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Dear readers,

We are pleased to inform you that a new version of the HumGen website will be launched in the next few weeks. The interface and the search engine will be improved in order to make access to the documents more user-friendly.

As of its next publication, GenInfo will also be updated, just like GenEdit. Be the first to discover HumGen's new look!

In addition, we would like to congratulate Mme Michèle S. Jean on her nomination as President of the Canadian Commission for UNESCO. Mme Jean is a visiting scholar at the Centre de recherche en droit public at the Université de Montréal, and we are delighted to have her as a member of the HumGen team. Amongst her many achievements, Mme Jean presided over UNESCO's International Bioethics Committee from 2002 until 2005.

Enjoy!



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 2006

6èmes journées génétiques du RMGA: La génétique humaine au Québec - Qui fait quoi?
Date: May 1-2, 2006

Location: Montréal, Québec, Canada

Host: Quebec Network of Applied Genetic Medicine (RMGA)

Information and registration: For additional information and to register, visit: http://www.rmga.qc.ca/en/f_acti_jg.htm

IIREB's International Conference. Responding to End-of-Life Decisions: Perspectives from Medicine, Law and Ethics

Date: May 5, 2006

Location: Montréal, Québec, Canada

Host: International Institute of Research in Ethics and Biomedicine (IIREB)

Information and registration: For additional information and to register, visit: http://www.iireb.org/doc_nouvelles/conference20061.pdf

Reasons for Hope, 4th Scientific Conference of the Canadian Breast Cancer Research Alliance (CBCRA)

Date: May 6-8, 2006

Location: Montréal, Québec, Canada

Host: Canadian Breast Cancer Research Alliance (CBCRA)

Information and registration: For additional information and to register, visit: http://www.breast.cancer.ca/reasons_for_hope_conferences/Default.asp?language=English

74ème congrès de l'Association francophone pour le savoir (ACFAS) : le savoir, trame de la modernité

Date: May 15-19, 2006

Location: Montréal, Québec, Canada

Host: Association francophone pour le savoir (ACFAS)

Information and registration: For additional information and to register, visit: <http://www.acfas.ca/congres/>

97th Annual Conference - What Determines the Public's Health?

Date: May 28-31, 2006

Location: Vancouver, British Columbia, Canada

Host: Canadian Public Health Association (CPHA)

Information and registration: For additional information and to register, visit: <http://www.conference.cpha.ca/english/index.html>

JUNE 2006

4th International DNA Sampling Conference - Genomics and Public Health

Date: June 4-7, 2005

Location: Montréal, Québec, Canada

Host: Centre de Recherche en Droit Public (CRDP), Université de Montréal; Centers for Disease Control (CDC); Public Health Genetics Unit (U.K.); Public Health Agency of Canada

Information and registration: For additional information and to register, visit: <http://www.humgen.umontreal.ca/events/dnasampling>

AUGUST 2006

16th World Congress on Medical Law

Date: August 7-11, 2006

Location: Toulouse, France

Host: World Association for Medical Law, Association for Research and Formation in Medical Law (ARFDM)

Information and registration: For additional information and to register, visit: <http://www.arfdm.com/congress/index.php>

SEPTEMBER 2006

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

Date: September 28-29, 2006

Location: Montréal, Québec, Canada

Host: Université de Montréal

Information and registration: For additional information and to register, visit: <http://www.fes.umontreal.ca/bioethique/bryn-j/colloq2006.html>

PUBLICATIONS

BOOK CHAPTERS & ARTICLES

Avard D., Bridge P., Bucci L.M., Chiquette J., Dorval M., Durocher F., Easton D., Godard B., Goldgar D., Knoppers B.M., Laframboise R., Lesperance B., Plante M., Tavigian S.V., Vezina H., Wilson B., Simard J., INHERIT BRCA, "Partnering in Oncogenetic Research - The INHERIT BRCA Experience: Opportunities and Challenges", (2006) 5:1 *Familial Cancer*, 3-13.

Abstract: Today it is common to conduct research in collaboration with colleagues from different disciplines and institutions. The INterdisciplinary HEalth Research International Team on BREast CAncer susceptibility (INHERIT BRCA), involves Canadian and international experts from diverse fields working with health service providers, patients and collaborators from the World Health Organization and other European networks. Evidence-based information and knowledge transfer drive our efforts to advance genomic research to understand the genetic basis of cancer susceptibility and treatment response. Several goals reveal the interdisciplinary team approach: (a) to estimate the prevalence and penetrance of BRCA1 and BRCA2 mutations and their deleterious impact upon different populations; (b) to pinpoint novel breast cancer susceptibility loci; (c) to assess the efficacy of clinical interventions; (d) to address changes in quality of life and health-related behaviour from the decision to undergo genetics testing and during follow-up; (e) to evaluate legal, social and ethical implications; and, finally; (f) to promote professional and public education by facilitating the transfer of research findings to clinical practice and informing policy makers. The lessons learned by the INHERIT research team and future challenges are presented.

Doucet H., Gaudreau E., Grimaud M.A., *Éthique et recherche qualitative dans le secteur de la santé : échanges sur les défis*, (Montréal : Association francophone pour le savoir, 2006)

Godard B., Hurlimann T., Letendre M., Egalite N., INHERIT BRCA, "Guidelines for disclosing genetic information to family members: from development to use", (2006) 5:1 *Familial Cancer*, 103-16.

Abstract: This paper presents the existing legal frameworks, professional guidelines and other documents related to the conditions and extent of the disclosure of genetic information by physicians to at-risk family members. Although the duty of a physician regarding disclosure of genetic information to a patient's relatives has only been addressed by few legal cases, courts have found such a duty under some circumstances. Generally, disclosure should not be permitted without the patient's consent. Yet, due to the nature of genetic information, exceptions are foreseen, where treatment and prevention are available. This duty to warn a patient's relative is also supported by some professional and policy organizations that have addressed the issue. Practice guidelines with a communication and intervention plan are emerging, providing physicians with tools that allow them to assist patients in their communication with relatives without jeopardizing their professional liability. Guidelines aim to improve the appropriateness of medical practice and consequently to better serve the interests of patients. It is important to determine to what degree they document the 'best practice' standards. Such an analysis is an essential step to evaluate the different approaches permitting the disclosure of genetic information to family members.

Godard B., Knoppers B.M., "Emerging Duties Re: Professional Disclosure", in Sharpe N.F. and Carter R.F. (ed.), *Genetic Testing: Care, Consent, and Liability*, Hoboken, NJ: Wiley and Sons, 2006, p. 409-415.

Abstract: The proliferation of tests to identify individuals with an increased risk of genetic disease has led to a reevaluation of the duties of medical geneticists, genetic counsellors, and other health care professionals. Considering the speed at which genetic technologies are moving from bench to bedside, the questions of (1) whether researchers should communicate research results, (2) whether physicians should recontact patients concerning new information that might be useful to them, and (3) whether physicians should inform family members of relevant genetic information are becoming increasingly important. These questions correspond to the current changes taking place in the spheres of knowledge, social and cultural values and norms, and individual life experience.

Joly Y., Knoppers B.M., " Pharmacogenomic data sample collection and storage: ethical issues and policy approaches ", (2006) 7:2 *Pharmacogenomics*, 219-26.

Résumé : This perspective report will focus on the ethical, legal and social issues raised by pharmacogenomic research using large population-based databases. Access to databases established or developed at the level of whole populations or communities (e.g., the Estonian Genome Project, the UK Biobank, CARTaGENE, GenomEUtwin, and so on) will become increasingly important in pharmacogenomic research for the purpose of confirming associations between genetic variations and drug-related effects. The capacity of database creators and managers, along with that of researchers, to meet the ethical issues raised by such vast public projects will determine the integration of pharmacogenomics into mainstream clinical practice.

Lévesque E., Knoppers B.M., Avar D., "La protection de l'information génétique dans le domaine médical au Québec : principe général de confidentialité et questions soulevées par les dispositions d'exception", (2005-2006) 36:1-2 *Revue de droit de l'Université de Sherbrooke*, 101 [French version only].

Abstract: Providing healthcare services sometimes involves collecting and storing patients' genetic information. Often, this data is considered personal information for which confidentiality must be ensured. In Quebec, no legislative framework specifically protects genetic information. This article considers the protection that is provided by Quebec legislation to genetic information used in healthcare. Is this information covered by current provisions on confidentiality and privacy? What specific questions arise regarding the protection of this type of information?

The study analyses the rules that govern healthcare establishments, healthcare professionals, and private businesses. In conclusion, the article discusses some public health protection measures related to the protection of genetic information.

Mykitiuk R., Lacroix M., Turnham S., "Prenatal Diagnosis and Preimplantation Genetic Diagnosis: Legal and Ethical Issues", in Sharpe N.F. and Carter R.F. (ed.), *Genetic Testing: Care, Consent, and Liability*, Hoboken, NJ: Wiley and Sons, 2006, p. 189-218. **Abstract:** Prenatal diagnosis (PND) of genetic disorders and fetal anomalies has expanded significantly. The purpose of prenatal diagnosis is to rule out the presence in the fetus of a particular medical condition for which the pregnancy is at an increased risk. This information is provided to the individual or couple to assist in the decision-making process during the pregnancy regarding the possible options. Preimplantation genetic diagnosis (PGD) involves the creation of embryos outside the body and their subsequent biopsy in order to test for a genetic disorder. The stated advantage of PGD over prenatal diagnosis or testing is that the genetic diagnosis takes place at a much earlier stage. Prenatal genetic testing and preimplantation diagnosis raise a number of ethical and legal issues. This article presents a brief description of PND and PGD techniques, followed by a discussion of ethical and legal issues such as: access to PND and PGD, practice guidelines, obligations of the health care provider, public policy concerns, sex selection, testing for susceptibility and late-onset conditions, selecting for disability, abortion laws, informed consent, and confidentiality.



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.

CURRENT ISSUE

Volume IV No.1 (2006)

Title : The Legal Framing of Computerized Processing of Health Data: A European and Canadian Perspective.

Authors : Cynthia Chassigneux, Pierre Trudel, Bartha Maria Knoppers Knoppers

Abstract : The use of information and communication technologies in every sphere of political, economic and social life must come with reflection about the relevance of completing or not, or even revising the whole or part of the legal framework of a specific domain. This reflection is particularly important when it comes to the computer-assisted processing of health-related data. In order to understand the crucial elements of this issue, the authors examine the current framework and some issues specific to this "new" way of considering the management of such data from a European and Canadian perspective.

PAST ISSUES

Volume III No.3 (2005)

Warning Patients' Relatives of Genetic Risks: Policy Approaches

Mireille Lacroix, Béatrice Godard, and Bartha Maria

Volume III No.2 (2005)

Genetic Research Tools, the Research Exception and Open Science

E. Richard Gold, Yann Joly, Timothy Caulfield

Volume III No.1 (2005)

Populational Genetic Databases: Is a Specific Ethical and Legal Framework Necessary?"

Anne Cambon-Thomsen, Clémentine Sallée, Emmanuelle Rial-Sebbag, Bartha Maria Knoppers

Volume II No.3 (2004)

Newborn Screening, Banking and Consent

Claude Laberge, Linda Kharaboyan, Denise Avar

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 Régnier 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.

American College of Medical Genetics (ACMG) - Laboratory Quality Assurance Committee, "Technical Standards and Guidelines: Molecular Genetic Testing for Ultra-Rare Disorders", (2005) 7:8 *Genetics in Medicine*, 571, <http://www.geneticsinmedicine.org/pt/re/gim/pdfhandler.00125817-200510000-00007.pdf?jsessionid=ERQfJSa3djXL8cRcxcAwaWjtSKOxBv9iOFIMc3Il4J03gLBfsf5b!-1070481199!-949856145!9001!-1> (date accessed: April 7, 2006).

One mission of the ACMG Laboratory Quality Assurance (QA) Committee is to develop standards and guidelines for clinical genetics laboratories in an effort to maintain high technical standards for the performance and interpretation of genetic tests. This document was developed by the Ultra-Rare Disorders (URD) Working Group under the auspices of the Molecular Subcommittee of the Laboratory Quality Assurance Committee. It is intended to provide laboratories currently testing for ultra-rare disorders using molecular methods, and those considering expanding their test menus to include one or more such disorders, an overview of the specific issues that arise when performing molecular diagnosis for disorders in which the test is available in only one laboratory or very few laboratories. Specific issues that are addressed include custom mutation analysis and prenatal diagnosis, choice of analytic technique to identify private mutations, concerns about test validation, and interpretation of results. Ultra-rare disorders requiring diagnostic testing using cytogenetic or biochemical analyses are beyond the scope of this guideline and will be addressed in a separate document.

American College of Occupational and Environmental Medicine (ACOEM), *Genetic Screening in the Workplace*, Arlington Heights, December 13, 2005, <http://www.acoem.org/guidelines/consensus/Genetic%20Position%20Statement.pdf> (date accessed: March 10, 2006).

The position of the American College of Occupational and Environmental Medicine (ACOEM) is that genetic screening is not conceptually different from other types of medical testing or screening and that adherence to existing ethical standards, good scientific practices, and laws regulating medical confidentiality protect the rights of the individual appropriately, while allowing the new information to be used to further safeguard the health of individuals in the workplace and elsewhere. Since genetic screening may be conducted in the workplace, or employees may present genetic testing information to their employers, it is imperative that practitioners of occupational and environmental medicine be well-grounded in the relevant ethical, legal, social and scientific considerations, and be prepared to offer sound advice to employees, employers, insurance companies, and regulatory agencies. Although the application of genetic screening in the workplace has been limited to date, the ethical considerations of such testing in the workplace (and elsewhere) have been extensively examined and have led to the endorsement of guiding principles presented in this text.

Organisation for Economic Co-operation and Development, *Guidelines for the Licensing of Genetic Inventions*, Paris, 2006, <http://www.oecd.org/dataoecd/39/38/36198812.pdf> (date accessed: April 7, 2006).

These Guidelines offer principles and best practices for the licensing of genetic inventions used in human health care. 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 inventions in order to more effectively and efficiently address health care needs in both OECD member and non-member countries. These Guidelines apply to the licensing of intellectual property rights that relate to genetic inventions used for the purpose of human health care.

Canadian Biotechnology Advisory Committee (CBAC), *Human Genetic Materials, Intellectual Property and Health Sector*, Ottawa, March 2006, [http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/CBAC_Report_e.pdf/\\$FILE/CBAC_Report_e.pdf](http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/CBAC_Report_e.pdf/$FILE/CBAC_Report_e.pdf) (date accessed: April 7, 2006).

The Canadian Biotechnology Advisory Committee (CBAC) was asked by the federal departments of Health and Industry to study and make recommendations on matters pertaining to intellectual property protection of inventions involving human genetic material and their applications in the health sector. To assist it in this task, CBAC established an Expert Working Party (EWP) that began its work in January 2005. This document provides CBAC's views on the conclusions and recommendations contained in the EWP report together with complementary or alternative advice on key issues of particular importance to those engaged in the provision of health services. The observations, conclusions and recommendations take into account the comments received on the EWP report insofar as those comments relate to its conclusions and recommendations.

National Consultative Ethics Committee (CCNE), *Avis (No. 90) Accès aux origines, anonymat et secret de la filiation*, Paris, November 24, 2005, <http://www.ccne-ethique.fr/francais/pdf/avis090.pdf> (date accessed: April 7, 2006) [french version only].

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The Medical research Council (MRC) - The Wellcome Trust, *Access to Collections of Data and Materials for Health Research*, London, March 2006, http://www.mrc.ac.uk/pdf-access_report_march_2006.pdf (date accessed: April 21, 2006).

This is a report from an independent consultant to the Medical Research Council (MRC) and the Wellcome Trust. The charge was to review the issues surrounding research access to population-based collections of data and materials in the UK, principally collections that the two organisations fund or have some responsibility for.

Council of Europe - Committee of Ministers, *Recommendation Rec(2006)4F of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin*, Strasbourg, March 15, 2006, <https://wcd.coe.int/ViewDoc.jsp?id=977859&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75> (date accessed: April 21, 2006).

This recommendation applies to the full range of research activities in the health field involving the removal of biological materials of human origin to be stored for research use. It also applies to the full range of research activities in the health field involving the use of biological materials of human origin that were removed for a purpose other than that mentioned in the previous paragraph; this includes material removed for a previous research project.

Comité d'éthique de la recherche - Hôtel-Dieu de Lévis, *La recherche en génétique humaine - Formulaire de consentement - Guide du chercheur*, Lévis, January 2006, http://www.hdl.qc.ca/fr/Comite_Ethique_de_la_Recherche/documents/Formulaire%20de%20consentement%20-%20G%E9n%E9tique%20-%20Guide%20-%20Janvier%202006.pdf (date accessed: April 21, 2006) [french version only].

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Clinical Genetics Society (CGS) - Clinical Governance Sub-Committee, *Clinical Standards for a Genetics Unit*, Birmingham, August 2005, <http://www.clingensoc.org/Docs/Standards/ClinicalStandards.pdf> (date accessed: April 21, 2006).

The aim of clinical governance is to provide a framework through which NHS organisations are accountable for continually improving the quality of their services, and to safeguard high standards of care by creating an environment in which excellence in clinical care will flourish. There should therefore be processes and systems in place to monitor quality of care, with mechanisms to flag up any deficiencies in the system. Each Genetics Unit should have quality monitoring processes in place and believe that most units already do. The purpose of this document is to provide a quality standard template for the clinical genetics community.

Disabled People's International (DPI), *DPI Position Paper on Bioethics*, Winnipeg, May 19, 2005, <http://v1.dpi.org/lang-en/resources/details.php?page=49> (date accessed: April 21, 2006).

The goals of Disabled Peoples' International are to promote the human rights of disabled persons, to promote the economic and social integration of disabled persons, and to develop and support organizations of disabled persons. Bioethics issue affects disabled people, their self-perception and how they are perceived by others. Recognizing that disabled people are unquestionably the largest minority group in the world whose human rights are systematically violated, this document affirms DPI's support for the bioethics resolutions of the Sapporo DPI World Assembly of 2002, and demands attention regarding several issues.

Information Commissioner's Office (ICO), *Employment Practices Code*, June 2005, Wilmslow, http://www.informationcommissioner.gov.uk/cms/DocumentUploads/ICO_EmpPracCode.pdf (date accessed: April 3, 2006).

This Code is intended to help employers comply with the *Data Protection Act* and to encourage them to adopt good practice. The Code aims to strike a balance between the legitimate expectations of workers that personal information about them will be handled properly and the legitimate interests of employers in deciding how best, within the law, to run their own businesses. It does not impose new legal obligations.

Information Commissioner's Office (ICO), *The Employment Practices Code: Supplementary Guidance*, Wilmslow, June 2005, http://www.ico.gov.uk/documentUploads/ICO_SuppGdnce.pdf (date accessed: April 21, 2006).

This supplementary guidance does not in itself form part of the Information Commissioner's 'Employment Practices Data Protection Code'. It is intended to complement the main Code by giving supplementary information about the issues covered in it. This guidance includes notes and examples which are intended to give readers a better understanding of some of the practical issues that may arise when implementing the Information Commissioner's good practice recommendations. It also includes a set of frequently asked questions and useful contact details.

World Health Organisation - Commission on Intellectual Property Rights, *Innovation and Public Health, Public Health, Innovation and Intellectual Property Rights*, Geneva, April 2006, <http://www.who.int/intellectualproperty/documents/thereport/CIPIHReport23032006.pdf> (date accessed: April 21, 2006).

Against the background of an ongoing international debate concerning the relationship between intellectual property rights, innovation and public health, in international organizations and more generally among governments and civil society organizations, the World Health Assembly decided to give an independent Commission the task of analysing this key issue. The Commission accepts this report as a solid contribution towards continued international dialogue, and progress towards the objectives for which the Commission was established.

Danish Board of Technology, *Recommendations for a Patent System of the Future*, Copenhagen, May 2005, http://tekno.dk/pdf/projekter/p05_recommendations_for_a_patent_system_of_the_future.pdf (date accessed: April 21, 2006).

This report was prepared by a working group under The Danish Board of Technology. Its goal was to thoroughly review the patent system, discuss its implications, and provide ideas and recommendations to resolve the problems that were identified.

Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS), *Contribution of BRCA1/2 Mutation Testing to Risk Assessment for Susceptibility to Breast and Ovarian Cancer, Summary Report*, Montreal, March 2006, <http://www.aetmis.gouv.qc.ca/site/download.php?38840343219c5471a83ea0fe5ca10d67> (date accessed: April 21, 2006).

The document summarizes a monograph which is the result of the analysis undertaken at AETMIS on 1) prevalence and penetrance of BRCA1/2 mutations; 2) risk assessment models and testing indications; 3) clinical validity of molecular tests; and 4) the impact of molecular testing on risk assessment and genetic counselling.

Canadian Coordinating Office for Health Technology Assessment, *A Clinical Systematic Review of BRCA1 and BRCA2 Genetic Testing for Breast and Ovarian Cancers*, Ottawa, March 2006, http://www.cadth.ca/media/pdf/421_brca_to_e.pdf (date accessed: April 21, 2006).

Some individuals are more likely to have BRCA1 and BRCA2 gene mutations. Genetic testing for these mutations is available in Canada, and can be accessed as a clinical laboratory service or through a research study. There is a need to better understand the benefits and harms that are associated with testing, the available tests and how they compare with each other, the social factors that influence testing, and the psychological and ethical issues that are associated with testing.



DRAFTS

Académie nationale de médecine, *Avis - Projet de décret relatif aux examens des caractéristiques génétiques à des fins médicales*, Paris, January 10, 2006, http://www.academie-medecine.fr/upload/base/rapports_255_fichier_lie.rtf (date accessed: April 7, 2006) [french version only].

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Council of Europe, Steering Committee on Bioethics (CDBI), *Draft Explanatory Memorandum to the Draft Recommendation on Research on Biological Materials of Human Origin*, Strasbourg, March 15, 2006, http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/News/CDBI_2005_5e%20REV2%20FINAL1.pdf (date accessed: April 7, 2006).

This draft explanatory memorandum to the draft recommendation on research on biological materials of human origin was drawn up under the responsibility of the Secretary General of the Council of Europe. It takes into account the discussions held in the Steering Committee on Bioethics (CDBI), and it also takes into account the remarks and proposals made by Delegations. The explanatory memorandum is not an authoritative interpretation of the draft recommendation. Nevertheless it covers the main issues of the preparatory work and provides information to clarify the object and purpose of the recommendation and to better understand the scope of its provisions. The purpose of this recommendation is to set out and safeguard fundamental rights of individuals whose biological materials are used in biomedical research, while recognizing the importance of freedom of research.

Australian Government, Gene Technology Ethics Committee, *Draft National Framework for the Development of Ethical Principles in Gene Technology*, Woden, January 2006, <http://www.ogtr.gov.au/rtf/committee/ethicalprinciplesgtconsultjan06.rtf> (date accessed: April 7, 2006).

This National Framework sets out a national reference point for the development of ethical principles for ethical conduct in working with gene technology. It incorporates some well-established principles for dealing with human health and animal welfare, and some less well-established principles of environmental ethics. The National Framework does not provide mandatory regulation on gene technology. The National Framework has been developed by the Gene Technology Ethics Committee (GTEC), established under the Gene Technology Act 2000. GTEC has identified nine principles for ethical conduct in working with gene technology for scientists, research institutions, regulatory and ethics committees, and the general community.

British Medical Association (BMA), *Confidentiality as Part of a Bigger Picture - A Discussion Paper from the BMA*, London, May 2005, <http://www.bma.org.uk/ap.nsf/Content/ConfidentialityBiggerPicture> (date accessed: April 7, 2006).

The BMA currently advises that legally and ethically health professionals are responsible to patients for the confidentiality of the health information they hold. When they provide information, patients imply consent to some sharing with other healthcare professionals. There should be no use or disclosure of any confidential patient identifiable information gained in the course of professional work for any purpose other than the clinical care of the patient to whom it relates. It would seem timely, however, for the BMA to debate how data currently, and in the future, flow within the healthcare system given the move away from a more personalised healthcare service. Exploration of an information governance/data protection position in this paper is not for the purpose of advocating a change in BMA policy, but instead to reflect a viewpoint that differs from traditional policy and practice, and consequently to enliven debate about data issues.

World Health Organisation, *Sickle-cell Anaemia (Recommendation of the Executive Board)*, Geneva, January 25, 2006, http://wwwlive.who.ch/gb/ebwha/pdf_files/EB117/B117_R3-en.pdf (date accessed: April 21, 2006).

The Executive Board, having examined the report on sickle-cell anaemia, recommends to the Fifty-ninth World Health Assembly the adoption of several resolutions regarding the prevention and management of sickle-cell anaemia.

Australian Academy of Science, *A Submission to the National Health and Medical Research Council (NHMRC), Australian Research Council (ARC), and the Australian Vice-Chancellors' Committee (AVCC) - Second Consultation Draft of the National Statement on Ethical Conduct in Human Research*, Canberra, March 15, 2006, <http://www.science.org.au/reports/15march06.pdf> (date accessed: April 21, 2006).

The Australian Academy of Science has considered the 2006 Draft of the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and the Australian Vice-Chancellors' Committee (AVCC)'s *National Statement on Ethical Conduct in Human Research*. The Academy has serious reservations about aspects of this Draft and presents its comments in this document.

Department of Biotechnology, Ministry of Science & Technology, Government of India, *National Biotechnology Development Strategy*, New Dehli, March 30, 2006, <http://dbtindia.nic.in/biotechstrategy/BiotechStrategy.pdf> (date accessed: April 21, 2006).

The Indian biotechnology sector has, over the last two decades, taken shape through a number of scattered and sporadic academic and industrial initiatives. The time is now ripe to integrate these efforts through a pragmatic National Biotechnology Development Strategy. It is imperative that the principal architects of this sector along with other key stakeholders play a concerted role in formulating such a strategy to ensure that it not only builds on the existing platform but expand the base to create global leadership in biotechnology by unleashing the full potential of all that India has to offer.

Health Canada, *Release of Draft Guidance Document: Submission of Pharmacogenomic Information*, Ottawa, March 15, 2006, http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/draft_pharmaco_ebauche_e.pdf (date accessed: April 21, 2006).

The guidance document is intended to clarify how and when to submit pharmacogenomic information to Health Canada. The document applies to sponsors intending to submit pharmacogenomic information, either in support of an application or submission for a drug, biologic, or medical device intended for human use. The document also applies to the submission of pharmacogenomic information as part of ongoing post-market activities.



FAQ

The Frequently Asked Questions section gives information about several issues raised by human genetics. Here, our goal is to approach these questions in a simple way.

Q What is pharmacogenomics research?

A The goals of pharmacogenomics research are to: a) study the interactions between genetics and an individual's response to treatments and/or; b) to identify new targets for treatments. For example, a study in pharmacogenomics may explore whether a particular version of a gene could influence the effectiveness or the side effects of a given medication. Another study in pharmacogenomics could seek to identify a human gene involved in the response to medications.

Two terms are used by experts to describe this type of research: pharmacogenomics and pharmacogenetics. These two terms are sometimes used as synonyms or to refer to two distinct concepts. Several definitions have been ascribed to these terms and not all experts are in agreement. In this section of FAQ, we have chosen to use only the term pharmacogenomics.

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



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