

March-April 2005

[Close](#)

| [Welcome](#) | [News](#) | [GenEdit](#) | [New Laws & Policies](#) | [FAQ](#) | [Feedback](#) | [Subscribe to GenInfo](#) | [Sponsors](#) | [Contact us](#) |

**Editorial Team****Editor**

Yann Joly

**Editorial Assistant**

Eve-Lyne Comtois-Dinel

**Communication**

Denise Avard

Isabelle Ganache

Emmanuelle Lévesque

**Copy Editors**

Alexandra Saginur

Clémentine Sallée

**Web Publishing**

François Brouillet

**Advisory Board**

José Maria Cantu

Ruth Chadwick

Donald R. Chalmers

Michèle Jean

Darryl Macer

Linda Nielsen

Elettra Ronchi

Charles R. Scriver

Lap-Chee Tsui

**Genetics and Society Project****Director**

Bartha M. Knoppers

**Research Directors**

Denise Avard

Béatrice Godard



Yann Joly  
Editor

This month, GenInfo's editorial team would like to highlight the *Preliminary Draft Declaration on Universal Norms on Bioethics* adopted by UNESCO's International Bioethics Committee. This ambitious, landmark *Declaration* aims to provide universal principles for bioethics. The lengthy, complex and subtle negotiation process that led to this *Preliminary Draft* was presented by the president of the International Bioethics Committee, Ms. Michèle Jean at the conference series of Canada's Research Chair in Law and Medicine, held in Montreal on February 16th, 2005.

**NEWS**

The "News" section of GenInfo provides a brief listing of events for the coming year (if organized by our team or partner organizations). We are also pleased to include a "Publications" section with a summary of books, articles and editorials published by members of our team.

## EVENTS

**MARCH 2005****"Complex Genetics: Banking on our Future"****Date:** March 13-18, 2005**Location:** Newcastle, United Kingdom**Host:** British Council Seminars**Informations and registration:**To register visit <http://www.britishcouncil.org/seminars-science-0404.htm>

Telephone: +44 (0) 1865 302702

Fax: +44 (0) 1865 557368, 516590

E-mail: [redteam.seminars@britishcouncil.org](mailto:redteam.seminars@britishcouncil.org)**APRIL 2005****"From Genomes to Functions"****Date:** From March 31 to April 5, 2005**Location:** San Diego Convention Center, San Diego, California**Host:** XXXV International Congress of Physiological Sciences**Informations and registration:**To register or for additional information visit: <http://www.faseb.org/meetings/eb2005/call/default.htm>.E-mail: [eb@faseb.org](mailto:eb@faseb.org)

## PUBLICATIONS

**BOOK CHAPTERS & ARTICLES**Isasi, R.M., Knoppers, B.M., Singer, P.A., and Daar, A.S., "Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia, and Africa", (2004) 32(4) *Journal of Law, Medicine and Ethics*, 626-57.**Abstract:** This article surveys policies for human embryonic stem cell research and cloning in sixteen countries in Asia, Africa, and Latin America. It details policy development within each country and examines both the current policy framework as well and possible future directions.Kharaboyan, L., Avard, D. and Knoppers, B.M., "Storing Newborn Bloodspots: Modern Controversies" (2004) 32(4) *Journal of Law, Medicine and Ethics*, 741-48.**Abstract:** In the first days following birth, blood is drawn from a newborn's heel and saved on a Guthrie card to allow for genetic screening diagnosis and follow-up. The storage, subsequent use, as well as the information that may be revealed from dried blood spots raise a number of social, ethical and legal issues. The privacy and confidentiality of such genetic information deserve special protective measures. This paper provides an overview of some of the issues that need to be addressed when implementing a newborn screening program (i.e. storage, and secondary uses in light of existing international, regional and national policies).

## GENEDIT

**The primary focus of the editorial GenEdit, which is written exclusively for HumGen, is to enhance our current understanding of policy statements related to human genetics through comparative international, legal and socio-ethical analysis.**

## NEXT ISSUE

Volume III No.1  
Biobanks: Need for a specific ethical and legal framework?  
Anne Cambon-Thomsen, Clémentine Sallée, Bartha Maria Knoppers

## PAST ISSUES

Volume II No.3 (2004)  
Newborn Screening, Banking and Consent  
Claude Laberge, Linda Kharaboyan, Denise Avard

Volume II No.2 (2004)  
Genetics and Life Insurance : A Comparative Analysis  
Trudo Lemmens, Yann Joly and Bartha Maria Knoppers

Volume II No.1 (2004)  
Protecting Genetic Information: A Comparison of Normative Approaches  
Patricia Kosseim, Martin Letendre and Bartha Maria Knoppers

Volume I No.1 (2003)  
Stem Cells in a Pluralistic Society: Consequences of Proposed Canadian Legislation  
Dorothy C. Wertz, Marie-Hélène Régner and Bartha Maria Knoppers



## NEW LAWS & POLICIES

The following section contains new policy (legal, socio-ethical) statements on human genetics from international, regional and national sources.

We are constantly searching for documents to enrich our databank. If your organisation has published policy statements relating to genetics, or if you are aware of such new publications, kindly send us the relevant information and we will consider including it in the databank.

United Nations Economic and Social Council (ECOSOC), *Genetic Privacy and Non-Discrimination*, Res. E/2004/INF/2/Add.2, 46th plenary meeting, New York, July 21, 2004, p. 27, <http://daccessdds.un.org/doc/UNDOC/GEN/N04/453/39/PDF/N04453339.pdf?OpenElement> (date accessed: February 18, 2005).

Indigenous Peoples Council on Biocolonialism (IPCB) et al., "Collective Statement of Indigenous Peoples on the Protection of Indigenous Knowledge", *UN Permanent Forum on Indigenous Issues*, Agenda item 4(e): Culture, Third session, New York, May 10-21, 2004, <http://www.ipcb.org/resolutions/htmls/pf2004.html> (date accessed: February 21, 2005)

The following are our recommendations for the Permanent Forum in relation to the discussions on the protection of Indigenous knowledge in the CBD, and other UN agencies such as WIPO and UNESCO.

Commission de l'éthique de la science et de la technologie, *Le don et la transplantation d'organes: dilemmes éthiques en contexte de pénurie*, Québec, novembre 2004, [http://www.ethique.gouv.qc.ca/fr/ftp/AvisIntegralDon\\_organes.pdf](http://www.ethique.gouv.qc.ca/fr/ftp/AvisIntegralDon_organes.pdf) (date accessed: February 18, 2005) [french version available only].

U.S. Preventive Services Task Force, "Screening for Ovarian Cancer: Recommendation Statement", (2004) 2 (3) *Annals of Family Medicine*, p. 260-2, <http://www.annfammed.org/cgi/reprint/2/3/260> (date accessed: February 21, 2005).

This statement summarizes the current U.S. Preventive Services Task Force (USPSTF) recommendation on screening for ovarian cancer and the supporting evidence. It updates the 1996 recommendations contained in the Guide to Clinical Preventive Services, Second Edition: Periodic Updates. In 1996, the USPSTF recommended against routine screening for ovarian cancer (a "D" recommendation). Explanations of the ratings and of the strength of overall evidence are given in Appendix A and in Appendix B, respectively. The complete information on which this statement is based, including evidence tables and references, is available in the brief evidence update "Screening for Ovarian Cancer, available through the USPSTF Web site at <http://www.preventiveservices.ahrq.gov> and through the National Guideline Clearinghouse™ (<http://www.guideline.gov>). The recommendation statement and brief evidence updates are also available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse in print through subscription to the Guide to Clinical Preventive Services, Third Edition: Periodic Updates.

Canadian Biotechnology Advisory Committee (CBAC), *Statement on Renewal of the Canadian Biotechnology Strategy and the Evolving Role of CBAC*, Ottawa, December 2004, [http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/FINAL-CBS\\_Renewal-E.pdf/\\$FILE/FINAL-CBS\\_Renewal-E.pdf](http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/FINAL-CBS_Renewal-E.pdf/$FILE/FINAL-CBS_Renewal-E.pdf) (date accessed: February 21, 2005).

The Canadian Biotechnology Advisory Committee (CBAC) strongly advises the Government of Canada to renew and build on the Canadian Biotechnology Strategy established in 1998 and, as part of that renewal and enhancement, continue and reinforce the mandate of and support for CBAC.

Advisory Council on Intellectual Property, *Patents and Experimental Use, Options paper*, Woden, December 2004, <http://www.acip.gov.au/library/Experimental%20Use%20Options%20Paper%20A.pdf> (date accessed: February 25, 2005).

In recent years, there has been increasing concern, both in Australia and overseas, that patent rights may be inhibiting research and development, particularly in biotechnology.

Australia spends, through public and private sources, considerable funds on research and development. There has also been concern that there has been insufficient return on this investment through commercialisation of research and development in Australia and that inadequate use of the patent system by researchers may play a part in this.

ACIP intends to examine whether some types of patents are inhibiting research and development in Australia and determine whether both Australian researchers and business would benefit from introducing an experimental use exception provision (or some other provision) into the Australian patent legislation. In examining this question, ACIP will consider whether an experimental use exemption would help researchers more effectively use the patent system to commercialise their research and development.

The Bioethics Advisory Committee, *Research Involving Human Subjects: Guidelines for IRBs*, Biopolis, November 23, 2005, <http://www.bioethics-singapore.org/resources/reports3.html> (date accessed: February 25, 2005).

This report, *Research Involving Human Subjects: Guidelines for IRBs*, embodies the third set of recommendations by the BAC, which has been submitted to and accepted by the Life Sciences Ministerial Committee. It is the product of the Human Genetics Subcommittee (HGS) of the BAC after a thorough process of research and consultation, which began in April 2003.

International Center for Technology Assessment, *Altered Nuclear Transfer-ANT Crosses Ethical Boundaries*, Washington, December 3, 2004, [http://www.genetics-and-society.org/resources/items/20041203\\_icta\\_ant.pdf](http://www.genetics-and-society.org/resources/items/20041203_icta_ant.pdf) (date accessed: February 28, 2005).

In December the President's Council on Bioethics heard a proposal from one of its religious conservative members that was meant to circumvent opposition to the use of embryos for stem cell research. The basic plan was to use somatic cell nuclear transfer to create embryos that had no chance of being viable, and use those "altered" embryos to extract stem cells for research. Few commentators seemed to notice two serious problems with this proposal: first, that it still requires women's eggs, and thus that women undergo risky egg extraction procedures; and second, that the procedure would set dangerous precedents that could further the development of eugenic technologies.

The Human Genome Organisation (HUGO), *HUGO Ethics Committee-Statement on Stem Cells*, London, November 2004 [electronic version not available].

Stem cells are undifferentiated, self-replicating cells that can be stimulated to develop into more specialised cell types. Stem cells of various types have been used in medical therapy for a number of years, most notably in bone marrow transplants. It is hoped that the regenerative capacities of stem cells at earlier stages of differentiation can be harnessed in order to develop therapies for disorders and illness caused by organ or tissue dysfunction. The implications of the use of stem cells in research, and perhaps later in general therapeutic practice, are controversial due to questions of their source, their actual application, the further potential applications of related technologies developed in the process of research, and the effect these may have on society as a whole. [...] Investigation of all potential sources of stem cells should be pursued. [C]oherent regulation should replace prohibition of research.

France/Government, *Loi n° 2004-806 du 9 août 2004 relative à la politique de santé publique*, France, August 9, 2004, [http://www.europa.eu.int/comm/research/biosociety/pdf/french\\_law.pdf](http://www.europa.eu.int/comm/research/biosociety/pdf/french_law.pdf) (date accessed: February 24, 2005) [french version available only].

Comité consultatif de bioéthique de Belgique, *Avis n°32 du 5 juillet 2004 relatif à la libre disposition des tests génétiques*, Brussels, July 5, 2005, <http://www.health.fgov.be/bioeth/fr/avis/avis-n32.htm> (date accessed: February 21, 2005) [french version available only].

Medical Research Council (MRC), *MRC Ethical Guidance: Research Involving Human Participants in Developing Societies*, London, May 1, 2004, <http://www.mrc.ac.uk/pdf-devsoc-2004.pdf> (date accessed: February 18, 2005).

These guidelines are designed to be of use to researchers preparing proposals for MRC support for research involving children, and to those planning, undertaking or collaborating in such research. They will also be helpful to other researchers and to doctors and other health professionals whose patients may be involved in research, to ethics committees, to others reviewing or supervising research, and to the public.

Council for International Organizations of Medical Sciences (CIOMS), *Pharmacogenetics Towards Improving Treatment With Medicines*, Geneva, 2005 [electronic version note available]

The Council for International Organizations of Medical Sciences announces the publication of *Pharmacogenetics - Towards improving treatment with medicines*. [T]his Report addresses many issues in detail. The reader may find that there is duplication of information in various chapters. This is deliberate. The CIOMS Working Group on Pharmacogenetics considered that each chapter should be self-standing with its own references.

New Zealand/Government, *Human Assisted Reproductive Technology Act 2004*, no 92, New Zealand, November 21, 2004, [http://www.legislation.govt.nz/browse\\_vw.asp?content-set=pal\\_statutes](http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes) (date accessed: February 14, 2005).

Austria Bioethics Commission, *Preimplantation Genetic Diagnosis (Report of the Bioethics Commission at the Federal Chancellery)*, Vienna, July 2004, [http://www.austria.gv.at/2004/11/26/pgd\\_gesamtbericht\\_engl.pdf](http://www.austria.gv.at/2004/11/26/pgd_gesamtbericht_engl.pdf) (date accessed: February 21, 2005).

This report of the Bioethics commission on PGD consists of three parts: part I presents the arguments brought forward in the current national and international discussion in a descriptive way. Besides the scientific-medical aspects of PGD, the report summarizes thoughts on the ethical and legal admissibility of this method as well as on possible options of legal policy. Part I also meets the approval of all members of the Bioethics Commission.

The subsequent parts of this report contain on the one hand, an opinion in favour of a restricted approval of PGD (Part II) and on the other hand, an opinion in favour of maintaining the present legislation unchanged (Part III). The essential arguments as well as the subsequent recommendations for each one of these different opinions is discussed.

UK Newborn Screening Programme Centre, *Policies and Standards for Newborn Blood Spot Screening*, London, December 9, 2004, [http://www.ich.ucl.ac.uk/newborn/download/policies\\_standards.pdf](http://www.ich.ucl.ac.uk/newborn/download/policies_standards.pdf) (date accessed: February 18, 2005).

This document is intended to inform health professionals of the UK standards and policies for newborn blood spot screening and illustrate their important role in providing high quality screening services. It will be of particular use to Directors of Public Health, Antenatal and Child Health Screening Co-ordinators, Departmental Screening Leads, Laboratory Directors, Heads of Midwifery, and Specialist Commissioners.

The Paediatric Society of New Zealand, *Position Statement: Expanded Newborn Metabolic Screening*, Wellington, October 2004, <http://www.paediatrics.org.nz/documents/2004%20documents%20denise/Newborn%20screening%20final.doc> (date accessed: February 18, 2005).

The Paediatric Society of New Zealand recommends the following:

The Ministry of Health requests that the committee for Newborn Screening consider the evidence related to the benefits of expanded newborn screening with a view to the purchase of a tandem mass spectrometer;

That in establishing the need for such a service appropriate resources are made available for treatment of affected infants;

That funding is allocated for the ongoing screening including quality initiatives and audit of the service.

March of Dimes, *March of Dimes Statement on Newborn Screening Report*, White Plains, September 22, 2004, [http://www.marchofdimes.com/printableArticles/10651\\_13507.asp?printable=true](http://www.marchofdimes.com/printableArticles/10651_13507.asp?printable=true) (date accessed: February 18, 2005).

The March of Dimes issued a statement on the report on newborn screening prepared for the Maternal and Child Health Bureau of the U.S. Health Resources and Services Administration by the American College of Medical Genetics (ACMG).

National Marrow Donor Program, *Position Paper: National Cord Blood Program*, Minneapolis, June 2004, [http://www.marow.org/NMDP/paper\\_position\\_on\\_cord\\_blood.pdf](http://www.marow.org/NMDP/paper_position_on_cord_blood.pdf) (date accessed: February 18, 2005).

The National Marrow Donor Program (NMDP) supports the continued investment of public and private dollars to increase the number of cord blood units available for research and transplant in the United States. The NMDP understands that cord blood plays an important and growing role in the treatment of leukemia and other life-threatening blood diseases. Because of the need to increase the number of cord blood units available, the NMDP is providing \$8 million from its reserves to assist cord blood banks throughout the United States to increase the number of units they collect and store and to help diversify the ethnic composition of their inventory.

Medical Research Council (MRC), *MRC Ethics Guide-Medical Research Involving Children*, London, December 1st, 2004, [http://www.mrc.ac.uk/pdf-ethics\\_guide\\_children.pdf](http://www.mrc.ac.uk/pdf-ethics_guide_children.pdf) (date accessed: February 18, 2005).

These guidelines are designed to be of use to researchers preparing proposals for MRC support for research involving children, and to those planning, undertaking or collaborating in such research. They will also be helpful to other researchers, and to doctors and other health professionals whose patients may be involved in research, to ethics committees, to others reviewing or supervising research, and to the public.

American College of Medical Genetics (ACMG), *Newborn Screening: Toward a Uniform Screening Panel and System*, Rockville, March 2, 2005, <http://mchb.hrsa.gov/screening/> (date accessed: March 9, 2005).

In 2002, the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services (DHHS) commissioned the American College of Medical Genetics (ACMG) to:

1. Conduct an analysis of the scientific literature on the effectiveness of newborn screening.
2. Gather expert opinion to delineate the best evidence for screening for specified conditions and develop recommendations focused on newborn screening, including but not limited to the development of a uniform condition panel.
3. Consider other components of the newborn screening system that are critical to achieving the expected outcomes in those screened.



## DRAFTS

UK Biobank, *Policy on Intellectual Property ("IP") And Access*, Manchester, January 11, 2005, <http://www.ukbiobank.ac.uk/docs/UKBiobankIPandAccesspolicyfirstpublicdraft11.1.5final2.pdf> (date accessed: March 9, 2005).

The UK Biobank Resource is a managed research resource for the public good.

Access to the Resource has to be managed so as to:

- protect participants, honour commitments made to them and act within the scope of their consents;
- ensure compliance with legal and regulatory requirements (e.g. the Data Protection Act 1998);
- prioritise access to those parts of the Resource that are limited in availability (particularly samples, which are depletable);
- manage intellectual property rights in the Resource and the results that flow from it.

United Nations Educational, Scientific and Cultural Organisation (UNESCO), *Preliminary Draft Declaration on Universal Norms on Bioethics*, Paris, February 9, 2005, [http://portal.unesco.org/shs/en/file\\_download.php/10d16a8d802caebf882673e4443950fdPreliminary\\_Draft\\_EN.pdf](http://portal.unesco.org/shs/en/file_download.php/10d16a8d802caebf882673e4443950fdPreliminary_Draft_EN.pdf) (date accessed: February 25, 2005).

This Preliminary Draft Declaration on Universal Norms on Bioethics was finalized by the International Bioethics Committee (IBC) at its Extraordinary Session on 28 January 2005 after six meetings of its Drafting Group held between April and December 2004, three sessions of IBC (April 2004, August 2004, January 2005), two written consultations (January-March 2004 and October-December 2004), numerous consultations at international, regional and national levels (including within the framework of the UN Interagency Committee on Bioethics), a session of the Intergovernmental Bioethics Committee (IGBC) and a joint session of IBC and IGBC (January 2005).

Organisation for Economic Co-operation and Development (OECD), *Draft Guidelines for the Licensing of Genetic Inventions*, Paris, February 2005, <http://www.oecd.org/dataoecd/44/44/34343903.pdf> (date accessed: February 21, 2005).

These Guidelines offer principles and best practices for the licensing of genetic inventions used in human health care. They are targeted at all those involved with innovation and the provision of services in health, and particularly at those involved in the licensing of such inventions. The Guidelines are intended to assist both OECD and non-OECD governments in the development of governmental policies as well as in their efforts to encourage appropriate behaviour in the licensing and transferring of genetic inventions. Overall, the Guidelines seek to foster the development and delivery to the market of products and services based on genetic innovations, such as therapeutics and diagnostics, in order to more effectively and efficiently address health care needs in both OECD member and non-OECD countries.



**Q** What is population genetics?

**A** Population genetics is the study of genetic composition, and of the factors which influence its composition and explain its evolution and adaptation. These factors include natural selection, mutation, migration and the environment. For example, the size of a population or the geographical migrations that have occurred could potentially explain the existence of certain genetic characteristics and their manifestations.

In human population genetics, it is not only the individual who is studied, but the entire group to which that individual belongs.

A research project in human population genetics could examine the presence or absence of certain forms of genes in the population (e.g., a gene involved in the development of familial hypercholesterolemia). Such a study could observe both the frequency of physiological characteristics (such as blood pressure) and diseases (such as cardiac illnesses) within a population. It could also study the interaction between genes and between genes and environmental factors. This type of project involves the participation of a large number of people, allows statistical analyses and implies the creation of genetic databases and associated data.

**Q** What is a genetic database?

**A** A genetic database is a collection of samples to which genetic, medical, biochemical or genealogical data can be associated. Such databases are organized in a systematic manner and are generally used for research purposes. According to the Commission de l'éthique, de la science et de la technologie du Québec (CEST), genetic databases can exist in several forms. Some contain DNA samples, cell samples or tissues samples. The information contained in such databases varies from genetic to proteomic (pertaining to proteins) or medical data. Psychological or social information can also be included in such data.

Certain databases contain information on an entire population, or sub-population (e.g., a portion of the population that has a particular disease). These databases are often used for population genetics research projects.



**We believe that information exchange is a two-way process and we would appreciate some feedback, especially your thoughts on the new format of the GenInfo Newsletter. Completing the following brief survey will allow us to tailor future newsletters to serve you better.**

**1. How would you describe yourself? Specify, if possible.**

Specify

**2. How useful do you find the information that is provided by GenInfo?**

Not useful

Very useful

1 2 3 4 5 6 7 8 9 10

**3. Following a reading of GenInfo, have you taken any of the following measures?**

**(Check all that apply)**

**You have :**

Other

**4. How could we improve GenInfo so that it better responds to your needs?**



**Disclaimer**

All texts might be reprinted without permission, but the source must be credited.



| [Welcome](#) | [News](#) | [GenEdit](#) | [New Laws & Policies](#) | [FAQ](#) | [Feedback](#) | [Subscribe to GenInfo](#) | [Sponsors](#) | [Contact us](#) |