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This month in GenInfo you will find the reference to the new guidelines on stem cells from the American National Academy of Sciences (Laws and Policies section of GenInfo).

With the aim of improving the coverage of the latest developments in policymaking on the social, legal and ethical issues of human genetics, the GenInfo editorial team is proud to announce the forthcoming addition of a new section to its electronic newsletter. The section "Subscriber's Contribution" will include announcements of lectures, conferences and recent laws & policies relevant to the social, ethical and legal aspects of Human Genetics brought to our attention by GenInfo subscribers. We have no doubt that sharing this important information will be of benefit to you and that you will play an active role in the success of this new section of GenInfo.

Yann Joly
Editor

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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

MAY 2005

"37th European Human Genetics Conference"

Date: May 7-10, 2005

Location: Prague Congress Centre, Prague, Czech Republic

Host: European Society of Human Genetics (ESHG)

Information and registration:

To register or for additional information, visit www.eshg.org/eshg2005/index.html

"The Biology of Genome"

Date: May 10-15, 2005

Location: Melville, New York, United States

Host: Cold Spring Harbour

Information and registration:

To register or for additional information visit: meetings.cshl.edu/meetings/genome05.shtmlm.

"Genetic Information and the Law : Issues in the Insurance and Employment Settings"

Date: May 20, 2005

Location: University of Toronto, Toronto, Canada

Host: Faculty of Law, University of Toronto

Information and registration:

Mr. Tom Archibald

tom.archibald@utoronto.ca.

"Storage of Newborn Blood Spots: Genetics, Health Service and Research Policy Implication"

Date: May 28, 2005, at 12h00 to 16h00

Location: Children Hospital of Eastern Ontario, Ottawa, Canada

Host: Garrod Society Meeting

Information and registration:

Ms. Chantal Clément

613-737-7600

cclement@cheo.on.ca

PUBLICATIONS

BOOK CHAPTERS & ARTICLES

Knoppers, B. M. and R. Chadwick, "Human Genetic Research: Emerging Trends in Ethics", (2005) 6 *Nature Reviews Genetics*, 75-79.

Abstract: Genetic research has moved from Mendelian genetics to sequence maps to the study of natural human genetic variation at the level of the genome. This past decade of discovery has been accompanied by a shift in emphasis towards the ethical principles of reciprocity, mutuality, solidarity, citizenry and universality.

Knoppers, B.M., "Biobanking : International Norms", (2005) 33 :1, *The Journal of Law, Medicine & Ethics*, p. 7-14.

Abstract: From use for diagnosis and treatment or, for pathology and research, banked tissue samples are now seen as valuable for the study of whole populations. Discrepancies exist however, between the socio-ethical and legal frameworks governing biobanks at the international, regional and national levels. Indeed, unless some harmonization is promoted, the proposed benefits may never be achieved.

Deschênes, M. and C. Sallée, "Accountability in Population Biobanking: Comparative Approaches", (2005) 33: 1, *The Journal of Law, Medicine & Ethics*, p. 40-53.

Abstract: The recent rise of large-scale population-based biobanks poses unique challenges in terms of governance structures, key components of the success of such endeavors. This article proposes a review and comparative analysis of the surveillance and accountability mechanisms adopted by selected population research projects, and proposes avenues for consideration.



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.

AVAILABLE SOON

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.

Brazil, *Law on Biosafety PL. 2401-C/03*, Brazil, March 2, 2005. [Portuguese version only].

Article 6 of the Law prohibits genetic manipulation of the human germline. It also bans the intervention on human genetic material *in vivo*, with the exception of "procedures for diagnostic, preventive and treatment purposes of illnesses and anomalies" with the prior approval from the National Technical Committee on Biosafety (CTNBio), and in the case of clinical research, with the prior approval of the National Committee of Ethics Research (CONEP). This article also prohibits the creation, banking and manipulation of human embryos destined to be used as "disposable biological material". The Biosafety law is awaiting Presidential signature.

National Consultative Ethics Committee for Health and Life Sciences, *Problems Connected to Marketing Self-Test Kits for HIV Screening and Diagnosis of Genetic Disease*, Opinion n° 86, Paris, November 04, 2005, <http://www.ccne-ethique.fr/francais/start.htm> (date accessed: April 1, 2005) [French version only, English version in process of translation]

United Kingdom, House of Commons, Science and Technology Committee, *Human Reproductive Technologies and the Law*, Fifth Report, vol. I-II, London, March 24, 2005, <http://www.publications.parliament.uk/pa/cm/cmsctech.htm> (date accessed: April 1, 2005).

Topics discussed include:

- regulation of assisted reproduction - problems with HFEA Act
- the operation of the Act
- provision of infertility services
- review of the Act
- legislative and regulatory models

Recommendations are made on issues such as:

- choosing the sex of babies
- the need for a separate review of abortion
- the regulatory bodies required a legislative framework that balances the freedom of the individual with the interests of the state to ensure that any intervention has a sound ethical base

Sweden, *Act 1991:115 on Measures for Purposes of Research and Treatment Involving Fertilized Human Ova*, Sweden (amended in force April 1, 2005) [Electronic version not available, Swedish version only].

The amended "Act (1991:115) on Measures for Purposes of Research and Treatment Involving Fertilized Human Ova" clarifies Sweden's policy with regard to stem cell research. Under the Act, research on stem cells from fertilized eggs are permitted under the conditions formulated in the Act concerning research on fertilized eggs. It also allows somatic cell nuclear transfer (therapeutic cloning) in the context of research and subject to the same kinds of limitations as those applied to research on fertilized eggs. The Act also places an unequivocal ban on human reproductive cloning, which is defined as 'making a copy of another individual by implanting a genetically altered egg into a woman's womb'.

The Bioethics Advisory Committee, *Ethical, Legal and Social Issues in Genetics Testing and Genetics Research: A Consultation Paper*, Singapore, April 5, 2005, <http://www.bioethics-singapore.org/resources/pdf/GT%20CP%20Final.pdf> (date accessed: April 25, 2005).

The focus is on two main aspects in this Consultation Paper :

- (a) genetic testing for certain specified purposes; and
- (b) the genetic information thereby derived.

Société des obstétriciens et gynécologues du Canada (SOGC), "Mise en banque du sang de cordon ombilical: Implications pour les fournisseurs de soins périnataux", (2005) Vol: 156 *Journal d'obstétrique et gynécologie du Canada*, p. 275-290.[electronic version not available]

Human Genetics Commission, *Profiling the Newborn: A Prospective Gene Technology?*, London, March 2005, <http://www.hgc.gov.uk/UploadDocs/Contents/Documents/Final%20Draft%20of%20Profiling%20Newborn%20Report%2003%2005.pdf> (date accessed: April 7, 2005).

The Human Genetics Commission (HGC) has concluded that there are important ethical, legal and social barriers to the introduction of genetic profiling of babies at birth as a public health service. Apart from these, it is unlikely to be publicly affordable within the next 20 years, though commercial services are likely to be offered in this timeframe, potentially raising issues of regulation. It is important that research continues in order to establish how far profiling could be clinically useful, and it is critical that developments are kept under review. Specifically, the HGC is recommending to government that the entire topic should be revisited in five years when technologies will have moved on and the prospect of this becoming a reality is closer.

World Health Organization (WHO), *Report on the Forty-Second Session of the Advisory Committee on Health Research (ACHR), Report by the Secretariat*, Geneva, December 02, 2004, http://www.who.int/gb/ebwha/pdf_files/EB115/B115_26-en.pdf (date accessed: April 14, 2005).

This document provides a brief summary of the deliberations of the global ACHR at its forty second session (Geneva, 3 to 5 May, 2004).

National Institutes of Health (NIH), Department of Health and Human Services, "Best Practices for the Licensing of Genomic Inventions", (2004) 69: 223 *Federal Register*, <http://ott.od.nih.gov/NewPages/LicGenInv.pdf> (date accessed: April 11, 2005).

The Public Health Service's (PHS) primary mission is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. PHS seeks to maximize the public benefit whenever PHS owned or funded technologies are transferred to the commercial sector. These best practices for the licensing of government-funded genomic inventions are recommendations to the intramural PHS technology transfer community as well as to PHS funding recipients.

World Health Organization (WHO), *Reproductive Cloning of Human Beings: Status of the Debate in the United Nations General Assembly, Report by the Secretariat*, Geneva, December 16, 2005, http://www.who.int/gb/ebwha/pdf_files/EB115/B115_ID2-en.pdf (date accessed: April 14, 2005).

The elaboration of an international convention against the reproductive cloning of human beings has been under consideration in the United Nations since December 2001 when the subject was included in the agenda of the fiftysixth session as a supplementary agenda item at the request of France and Germany. The present report gives an overview of the terms and methods used in cloning and summarizes the debates in the General Assembly prior to 2005.

Genetics and Public Policy Center, *Reproductive Genetic Testing: Issues and Options for Policymakers*, Washington, November 1, 2004, <http://tools-content.labvelocity.com/pdfs/5/66755.pdf> (date accessed: April 14, 2005).

This report, *Reproductive Genetic Testing: Issues and Options for Policymakers*, aims to help focus and facilitate the discussion about reproductive genetic testing by outlining key scientific and medical facts, considering ethical and social implications, and assessing both current and potential oversight for the development and use of reproductive genetic tests. It presents a range of policy options, supported by expert analysis that consider the potential effects, positive and negative, of distinctly different policy directions. Our goal at the Genetics and Public Policy Center is not to advocate for or against any technology or policy outcome but to make sure that policy decisions, including the decision to maintain the status quo, are undertaken with a clear-eyed understanding of their potential impact.

Ministère des solidarités, de la santé et de la famille, *Décrets, arrêtés, circulaires, Décret n° 2005-420 du 4 mai 2005 relatif à l'Agence de la biomédecine et modifiant le code de la santé publique (partie réglementaire)*, *Journal officiel de la République française*, France, 4 mai 2005, http://reductiondesrisques.free.fr/doc/decret_C.pdf (date accessed: May 6, 2005).

National Research Council, *Guidelines for Human Embryonic Stem Cell Research*, Washington, National Academy of Science, 2005, 240 p, <http://www.nap.edu/books/0309096537/html/> (date accessed: May 2, 2005).

Since 1998, the volume of research being conducted using human embryonic stem (hES) cells has expanded primarily private funds because of restrictions on the use of federal funds for such research. Given the limited federal involvement, privately funded hES cell research has thus far been carried out under a patchwork of existing regulations, many of which were not designed with this research specifically in mind. In addition, hES cell research touches on many ethical, legal, scientific, and policy issues that are of concern to the public. This report provides guidelines for the conduct of hES cell research to address both ethical and scientific concerns. The guidelines are intended to enhance the integrity of privately funded hES cell research by encouraging responsible practices in the conduct of that research.

European Commission Expert Group, "Ethical, Legal and Social Implications of Genetic Testing", (January 2005) *Bulletin of Medical Ethics*, p. 9-11 [Electronic version not available].

In view of the rapid increase in genetic tests available, and of ways in which those tests are changing strategies in healthcare, the European Commission's Research Directorate invited a group of experts to discuss the issues and make recommendations.

Food and Drugs Administration (FDA), Office of Clinical Pharmacology and Biopharmaceutics, *Processing and Reviewing Voluntary Genomic Data Submissions (VGDSs)*, MAPP 4180.3, March 16, 2005, <http://www.fda.gov/cder/mapp/4180.3.pdf> (date accessed: May 6, 2005).

This MAPP explains how the Center for Drug Evaluation and Research (CDER) will process and review voluntary genomic data submissions (VGDSs) to the Food and Drug Administration (FDA).

Food and Drug Administration (FDA), Office of Clinical Pharmacology and Biopharmaceutics, *Management of the Interdisciplinary Pharmacogenomics Review Group*, MAPP 4180.2, Rockville, March 16, 2005, <http://www.fda.gov/cder/mapp/4180.2.pdf> (date accessed: May 6, 2005).

This MAPP describes:

- The role and responsibilities of the Interdisciplinary Pharmacogenomics Review Group (IPRG)
- Procedures to be used in designating members to serve on the IPRG
- The structure and function of the IPRG within the FDA

Wellcome Trust, *Wellcome Trust-Funded Research Involving People Living in Developing Countries: Position Statement and Guidance Notes For Applicants*, London, March 2005, http://www.wellcome.ac.uk/doc_wtd015295.html (date accessed: April 1, 2005).

Purpose of the position statement

The Wellcome Trust has produced this Position Statement and Guidance Notes in order to:

- communicate the ethical principles that underlie the Wellcome Trust's funding decisions on research projects that involve people living in developing countries;
- provide practical advice and highlight issues for applicants to consider when designing and submitting a research proposal to the Wellcome Trust for funding;
- set out the roles and responsibilities of the various parties involved in Wellcome Trust-funded research involving people living in developing countries.

Department of Health, Association of British Insurers, *Concordat and Moratorium on Genetics and Insurance*, London, March 14, 2005, <http://www.dh.gov.uk/assetRoot/04/10/60/50/04106050.pdf> (date accessed: April 7, 2005).

The Government and the insurance industry recognise and wish to respond to understandable concerns about the potential use of personal genetic data by insurance companies. They consider that the relationship between medical data and insurance underwriting should be proportionate and based on sound evidence. They also accept the commercial principle that, unless otherwise agreed, insurance companies should have access to all relevant information to enable them to assess and price risk fairly in the interest of all their customers.

This document provides a single high-level policy agreement on the use of genetic test results in insurance underwriting practices. It is informed by discussions between the Association of British Insurers, its member companies and the Government, the Genetics and Insurance Committee (GAIC) the Human Genetics Commission (HGC), patient groups and other interested parties.

U.S. Department of Health and Human Services, Food and Drug Administration (FDA), *Guidance for Industry: Pharmacogenomic Data Submissions*, Rockville, March 2005, <http://www.fda.gov/cder/guidance/6400fnl.pdf> (date accessed: May 6, 2005).

This guidance is intended to facilitate scientific progress in the field of pharmacogenomics and to facilitate the use of pharmacogenomic data in drug development. The guidance provides recommendations to sponsors holding investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) on (1) when to submit pharmacogenomic data to the Agency during the drug or biological drug product development and review processes, (2) what format and content to provide for submissions, and (3) how and when the data will be used in regulatory decision making.

Society of Obstetricians and Gynaecologists of Canada, "Umbilical Cord Blood Banking : Implications for Perinatal Care Providers", (2005) 156 JOGC , p. 263-264, <http://www.sogc.org/JOGC/documents/Abs-Armson-CPD-JOGC-march-05.pdf> (date accessed : May 1, 2005)



DRAFTS

The National Academy of Clinical Biochemistry (NACB), *Guidelines and Recommendations for Laboratory Analysis and Application of Pharmacogenetics to Clinical Practice*, Washington, http://www.nacb.org/Impg/2006_Impg_pgx.pdf (date accessed: April 1, 2005).

Objective: The objective of this LMPG on pharmacogenetics (PGx) is to provide a systematic rigorous assessment of the discipline of pharmacogenetics as it applies to clinical laboratory testing and its application to clinical practice. Issues to be addressed will be: methodological (pre-analytical and analytical) considerations, standardization and quality assurance of testing; selection of appropriate PGx testing profiles; recommended reporting of test results and interpretation; standards needed for demonstration of clinical utility and efficacy; and, recommendations for effective use of pharmacogenetic information in a clinical setting.

European Medicines Agency (EMA) - Committee for Medicinal Products for Human Use (CHMP), *Concept Paper on the Development of a Guideline on Biobanks Issues Relevant to Pharmacogenetics*, March 17, 2005, <http://www.emea.eu.int/pdfs/human/pharmacogenetics/680605en.pdf> (date accessed : May 3, 2005).

The maintenance in biobanks of identifiable samples for pharmacogenetics use and the duration of their availability versus the handling of anonymous/anonymized samples will be discussed putting these issues in the context of the scientific needs and objectives of the regulatory requirements that must be taken into account. Activities of regulatory authorities in this context include benefit/risk assessment and GCP compliance inspections. This concept paper identifies issues relevant to the scientific validity of pharmacogenetics studies that would need to be covered by CHMP guidelines because of their impact on the development and assessment of medicinal products.

European Medicines Agency, *Guideline on Pharmacogenetics Briefing Meeting*, London, March 17, 2005, <http://www.emea.eu.int/pdfs/human/pharmacogenetics/2022704en.pdf> (date accessed: May 6, 2005).



FAQ

The judicial, ethical and social concerns raised in the regulative texts that provide the framework for human genetics are complex. Our goal, with the Frequently Asked Questions (FAQ), is to approach these questions in such a way as to render them accessible.

Q Can insurance providers have access to genetic information contained in medical files?

A Several legal provisions protect the confidentiality of medical files and prohibit health care professionals from divulging their contents without authorization. Therefore, insurance providers cannot access these files without the consent of the concerned individual.

For instance, in order for the insurers to have access to the medical files, they normally ask consent of the insurance applicant at the time the insurance contract is signed via a specific provision included in the application form.

For more FAQs, visit HumGen's FAQ section at <http://www.humgen.umontreal.ca/int/faq.cfm?lang=1>



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