

## WELCOME

The development of umbilical cord blood, as a source of haematopoietic stem cells for cellular therapies or regenerative medicine, has led to the emergence of public and private cord blood banks worldwide. Umbilical cord blood cells stored in public banks are made available to any suitably matched recipient, whereas, private banks allow parents to store their newborn's cord blood for the benefit of the donor or family members. This coexistence of public and private banks has created much debate and resulted in the adoption of policy statements and opinions by professional organizations or advisory groups. Thus, the focus of this month's issue of GenInfo is on cord blood banking. I invite you to read the latest *GenEdit* issue entitled, "Umbilical Cord Blood Banking," as well as the revised policy statement on cord blood banking adopted by the *American Academy of Pediatrics*.

Thu Minh Nguyen, Editor-in-Chief

## EDITORIAL

### Consent in Pharmacogenomic Research

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

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

**Hoffmann-La Roche Limited** : *Gene Patenting*

Nutley, January 1, 2005

<http://www.roche.com/sci-genepatenting.pdf>

Keywords: **Commercialization - DNA - Genetic Engineering - Intellectual Property - Patents - Reproductive Cloning - Stem Cell**

**Pharmacogenetics Working Group (PWG)** : *Returning Genetic Research Results to Individuals: Points to Consider*

Oxford, January 1, 2006

20:1 *Bioethics*, 24

<http://www.blackwell-synergy.com/doi/pdf/10.1111/j.1467-8519.2006.00473.x?cookieSet=1>

Keywords: **Communication of Results - Confidentiality - Consent - Data - Discrimination - Ethics Review Board - Family - Genetic Testing - Patient/Participant/Individual - Pharmacogenomics - Psychosocial Aspects - Research - Researcher**

**The Hinxton Group, an International Consortium on Stem Cells, Ethics and Law : *Consensus Statement***

Baltimore, February 24, 2006

[http://www.hinxtongroup.org/au\\_cs.html](http://www.hinxtongroup.org/au_cs.html)

Keywords: **Autonomy - DNA - Integrity - Patient/Participant/Individual - Professional - Research - Researcher - Stem Cell - Tissue**

---

**World Health Organization (WHO) : *Declaration of Ministers of South America Over Intellectual Property, Access to Medicines and Public Health***

Geneva , May 23, 2006

<http://lists.essential.org/pipermail/ip-health/2006-May/009594.html>

Keywords: **Access Info/Material - Developing Countries - Intellectual Property - Patents - Public Health - Research**

---

**European Society of Human Reproduction and Embryology (ESHRE) : *The need for interaction between assisted reproduction technology and genetics - Recommendations of the European Societies of Human Genetics and Human Reproduction and Embryology***

Grimbergen, May 1, 2006

(2006) Vol:14 *European Journal of Human Genetics*, 509

<http://www.nature.com/ejhg/journal/v14/n5/pdf/5201600a.pdf>

Keywords: **Counseling (general) - Donor - Embryo - Genetic Screening - Genetic Services - Genetic Testing - Pre-implantation - Preconception - Research - Surplus Embryos**

---

**EuroSOCAP : *European Standards on Confidentiality and Privacy in Healthcare***

Belfast, January 1, 2006

<http://www.eurosocap.org/Downloads/European-Standards-on-Confidentiality-and-Privacy-in-Healthcare.pdf>

Keywords: **Access Info/Material - Confidentiality - Consent - Data - Databases - Deceased - Follow-up - Incompetent Adult - Minor/Child - Patient/Participant/Individual - Privacy - Professional - Waiver of Consent**

---

**Nordic Committee on Bioethics : *PGD and Embryo Selection - Report from an International Conference on Preimplantation Genetic Diagnosis and Embryo Selection***

Copenhagen, January 1, 2005

[http://www.norden.org/pub/velfaerd/social\\_helse/uk/TN2005591.pdf](http://www.norden.org/pub/velfaerd/social_helse/uk/TN2005591.pdf)

Keywords: **Autonomy - Discrimination - Embryo - Equity - Eugenics - Genetic Screening - Genetic Testing - Pre-implantation - Respect for Human Life - Socio-Economic Aspects**

---

**NATIONAL**

**Académie nationale de médecine : *Pharmacogénétique et pharmacogénomique***

Paris, January 31, 2006

[http://www.academie-medecine.fr/upload/base//rapports\\_260\\_fichier\\_lie.rtf](http://www.academie-medecine.fr/upload/base//rapports_260_fichier_lie.rtf)

Keywords: **DNA - Duty to Warn - Family - Genetic Testing - Pharmacogenomics**

---

**Bioethics Advisory Committee : *The Use of Personal Information in Biomedical Research - A Consultation Paper***

Singapore, June 14, 2006

<http://www.bioethics-singapore.org/media/PI%20Consultation%20Paper.pdf>

Keywords: **Access Info/Material - Communication of Results - Confidentiality - Consent - Data -**

**Duty to recontact - Employer/Employment - Ethics Review Board - Incompetent Adult - Insurer/ Insurance - Minor/Child - Patient/Participant/Individual - Privacy - Research - Researcher - Right of Withdrawal - Storage**

---

**Biotechnology Industry Organization (BIO) :** *The Comments of the Biotechnology Industry Organization on the United States Patent & Trademark Office Proposed Rules Changes Concerning Continuation Practice and Claim Limitations*

Washington, May 2, 2006

<http://www.bio.org/ip/letters/20060502.pdf>

Keywords: **Education - Intellectual Property - Patents**

---

**Center for Genetics and Society :** *The California Stem Cell Research Program at One Year: A Progress Report*

Oakland, January 1, 2006

<http://www.genetics-and-society.org/policies/california/200601report.pdf#xml=http://genetics-and-society.org.master.com/tehis/master/search/mysite.txt?q=california+stem+cell+research+program+at+one+year&order=r&id=4890ead01c20827c&cmd=xml>

Keywords: **Embryo - Embryos (created for research) - Equity - Ethical Review - Intellectual Property - Reproductive Cloning - Research - Researcher - Stem Cell - Therapeutic Cloning**

---

**Comité consultatif de Bioéthique de Belgique :** *Avis no. 33 du 7 novembre 2005 relatif aux modifications géniques somatiques et germinales à visées thérapeutiques et/ou amélioratives*

Bruxelles, November 7, 2005

[https://portal.health.fgov.be/pls/portal/docs/PAGE/INTERNET\\_PG/HOME PAGE\\_MENU/GEZONDHEIDZORG1\\_MENU/OVERLEGSTRUCTUREN1\\_MENU/COMITEES1\\_MENU/BIOETHISCHECOMMISSIE1\\_MENU/AVIS25\\_MENU/AVIS25\\_DOCS/AVIS33-TH%C3%89RAPIES%20G%C3%89NIQUES.PDF](https://portal.health.fgov.be/pls/portal/docs/PAGE/INTERNET_PG/HOME PAGE_MENU/GEZONDHEIDZORG1_MENU/OVERLEGSTRUCTUREN1_MENU/COMITEES1_MENU/BIOETHISCHECOMMISSIE1_MENU/AVIS25_MENU/AVIS25_DOCS/AVIS33-TH%C3%89RAPIES%20G%C3%89NIQUES.PDF)

Keywords: **Access Info/Material - Autonomy - Community/Population - Disability - Discrimination - Embryo - Ethical Review - Eugenics - Foetus - Gene Therapy - Genetic Screening - Germline Therapy - Male/Paternity - Pre-implantation - Prenatal - Psychosocial Aspects - Public Health - Research - Somatic Therapy - State - Woman/Maternity**

---

**Commission Nationale de l'Informatique et des Libertés (CNIL) :** *Décision du 5 janvier 2006 portant homologation d'une méthodologie de référence pour les traitements de données personnelles opérés dans le cadre des recherches biomédicales (méthodologie de référence MR-001)*

Paris, January 5, 2006

J.O n° 43 du 19 février 2006

<http://www.admi.net/jo/20060219/CNIA0600001X.html>

Keywords: **Access Info/Material - Confidentiality - Databases - Privacy - Research - Storage**

---

**Dutch Ministry of Health :** *Evaluation of the Dutch Embryo Act*

The Hague, January 1, 2006

[http://www.minvws.nl/images/pg-2662449b.doc\\_tcm10-83953.pdf](http://www.minvws.nl/images/pg-2662449b.doc_tcm10-83953.pdf)

Keywords: **Dignity - Embryo - Embryos (created for research) - Foetus - Minor/Child - Research - Respect for Human Life - State - Stem Cell**

---

**Finnish National Ethics Committees :** *Human Stem Cells, Cloning and Research*

Helsinki, January 1, 2005

<http://www.etene.org/dokumentit/KantasoluENG.pdf>

Keywords: **Consent - Donor - Embryo - Embryos (created for research) - Foetus - Reproductive Cloning - Research - Stem Cell - Surplus Embryos - Therapeutic Cloning - Tissue**

---

**France/Government** : *Décret no. 2006-121 du 6 février 2006 relatif à la recherche sur l'embryon et sur les cellules embryonnaires et modifiant le Code de la santé publique (dispositions réglementaires)*  
Paris, February 6, 2006

<http://www.admi.net/jo/20060207/SANP0524383D.html>

Keywords: **Consent - Donor - Embryo - Researcher - Stem Cell - Storage - Surplus Embryos**

---

**Genetic Interest Group (GIG)** : *Human Rights, Privacy and Medical Research: Analysing UK Policy on Tissue and Data*

London, May 19, 2006

<http://www.gig.org.uk/docs/hrprivacypdf190506.pdf>

Keywords: **Access Info/Material - Autonomy - Community/Population - Confidentiality - Consent - Data - Databases - Deceased - Dignity - DNA - Family - Patient/Participant/Individual - Privacy - Professional - Public Health - Researcher - Tissue**

---

**Human Fertilisation and Embryology Authority (HFEA)** : *Authority Decision on the Use of PGD for Lower Penetrance, Later Onset Inherited Conditions*

London, May 10, 2006

<http://www.hfea.gov.uk/cps/rde/xchg/SID-3F57D79B-346F2374/hfea/hs.xsl/908.html>

Keywords: **Embryo - Genetic Testing - Pre-implantation**

---

**Legislation Review Committee** : *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002*

Canberra, December 1, 2005

[http://www.lockhartreview.com.au/\\_pdf/301-400/LRC373.pdf](http://www.lockhartreview.com.au/_pdf/301-400/LRC373.pdf)

Keywords: **Consent - Donor - Embryo - Embryos (created for research) - Pre-implantation - Reproductive Cloning - Research - Stem Cell - Surplus Embryos - Therapeutic Cloning - Tissue**

---

**National Council of Churches** : *Fearfully and Wonderfully Made: A Study Document on Human Biotechnologies*

New York, November 1, 2005

<http://www.nccusa.org/pdfs/BioTechStudyGuide.html>

Keywords: **Community/Population - Consent - Counseling (general) - Disability - Discrimination - DNA - Embryo - Equity - Eugenics - Gene Therapy - Genetic Testing - Germline Therapy - Justice - Minor/Child - Patents - Privacy - Reproductive Cloning - Research - Researcher - Respect for Human Life - Somatic Therapy - State - Stem Cell - Therapeutic Cloning**

---

**National Council of Churches** : *Fearfully and Wonderfully Made: A Policy on Human Biotechnologies*

New York, November 1, 2005

<http://www.nccusa.org/pdfs/BioTechPolicy.html>

Keywords: **Community/Population - Consent - Counseling (general) - Disability - Discrimination - DNA - Embryo - Equity - Eugenics - Gene Therapy - Genetic Testing - Germline Therapy - Justice - Minor/Child - Patents - Privacy - Reproductive Cloning - Research - Researcher - Respect for Human Life - Somatic Therapy - State - Stem Cell - Therapeutic Cloning**

---

**National Heart, Lung, and Blood Institute (NHLBI)** : *Reporting Genetic Results in Research*

*Studies: Summary and Recommendations of an NHLBI Working Group*

New York, May 15, 2006

(2006) 140A:10 *American Journal of Medical Genetics*, 1033

<http://www3.interscience.wiley.com/cgi-bin/fulltext/112572606/PDFSTART>

Keywords: **Communication of Results - Community/Population - Consent - Counseling (general) - Counseling (Post-test) - Criteria - Duty to recontact - Ethical Review - Ethics Review Board - Family - Genetic Testing - Patient/Participant/Individual - Psychosocial Aspects - Research - Researcher - Right not to Know**

---

**Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) : *Public Comment Draft: Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease***

Bethesda, May 22, 2006

<http://www4.od.nih.gov/oba/SACGHS.HTM>

Keywords: **Access Info/Material - Community/Population - Confidentiality - Consent - Data - Databases - DNA - Intellectual Property - Patient/Participant/Individual - Privacy - Recruitment - Research**

---

**Swiss Academy of Medical Sciences (SAMS) : *Biobanques: Prélèvements, conservation et utilisation de matériel biologique humain; Directives médico-éthiques et recommandations***

Bâle, May 23, 2006

[http://www.samw.ch/docs/Richtlinien/f\\_RL\\_Biobanken.pdf](http://www.samw.ch/docs/Richtlinien/f_RL_Biobanken.pdf)

Keywords: **Access Info/Material - Biobank - Communication of Results - Confidentiality - Consent - Data - Databases - Deceased - DNA - Education - Educational Institution - Ethical Review - Governance - Privacy - Professional - Researcher - Storage - Tissue**

---

**Swiss Confederation : *Loi fédérale relative à la recherche chez l'être humain (avant-projet)***

Berne, January 2, 2006

[http://www.admin.ch/ch/f/gg/pc/documents/1266/HFG\\_f.pdf](http://www.admin.ch/ch/f/gg/pc/documents/1266/HFG_f.pdf)

Keywords: **Biobank - Communication of Results - Confidentiality - Consent - Data - Databases - Deceased - Embryo - Ethics Review Board - Foetus - Patient/Participant/Individual - Research - Waiver of Consent**

---

**Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) : *Opinion no. 10/2005 - Preimplantation genetic diagnosis***

Bern, December 1, 2005

[http://www.nek-cne.ch/media/archive1/en/publikationen/stellungnahmen/pid\\_en.pdf](http://www.nek-cne.ch/media/archive1/en/publikationen/stellungnahmen/pid_en.pdf)

Keywords: **Embryo - Genetic Testing - Pre-implantation**

---

**The Australian National University : *Pan-European and Individual National Perspectives: Developing a Unified European Regulatory Approach?***

Canberra, February 1, 2006

<http://www.anu.edu.au/NEC/NEC%20EVENTS/Events%202006/SC%20PaperWebster.pdf>

Keywords: **Biobank - Embryo - Embryos (created for research) - Reproductive Cloning - Research - Researcher - Respect for Human Life - State - Stem Cell - Storage - Surplus Embryos**

---

**UK Stem Cell Initiative : *Report & Recommendations***

London, November 1, 2005

<http://www.advisorybodies.doh.gov.uk/uksci/uksci-reportnov05.pdf>

---

Keywords: **Consent - Donor - Embryo - Embryos (created for research) - Foetus - Intellectual Property - Reproductive Cloning - Research - Stem Cell - Surplus Embryos - Therapeutic Cloning - Tissue**

---

**University of London - Social Science Research Unit** : *The Storage and Use of Newborn Babies' Blood Spot Cards: a Public Consultation*

London, October 1, 2005

<http://www.ioe.ac.uk/ssru/reports/publicconsultationbloodspots.pdf>

Keywords: **Community/Population - Consent - Genetic Screening - Minor/Child - Newborn - Privacy - Research - Storage**

---

**Institut national de santé publique du Québec (INSPQ)** : *Rapport d'évaluation du programme québécois de dépistage sanguin des maladies génétiques chez le nouveau-né*

Québec, December 1, 2005

<http://www.inspq.qc.ca/pdf/publications/484-RapportDepistageSanguin.pdf>

Keywords: **Access Info/Material - Beneficence - Biobank - Communication of Results - Consent - Criteria - Data - Follow-up - Genetic Screening - Governance - Male/Paternity - Minor/Child - Newborn - Professional - Public Health - Research - Socio-Economic Aspects - Storage - Waiver of Consent - Woman/Maternity**

---

---

## UPCOMING EVENTS

**16th World Congress on Medical Law** organized by World Association for Medical Law, Association for Research and Formation in Medical Law (ARFDM)

Date: **August 7 - 11, 2006**

Location : **Toulouse, France**

Information:

---

**Symposium: The use of biological material and electronic data in the research context** organized by International Institute of Research in Ethics and Biomedicine

Date: **August 9, 2006**

Location : **Toulouse, France**

Information:

---

**Bien commun et mondialisation: historique et perspectives** organized by Canada Research Chair in Law and Medicine

Date: **September 20, 2006**

Location : **Montréal, Québec, Canada**

Information:

---

**4ème colloque annuel des programmes de bioéthique de l'Université de Montréal : la technologie en santé: fascination et fragilité** organized by Programmes de bioéthique de l'Université de Montréal

Date: **September 28 - 29, 2006**

Location : **Montréal, Québec, Canada**

Information:

---

**27ème congrès annuel: La génétique, le pari de la vie** organized by Société québécoise de biologie clinique (SQBC)

Date: **October 4 - 7, 2006**

Location : **La Malbaie, Québec, Canada**

Information:

---

**Frontiers in Biomedical Research, HKU 2006** organized by The University of Hong Kong Li Ka Shing Faculty of Medicine

Date: **December 8, 2006**

Location : **Hong Kong, China**

Information:

---

---

## TEAM PUBLICATIONS

Hervé C., Knoppers B.M., Molinari P.A., Moutel G., Grimaud M.-A., "**Éthique de la recherche et santé publique: où en est-on ?**", (Paris: Dalloz, 2006).

[French version only]

---

Isasi R., Knoppers B.M., "**Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries**", (2006) 13 *European Journal of Health Law*, 9 .

**Abstract** : This article provides an overview of (I) the moral and legal status of the human embryo and (II) the regulatory approaches to embryonic stem cells and cloning research by comparing the regulatory frameworks of 50 countries. The major goal of this study is to provide an analytical understanding of the policy landscape around the globe, with an aim to contribute to worldwide policy debates. The comparison of these policies underscores the hurdles that scientific consortia involving international jurisdictions and policy frameworks have to confront, as well as the challenges facing the international harmonization of such policies.

---

Joly Y., "**Life Insurers' Access to Genetic Information: A Way Out of the Stalemate?**", (2006) 14:3 *Health Law Review*, 14 .

**Abstract** : Despite intensive regulatory activity in Europe and in the United States, the socio-ethical debate on insurance and genetics has barely progressed during the last twenty years. After focussing on certain aspects of the genetics and insurance dilemma, this article provides a critical analysis of the evolution of the debate in France and Canada. The author argues for the need to redefine the dialogue by broadening its scope, adopting a long-term perspective and recognizing the need for transparency in order to exit the dead-end we are currently facing. In the current context, genetics could well be hiding a more fundamental debate about the place of insurance in the contemporary democratic state.

---

Knoppers B.M., Saginur M., Cash H., "**Ethical Issues in Secondary Uses of Human Biological Materials from Mass Disasters**", (2006) 34:2, *Journal of Law, Medicine & Ethics*, 352 .

**Abstract** : In the trauma surrounding mass disasters, the need to identify victims accurately and as soon as possible is critical. DNA identification testing is increasingly used to identify human bodies and remains where the deceased cannot be identified by traditional means. This form of testing compares DNA taken from the body of the deceased with DNA taken from their personal items (e.g. hairbrush, toothbrush, etc.) or from close biological relatives. Do the ethical norms governing the secondary use of biological samples apply to possible research uses of such tragic "de facto" biobanks?

---

Lévesque E., Petit E., "**L'encadrement juridique de la recherche en génétique au Québec**", dans

Raymond D. Lambert et Maria DeKoninck (dir.), *La conduite responsable de la recherche. Les cadres normatifs* (Québec: Faculté de médecine, Université Laval, 2006) , online: <http://www.cours.fmed.ulaval.ca/a05/eth64841/table-des-matieres/la-recherche-ingenetique/chapitre-14/>

[French version only]

---

Sheremeta L., Plant M., Knoppers B.M., "The Future of Cord Blood Banking in Canada", (2006) 14:3 *Health Law Review*, 51.

**Abstract** : The potential clinical utility of umbilical cord blood (UCB) as a source of stem cells has led to the emergence of several public and private cord blood banks across Canada. Although UCB banking in Canada remains in its early stages, there are many regulatory and policy issues that need to be addressed. The purpose of the Stem Cell Network Catalyst project entitled "The Future of Cord Blood Banking in Canada" is to examine the socio-ethical and legal issues surrounding UCB banking and to develop an ethical framework to guide policymakers in mapping out the future of cord blood banking in Canada.

---

The International Stem Cell Forum Ethics Working Party: Knoppers B.M., Richardson G., Lee E.H., Kure J., de Wert G., Ameisen J.C., Lötjönen L., Breen K., Isasi R., Mauron A., Murray T., Wahlström J., "Ethics Issues in Stem Cell Research", (2006) 312:5772 *Science*, 366.

**Abstract** : The International Stem Cell Forum (ISCF) supports research on all cell types, including adult stem cells, embryonic stem cells, and stem cells from umbilical cord blood. In 2004, the Ethics Working Party (EWP) of the ISCF defined its mission as (i) clarification of ethical issues and, where possible, the international harmonization of ethical standards; (ii) the sharing of stem cell lines; and (iii) an agreement on standards for the characterization and registration of lines. The EWP identified certain international trends, effective practices, and emerging issues that require further discussion and clarification.

---

## EDITORIAL TEAM

**Editor-in-chief:** [Emmanuelle Lévesque](#)

**Associate editor:** [Guillaume Sillon](#)

**Contributing editors:** Humgen Team

**Correctors:** [Thu Minh Nguyen](#) and [Karine Sénécal](#)

**Webmasters:** [Matthieu Layes](#) and [François Brouillet](#)

**Director:** [Bartha Maria Knoppers](#)

**Research Director:** [Denise Avaré](#)