the FAQs, do not hesitate to contact us.


Additionally, the HumGen team is happy to announce the publication of a new editorial in our GenEdit. The new issue is entitled: **Governance Mechanisms and Population Biobanks: Building a Framework for Trust**.

Happy reading!

Karine Sénécal and Gillian Nycum

Co-Editors in Chief, HumGen International

▶ EDITORIAL



Governance Mechanisms and Population Biobanks: Building a Framework for Trust

Wallace S., Bédard K., Kent A. and Knoppers B.M.

Abstract: Biobanks have become increasingly important for the study of health and disease. Population biobanks are resources for the study of common diseases. They link genetic data with information on health status, lifestyle and environmental factors. Public trust is vital to these biobanks, as they depend on the altruistic participation of individuals. To secure this trust and good will, population biobanks have put in place various governance mechanisms, for example, independent oversight committees and data access committees. In some countries, specific legislation has been enacted, while others rely on guidelines and existing general health, safety and data protection legislation. This article examines the importance of public legitimisation, why governance is important in the context of biobanks, and the governance mechanisms that biobanks currently use.

NATIONAL

American College of Medical Genetics (ACMG): *ACMG Statement on Direct-to-Consumer Genetic Testing*

Bethesda - April 7, 2008

Link: [URL](#)

Key Words: Access Info/Material - Adult - Communication of Results - Counseling (general) - Employer/Employment - Family - Genetic Testing - Insurer/Insurance - Privacy - Professional

American College of Medical Genetics (ACMG): *Technical Standards and Guidelines for Reproductive Screening in the Ashkenazi Jewish Population*

Bethesda - January 1, 2008

(2008) 10:1 *Genetics in Medicine*, 57

Link: [URL](#)

Key Words: Access Info/Material - Carrier Status - Consent - Counseling (general) - Education - Family - Genetic Screening - Genetic Testing - Liability - Preconception - Prenatal - Professional

American College of Medical Genetics (ACMG): *Carrier Screening in Individuals of Ashkenazi Jewish Descent*

Bethesda - January 1, 2008

(2008) 10:1 *Genetics in Medicine*, 54

Link: [URL](#)

Key Words: Access Info/Material - Adult - Carrier Status - Community/Population - Consent - Counseling (general) - Counseling (Post-test) - Counseling (Pre-test) - Education - Family - Genetic Screening - Genetic Testing - Preconception - Prenatal - Professional - Psychosocial Aspects - Waiver of Consent

American Medical Association (AMA): *REPORT 7 OF THE BOARD OF TRUSTEES (A-08): Direct-to-Consumer Advertising and Provision of Genetic Testing*

Chicago - June 1, 2008

Link: [URL](#)

Key Words: Commercialization - Communication of Results - Consent - Discrimination - Genetic Information - Genetic Screening - Genetic Testing - Insurer/Insurance - Newborn - Patient/Participant/Individual - Professional

Association of British Insurers (ABI): *Genetic tests and insurance: what you need to know - a guide for consumers*

London - June 1, 2008

Link: [URL](#)

Key Words: Access Info/Material - Communication of Results - Confidentiality - Family - Genetic Information - Genetic Testing - Insurer/Insurance - Research - Storage

British Fertility Society (BFS): *The current status of preimplantation genetic screening: British Fertility Society Policy and Practice Guidelines*

Bradley Stoke - June 1, 2008

Link: [URL](#)

Key Words: Donor - Embryo - Gamete - Genetic Screening - Genetic Testing - Patient/Participant/Individual - Pre-implantation - Woman/Maternity

EuroGentest Network of Excellence: *Definitions of Genetic Testing in European and Other Legislation - 1st Draft Version*

Leuven - April 30, 2008

Link: [URL](#)

Key Words: Carrier Status - Data - Discrimination - Genetic Information - Genetic Screening - Genetic Testing - Newborn - Pharmacogenomics - Pre-implantation - Predictive Testing - Prenatal - Privacy - Research

Toi te Taiao: the Bioethics Council: *Who Gets Born? A report on the cultural, ethical and spiritual aspects of pre-birth testing by Toi te Taiao: the Bioethics Council*

Wellington, New Zealand - June 1, 2008

Link: [URL](#)

Key Words: Autonomy - Carrier Status - Community/Population - Counseling (general) - Counseling (Post-

test) - Counseling (Pre-test) - Discrimination - Diversity - DNA - Education - Embryo - Equity - Eugenics - Family - Foetus - Genetic Screening - Genetic Services - Genetic Testing - Justice - Man/Paternity - Minor/Child - Newborn - Pre-implantation - Preconception - Prenatal - Professional - Psychosocial Aspects - Respect for Human Life - Socio-Economic Aspects - Standard of Care - State - Woman/Maternity

UK Newborn Screening Programme Centre: *Guidelines for Newborn Blood Spot Sampling*

London - January 1, 2008

Link: [URL](#)

Key Words: Access Info/Material - Communication of Results - Consent - Data - DNA - Genetic Screening - Man/Paternity - Newborn - Research - Storage - Waiver of Consent - Woman/Maternity

UK Newborn Screening Programme Centre: *Standards and Guidelines for Newborn Blood Spot Screening*

London - August 1, 2008

Link: [URL](#)


Key Words: Access Info/Material - Beneficence - Carrier Status - Communication of Results - Community/Population - Consent - Education - Family - Follow-up - Genetic Screening - Genetic Services - Genetic Testing - Liability - Man/Paternity - Minor/Child - Newborn - Prenatal - Professional - Public Health - Waiver of Consent - Woman/Maternity

United States/Government: *Newborn Screening Saves Lives Act of 2007, Pub. L. No. 110-204, 122 Stat. 705*

Washington - April 24, 2008

Link: [URL](#)

Key Words: Carrier Status - Counseling (general) - Education - Family - Follow-up - Genetic Screening - Man/Paternity - Minor/Child - Newborn - Patient/Participant/Individual - Professional - Public Health - Woman/Maternity

 **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**

Symposium: Access to Medicines

Organized by: Brocher Foundation and the Department of Pharmacy of the University of Geneva

Date: September 5, 2008

Location: Geneva, Switzerland

Information:

HUGO's 13th Human Genome Meeting

Organized by: Human Genome Organisation

Date: September 27-30, 2008

Location: Hyderabad, India

Information:

58th Annual Meeting of the American Society of Human Genetics

Organized by: American Society of Human Genetics

Date: November 11-15, 2008

Location: Philadelphia, Pennsylvania, United States

Information:

 **TEAM PUBLICATIONS**

Knoppers B.M. et Joly Y., dir., "**La santé et le bien commun**", (Montréal: Les Éditions

Thémis - Collection Droit, biotechnologie et société, 2008)

Abstract: [Available in French only] La santé publique soulève une gamme de problématiques qui s'étendent au-delà des frontières de l'intérêt individuel. De nombreux arguments incitent à parler de santé publique dans un contexte d'intérêt commun et général plutôt que de considérer cette notion comme un moyen de promouvoir le bien-être et la sécurité des individus. Le défi reste cependant de trouver un certain équilibre entre le pouvoir accordé au gouvernement, dans l'objectif d'assurer des conditions adéquates en santé publique, et le respect des droits de la personnes - la garantie d'un traitement égal et juste de tous les groupes et l'avancement de la justice sociale. Ce positionnement soulèvera vraisemblablement des dilemmes éthiques non négligeable. Comment organiser la recherche et les infrastructures de santé publique, sur quelles bases éthiques et à partir de quelles réponses politiques? Jusqu'à tout récemment, la littérature scientifique n'a pas suscité de discussions à ce sujet. Le présent recueil propose, sous l'angle novateur, une réflexion sur les enjeux socio-éthiques et juridiques soulevés par les interrelations entre la santé et le bien public. Il met en lumière le potentiel d'une meilleure organisation des ressources communes et du déploiement des stratégies de coopération dans le domaine de la santé humaine. Une des rares contributions en langue française sur le sujet, ce livre souhaite enrichir le bagage des connaissances théoriques pour faciliter l'établissement futur d'un encadrement éthique et la résolution des difficultés pratiques dans le domaine de la santé publique.

Knoppers B.M., Abdul-Rahman M.H., "**Biobanks in the Literature**", in Elger B., Capron A., et al (eds), *Ethical Issues in Governing Biobanks: Global Perspectives*, Ch. 2 (UK: Ashgate Publishing Ltd, 2008)

Abstract: This review of the literature on the ethical and regulatory aspects of human genetic databases reveals numerous outstanding issues pertaining to the issues of consent to the use of the samples, confidentiality and potential commercialization. The goal of this literature review is to discern whether these three areas of discussion in the literature reflect a gradual acceptance of the "legitimacy" of the approaches taken by the population biobanks or whether outstanding issues remain.

Knoppers B.M., Joly Y., "**La connaissance du génome : un instrument au service de l'humanité?**", dans B.M. Knoppers et Y. Joly, dir., *La santé et le bien commun*, (Montréal: Les Éditions Thémis - Collection Droit, biotechnologie et société, 2008) 249

Abstract: Not Available

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.

Editor-in-chief: [Karine Sénécal](#) | **Associate editor:** [Gillian Nycum](#) | **Contributing editors:** [HumGen Team](#) | **Correctors:** [Karine Sénécal](#) and [Gillian Nycum](#) | **Webmaster:** [Dan-Thanh Truong](#) | **Director:** [Bartha Maria Knoppers](#) | **Research Director:** [Denise Avard](#)

The GenInfo newsletter and the Editorial can be reproduced without permission.
The source has to be identified.