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The abundance of national, regional and international laws and policies display intense policy-making activities during this summer season. Among others, there are three new documents from the Human Genetics Society of Australasia and two from the Canadian Biotechnology Advisory Committee. The "news, laws & policies" section also feature the recently modified United Kingdom Human Tissue Bill.

The Genetics and Society members have also been busy, as one new module mentioned in the last edition of GenInfo (IPGen) is now online.



NEWS

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

EVENTS

JULY 2004

" Toward a consensus on cloning ? US policy and the global debate "

Date : July 9, 2004

Location : Capitol Hill Briefing (room HC-6) et National Press Club (Holeman Lounge)

Host : The Institute on Biotechnology and the Human Future (IBHF)

Description : Participants to include : Lori B. Andrews, Distinguished Professor of Law, Chicago-Kent College of Law, board chair, Institute on Biotechnology and the Human Future ; Nigel M. de S. Cameron, President, Institute on Biotechnology and the Human Future ; Director, Council for Biotechnology Policy ; Rosario Isasi, Center for Public Law Research, University of Montreal.

SEPTEMBER 2004

La génomique et l'industrie des biotechnologies (as part of the **Genomics and Public Health** conference series)

Date : September 13, 2004 at 12h00

Location : University of Montreal, Faculty of Law

Host : Canada Research Chair in Law and Medicine

Description : Guest speaker: Grégory Bénichou, Professor in Ethics and Biotechnologies, ESSEC, France. This conference is open to the public.

To register contact: (514) 343-2138 or marie-angele.grimaud@umontreal.ca

For additional information visit : <http://www.crcdm.umontreal.ca>

OCTOBER 2004

Symposium on Breast Cancer "S'informer pour aindre"

Date : October 2, 2004

Location : Hyatt Hotel (Complexe Desjardins), Montreal

Host : Réseau Québécois pour la Santé du Sein

Description : Invited speakers will present on the theme: What's new in diagnostic and surgical techniques, treatment and research?

The psychosocial aspects related to breast cancer will also be examined. This conference is open to the public. "Continuing education" credit is available for members of the medical community.

For additional information, contact Huguette Martin : Hmartin@rqss.qc.ca

La génomique et la vie socio-économique : assurance et emploi (as part of the **Genomics and Public Health** conference series)

Date : October 4, 2004 at 12pm

Location : University of Montreal, Faculty of Law, salon des professeurs, A-3464

Host : Canada Research Chair in Law and Medicine

Description : Guest speaker: Yves Millette, Vice-President, Quebec Affairs, Canadian Life and Health Insurance Association. This conference is open to the public.

For additional information, visit : <http://www.crcdm.umontreal.ca>

Dix-Septièmes Entretiens du Centre Jacques Cartier "Oncogenetics : Achievements and Challenges"

Date : October 7 & 8, 2004

Location : Crowne Plaza, Montreal

Hosts :

- Centre Jacques Cartier, Dix-septièmes entretiens
- The National Centre for Scientific Research(France)
- CIHR, INHERIT BRCA's (Canadian Institutes of Health Research, Interdisciplinary Health Research International Team on Breast Cancer Susceptibility)
- Université de Montréal, Centre for Research in Public Law, Canada Research Chair in Law and Medicine
- Université Laval, Canada Research Chair in Oncogenetics

Description : World experts will discuss the latest developments as well as achievements and challenges in cancer genetics. The topics will include genetic susceptibility to breast, ovarian, paediatric, gastro-intestinal cancers, as well as multiple endocrine neoplasia.

Note : Call for abstracts

• Submissions

Participants to the symposium are encouraged to submit an abstract for a poster presentation before August 15, 2004. Posters presentations should be consistent with the conference themes. The abstracts should be no more than 250 words excluding the title.

• The meeting will feature themes of hereditary cancers :

- Breast and Ovarian Cancer
- Gastro-Intestinal Tumours
- Ethical, Legal and Social Issues
- Paediatric Cancers/ Rare Cancers
- Défis méthodologiques
- Cancer Genetics Research and Management
- Multiple Endocrine Neoplasia

Registration fee :

After July 1, 2004 : \$300

Student Rate : \$150

For additional information visit: <http://www.humgen.umontreal.ca/CJC/>

Dix-Septièmes Entretiens du Centre Jacques Cartier "Allocations des ressources en santé, enjeux, perspectives et choix éthiques et bioéthiques"

Date : October 7&8, 2004

Location : Université du Québec à Montréal (UQAM), room D-2000, Pavillon Athanase David, 1430 St. Denis

Hosts :

- Centre de Recherche en Éthique de l'Université de Montréal (CREUM)
- Canada Research Chair in Law and Medicine (CRCLM)
- Institut de Formation et de Recherche sur les Organisations Sanitaires et Sociales et leurs réseaux (IFROSS)

Description : The main themes of the symposium are: 1) resources allocation: a new approach for the beginning and the end of life; 2) health policy and the aging population; 3) health services organizations: economic and ethical considerations; 4) access to healthcare: challenges and international perspectives.

Registration fee :

before September 20, 2004: \$135

after September 20, 2004: \$150

student rate: \$50

To register or for additional information, visit : <http://www.humgen.umontreal.ca/conf/allocationssante> or contact Michèle S. Jean (514) 343-6111 ext. 1449 or Marie Angèle Grimaud (514) 343-2138, or email : ejc.allocsante@umontreal.ca

La génomique et la santé publique : quel public ? (as part of the **Genomics and Public Health** conference series)

Date : October 20, 2004 at 12pm

Location : University of Montreal, Faculty of Law, salon des professeurs, A-3464

Host : Canada Research Chair in Law and Medicine

Description : Guest speaker: Christian Hervé, Professor and Director of the Medical Ethics, Health Law, and Public Health Laboratory, Paris.

This conference is open to the public.

For additional information, visit <http://www.crcdm.umontreal.ca>

PUBLICATIONS

BOOKS

Rothstein M.A. (ed.), *Genetics and Life Insurance: Medical Underwriting and Social Policy*, Massachusetts, The MIT Press, 2004.

Abstract : Genetics and Life Insurance addresses the socio-ethical and legal issues raised by the relationship between genetics and the life insurance industry. Professionals in the life insurance field will turn to this book as an authoritative discussion of the relevant viewpoints and issues. A strength of the book is the diversity of perspectives held by the authors of the various chapters and the recommendations that follow.

Duguet A-M. (ed.), *Séminaire d'actualité de droit médical - Droit et éthique de la recherche médicale*, Bordeaux, Les Études Hospitalière, 2004.

Abstract : This book is composed of a series of articles on medical research. The articles describe the current French legislative framework (one of the most restrictive) and provides evidence of the disregard by French researchers'. The articles also describe issues relating to specific types of research (e.g., embryos, consent of persons with Alzheimer's disease), constraints imposed by legal judgments and health research related to space travel.

BOOK CHAPTERS & ARTICLES

Knoppers B.M., Godard, B., Joly, Y., *A Comparative International Overview, in Rothstein, M.A. (ed.), Genetics and Life Insurance: Medical Underwriting and Social Policy*, Massachusetts, The MIT Press, 2004, p.73.

Abstract: The possibility of using genetic information and testing in life insurance underwriting has stimulated legislative and policy discussions at all levels (international, regional, and national). This chapter presents an international overview of laws, guidelines and other normative texts adopted to restrain insurers' access to genetic information for life insurance underwriting.

Knoppers, B.M., Sheremeta, L., *Beyond the Rhetoric : Population Genetics and Benefit-Sharing*, Health Law Journal, 2003, Vol. 11.

Abstract : Population genetics research necessitates the development of mechanisms to ensure that the benefits of this scientific innovation are shared equitably. The Human Genome Project provides a unique opportunity to develop a health ethic and a "culture of science." Biotechnological advances in genomics, if applied correctly and equitable in both the use and distribution of resources, have the potential to revolutionize medicine and health care.

RÉGNIER M-H., *Les embryons surnuméraires et la recherche sur les cellules souches : les enjeux relatifs au consentement*, dans Anne-Marie DUGUET (dir.), *Séminaire d'actualité de droit médical - Droit et éthique de la recherche médicale*, Bordeaux, Les Études Hospitalières, 2004, p. 143-154.

Abstract : In March 2002, Canadian Institutes of Health Research (CIHR) released guidelines for human stem cell research, which include provisions on the consent requirements for donor couples. In order to evaluate the conformity of consent forms and information fliers at Canadian fertility centres with CIHR's guidelines, we solicited the participation of Canadian fertility centres. After analyzing their consent forms and their information flyers, we examines these documents' conformity with the CIHR guidelines. This article analyzes actual practices, as well as their conformity with CIHR's guidelines and other Canadian ethical and legal documents.

JOLY Y., *La protection de l'information génétique dans la recherche en pharmacogénétique et en pharmacogénomique* dans Anne-Marie DUGUET (dir.), *Séminaire d'actualité de droit médical - Droit et éthique de la recherche médicale*, Bordeaux, Les Études Hospitalières, 2004, p. 155-168.

Abstract : Developments in genetics have allowed us to use our new knowledge about genes and DNA in various ways to improve the health of populations. One of the most recent developments in genetics, pharmacogenomics was developed thanks to the completion of the sequencing of the human genome and progress in biomedical informatics. The stakes of pharmacogenomic research, although different from those of research of susceptibility to disease genes, are no less important. These differences justify addressing the protection of confidentiality in the specific context of pharmacogenomics. From this perspective, the present text proposes, following a study of guidelines and recommendations of international, regional, and national organizations, to present certain benchmarks which will allow researchers, as well as research ethics boards, to determine the appropriate level of confidentiality protection for pharmacogenomic research.



GENEDIT

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

CURRENT ISSUE

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

The debate surrounding the role of life insurance, the necessity of risk rating, and the notion of "acceptable discrimination" has raised questions about the larger social role of insurance. This debate has been exacerbated by the availability of an increasing number of genetic tests, allowing insurers to make use of genetic results as a new underwriting tool.

The article presents a comparative study of approaches adopted by different countries or organizations when faced with issues in genetics and life insurance. We analyze the position of 44 countries with regards to their potential for ensuring equitable access to life insurance.

PAST ISSUES

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

Volume I No.1
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, ethical) statements on human genetics from international, regional and national sources.

We are constantly searching for documents to enrich our data bank. If your organisation has published policy statements relating to genetics, or if you are aware of such new publications, please be kind enough to send us the relevant information and we will consider including them in the data bank.

United Kingdom, House of Commons Science and Technology Committee, *Memorandum from the Scottish Council on Human Bioethics*, June 14, 2004, <http://www.publications.parliament.uk/pa/cm200304/cmselect/cmstech/599/599we21.htm> (date accessed : June 28, 2004).

The Scottish Council on Human Bioethics considers that the HFEA should become more accountable to Parliament. An appropriate parliamentary committee, such as the Science and Technology Committee of the House of Commons, should be able to closely monitor any regulatory decisions of the HFEA and intervene if it feels that a particular issue requires wider discussion and consideration.

The SCHB is also concerned that the 18 members of the HFEA are often selectively appointed to only represent certain views and that they have too much power to act, without consultation with Parliament, in the important area of human reproductive technologies.

The Science and Technology Committee announced the following terms of reference for its inquiry into Human Reproductive Technologies and the Law.

European Society of Human Genetics, *Polymorphic sequence variants in medicine : Technical, social, legal and ethical issues Pharmacogenetics as an example*, Vienna, June 10, 2004, <http://www.eshg.org/ESHG-IPTSPGX.pdf> (date accessed : June 28, 2004).

This document is intended to give an overview on the topic of polymorphic sequence variants in medicine, by delving into issues regarding pharmacogenetics as an example of this topic. Though this subject is not one that exemplifies all aspects of polymorphic sequence variants in medicine, it is one that is currently active in public discourse, and for that reason was investigated further by us at this time.

Medical Research Council (MRC), *Research Involving Human Participants in Developing Societies : Ethical Guidelines for MRC-sponsored Studies*, London, May 2004, <http://www.mrc.ac.uk/pdf-devsoc.pdf> (date accessed : June 28, 2004).

The MRC expects all researchers that it funds to follow these guidelines when their research involves developing countries. Other researchers and those involved in reviewing or supervising research will also find them helpful.

The guidance is brief, and encourage researchers to consult the key sources of further reading given at the end for detailed elaboration/guidance.

British-North American Committee (Atlantic Council of the United States, British-North American Research Association (UK), C.D. Howe Institute (Canada)), *A guide to the Benefits, Responsibilities and Opportunities of Embryonic Stem Cell Research*, Washington, London, Toronto, June 2004, <http://www.acus.org/BNAC/Publications/Cloning%20Paper%206.0.pdf> (date accessed : June 30, 2004).

The purpose of this guide is to create the framework for an informed discussion regarding embryonic stem cells (ESC) research.

Four specific areas are reviewed - the scientific background, ethical concerns, legislative activity in our three countries and elsewhere, and the potential impact on our economies and well being of our citizens.[...]

American College of Obstetricians and Gynecologists (ACOG), *Ethics in Obstetrics and Gynecology -second edition-*, Washington, 2004, http://www.acog.org/from_home/publications/ethics/index.cfm?printerFriendly=yes (date accessed : June 30, 2004).

Part I, "Ethical Foundations," describes various theoretical approaches to ethical decision making, offers a stepwise guideline for decision making, addresses common issues faced in daily practice, and offers detailed information on the rationale for obtaining the informed consent of patients and practical assistance as to how this is done.

Part II, "Caring for Patients," provides ethical guidance for obstetrician-gynecologists in providing specific health services to their patients.

Part III, "Professional Responsibilities," speaks to the ethical obligations that arise out of obstetrician-gynecologists' nonclinical duties as students, teachers, and researchers. This part also identifies appropriate interactions with patients expected as a part of professional behavior.

Part IV, "Societal Responsibilities," addresses the ethical obligations of obstetrician-gynecologists to society.

Swiss Society of Medical Genetics, *Best practice guidelines on reporting in molecular genetic diagnostic laboratories in Switzerland*, Berne, 2003, <http://www.ssgm.ch/sections/pdf/current/publications/SSGM%20reporting%20guidelines%20dna%20v1.pdf> (date accessed : June 30, 2004).

This text presents Best Practice Guidelines for Swiss laboratories reporting molecular genetic diagnostic testing of constitutional mutations.

The aim of the guidelines is to improve the quality of reporting in Switzerland and to help laboratories to provide the most understandable and complete reports of their analyses. [...]

Reports are specific formal documents from the laboratory to the referring doctor, recording the outcome of molecular genetic investigations on a patient. Their principal aim is to provide a clear, concise, accurate, fully interpretative and authoritative answer to a clinical question. [...]

Health Council of the Netherlands, *Prenatal Screening (2) ; Down's syndrome, neural tube defects*, The Hague, April 29, 2004, <http://www.gr.nl/adviezen.php?ID=969> (date accessed : June 22, 2004).

What are the best tests for detecting neural tube defects and Down's syndrome in a foetus during pregnancy? And what is the best way to conduct this prenatal screening? These are the central issues in this advisory report.

The aim of screening is to provide people who wish for it with information about the presence or absence of the disorder in question. This enables them to terminate the pregnancy where appropriate or to make preparations for the birth of a child with Down's syndrome or a neural tube defect.[...]

Centers for Disease Control and Prevention, *Genomics and Population Health: United States 2003*, Atlanta, March 1, 2004, http://www.cdc.gov/genomics/activities/ogdp/2003/2003_foreword.htm (date accessed : June 22, 2004).

With the completion of the Human Genome Project in 2003, the stage has been set for an accelerated pace of discovery of thousands of genetic variants. Many variants will be studied for association with diseases of major public health importance, including adult chronic diseases, childhood conditions, infectious, environmental and occupational diseases.

Applications of genetic information in diagnosis and prevention of various diseases must be driven by evidence on gene functions in normal and disease states as well as by the value of such information to improve health outcomes. In spite of the potential promise and excitement about human gene discoveries, there are still immense gaps in the knowledge needed for a successful translation of new research results into population health benefits. This "translation gap" calls for an important public health leadership role in applied research, policy development and integration of genomics into the practice of 21st century medicine.

In this first report, the CDC present some examples to show how public health is beginning to address three major gaps along the genomics "translation highway":

- conducting genomics and population health research,
- developing evidence on the value of genomic information, and
- integrating genomic information in practice and programs.

Human Genetics Society of Australasia (HGSA)/Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), *Guidelines on antenatal screening for Down syndrome and other fetal aneuploidy*, Alexandra, March 2004, <http://www.hgsa.com.au/PDF/Best%20practice%20Guidelines%20on%20antenatal%20screening%20for%20Down%20syndrome%20C-Obs%204%20Mar2004.pdf> (date accessed : June 23, 2004).

This document was developed by the Joint HGSA/RANZCOG Prenatal Diagnosis and Screening Committee who recommended "Best Practice" on antenatal screening and these guidelines are based on the data currently available on the performance of the screening tests.

It is acknowledged that new data on screening tests are being produced as programs continually audit their performance, and these may alter the recommendations below. It is recognised that not all women will want to use a pre-natal screening or diagnostic test. It is recognised that in both Australia and New Zealand some of the tests mentioned below may not be universally available at this point in time.[...]

Human Genetics Society of Australasia (HGSA)/Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), *Prenatal diagnosis policy*, Alexandra, March 2004, <http://www.hgsa.com.au/PDF/Prenatal%20diagnosis%20policy%20C-Obs%205%20Mar2004.pdf> (date accessed : June 23, 2004).

This document has been prepared by the Joint HGSA/RANZCOG Prenatal Diagnosis and Screening Committee.

Recommendations:

1. The increasing indications for prenatal diagnosis makes it necessary to have a specialised team for prenatal diagnosis for birth defects and genetic diseases. This team should consist of clinical and laboratory services.
2. There should be at least one specialised prenatal diagnostic service for each State/Territory. Such services should be located in tertiary obstetric facilities available in the public sector. Independent private practitioners should be encouraged to make use of the regional specialised prenatal diagnostic service for consultation and referral and the service would expect to provide some support for and collaborative work with the private sector.[...]

Human Genetics Society of Australasia (HGSA)/Royal Australian College of Physicians (RACP), *Newborn Screening*, Alexandra, March 2004, <http://www.hgsa.com.au/Word/HGSApolicyStatementNewbornScreening0204-18.03.04.doc> (date accessed : June 23, 2004).

Newborn blood-spot screening is a public health activity aimed at the early identification of infants who are affected by certain congenital disorders. Timely intervention in these disorders significantly reduces morbidity, mortality and associated disabilities. Newborn screening is an accepted part of neonatal health care in all developed countries and has been established in Australasia since the late 1960's.

All Australasian screening programs are voluntary and fully publicly funded. Newborn screening services for Australia are coordinated from the five centralised screening laboratories. There is a single laboratory service for New Zealand. Recommended screening policy for the programs is developed by a joint subcommittee of the Human Genetics Society of Australasia and the Division of Paediatrics of the Royal Australasian College of Physicians. The disorders to be included and other program policies are decided within each jurisdiction

Canadian Biotechnology Advisory Committee (CBAC), *Biotechnology and Health Innovation : Opportunities and Challenges*, Ottawa, March 2004, [http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/BHI_Discussion%20Paper_13May04_Final_English.pdf/\\$FILE/BHI_Discussion%20Paper_13May04_Final_English.pdf](http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/BHI_Discussion%20Paper_13May04_Final_English.pdf/$FILE/BHI_Discussion%20Paper_13May04_Final_English.pdf) (date accessed : June 30, 2004).

The discussion document *Biotechnology and Health Innovation: Opportunities and Challenges* has been prepared by the Canadian Biotechnology Advisory Committee (CBAC) as the first phase of a two-phase project on the role of biotechnology in health innovation (the BHI Project).

- The document is limited to identifying the opportunities and challenges that advances in biotechnology present with respect to health and health care. An analysis and discussion of public policy options and recommended actions for realizing the opportunities and responding to the challenges forms the second phase of the BHI Project, which we expect to complete in the next few months.
- The focus of the document is on the specific role of biotechnology-based health innovations and is not intended to deal with opportunities and challenges associated with other kinds of health innovation.

Canadian Biotechnology Advisory Committee (CBAC), *Genetic Research and Privacy*, Ottawa, 2004, <http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00436e.html> (date accessed : June 30, 2004).

The federal government and most of the provinces and territories have both privacy and human rights legislation. The federal laws generally apply only to federal employees and those industries that are federally regulated such as airlines and banking. Consequently, the privacy and human rights legislation affecting most Canadians lies within the jurisdictions of the provinces and territories.

While generally similar, the specific privacy and human rights protections available to Canadians vary from one province or territory to another. The federal government may be best placed to facilitate the development of a consistent approach to resolving the privacy and confidentiality issues that will enable all Canadians, no matter where they live, to benefit equally from new advances.

The following recommendations are CBAC's view of what will be required to achieve the balance between access to genetic information for research to improve the health of Canadians and respect of the right of Canadians to dignity, privacy and confidentiality. Although many of the recommendations are not within the direct fiat of the federal government, the Government of Canada can play a significant leadership role in encouraging their achievement.[...]

American Medical Association (Council on Ethical and Judicial Affairs), *Cloning for Biomedical Research (E-2.146)*, Chicago, December 2003, http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_1203e.pdf (date accessed : June 30, 2004).

At the 2003 Annual Meeting, the AMA House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs (CEJA) Report 7 – A-03, "Cloning-for-Biomedical- Research." The report offers guidelines for physicians who wish to pursue research on the potential benefits of stem cells derived from cloned human embryos resulting from somatic cell nuclear transfer (SCNT) technology. The Council issues this Opinion, which is based on CEJA Report 7 – A-03. [...]

Stem cells derived from cloned human embryos resulting from somatic cell nuclear transfer technology are promising as a potential source of treatment in a wide range of diseases. However, much controversy arises from the necessity to destroy embryos in order to extract their stem cells for use in biomedical research. The conflict centers on the moral status of embryos, a question that divides ethical opinion and that cannot be resolved by medical science. [...]

American Medical Association (Council on Ethical and Judicial Affairs), *Disclosure of Familial Risk in Genetic Testing*, Chicago, December 2003, http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_1203j.pdf (date accessed : June 30, 2004).

At the 2002 Annual Meeting, the AMA House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 2 – A-02, "Disclosure of Familial Risk in Genetic Testing" (see Policy H-140.899, AMA Policy Database).

However, in response to concerns that were raised, the Council carefully reconsidered the standard of disclosure that should apply to familial risk in genetic testing. At the 2003 Annual Meeting, the AMA House of Delegates adopted the recommendations of CEJA Report 9 – A-03, "Disclosure of Familial Risk in Genetic Testing," which amends H-140.899. The Council issues this Opinion, which is based on CEJA Report 9 – A-03. [...]

United Kingdom, Department of Health, *Operational Procedures for the Gene Therapy Advisory Committee in its Role as the National Ethics Committee for Gene Therapy Clinical Trials*, London, June 12, 2004, <http://www.advisorybodies.doh.gov.uk/genetics/gtac/sop12june2004.pdf> (date accessed : June 28, 2004).

This document gives guidance on the procedures that should be followed in the United Kingdom when proposals are made to conduct gene therapy research on human subjects.

It details the information that should be submitted in order to enable the Gene Therapy Advisory Committee (GTAC) to assess the acceptability of gene therapy research proposals.

It also sets out GTAC's practices and procedures to meet its obligations as the national research ethics committee for gene therapy clinical research, in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.

National Ethics Committee on Assisted Human Reproduction, *Guidelines for the Practice of Embryo Donation for Reproductive Purposes (consultation document)*, Wellington, May 2004, <http://www.newhealth.govt.nz/necahr/files/EmbryoDonation.pdf> (date accessed : June 28, 2004).

This discussion document and proposed guidelines are being distributed among fertility clinics, university departments, consumer groups, government agencies, and other organisations and individuals with an interest in embryo donation for reproductive purposes.

The discussion document is intended to give background information on embryo donation for reproductive purposes.



DRAFTS

German/Bundestag, Biopatentrichtlinie, Germany, March 11, 2004.

A law has been introduced in Germany's Bundestag, or lower house of parliament, that would make it easier for researchers and companies to obtain patents in the field of biotechnology and would bring Germany into compliance with the European Directive.

The bill which was given a first reading on March 11, 2004 in the Bundestag, was introduced by Chancellor Gerhard Schroeder's ruling coalition of the Social Democrat and Green Parties. It would grant commercial rights for gene sequences but allow scientists free use of those patented sequences for research purposes.

France/Gouvernement, *Projet de loi relatif à la bioéthique*, France, 8 juin 2004.

Le Sénat a adopté en deuxième lecture, après modifications, le projet de loi sur la bioéthique le 8 juin 2004. Celui-ci avait été préparé en 2001 et adopté en janvier 2002 par l'Assemblée Nationale; le Sénat a adopté en première lecture le 30 janvier 2003 les modifications souhaitées par le gouvernement sur ce texte. L'Assemblée Nationale l'a adopté en deuxième lecture, avec modifications, le 11 décembre 2003. Le Sénat a adopté ce projet en deuxième lecture, après modifications, le 8 juin 2004.

[Entre autres, le projet de loi :]

-autorise « *des recherches sur l'embryon et les cellules embryonnaires pour une période limitée à cinq ans lorsqu'elles sont susceptibles de permettre des progrès thérapeutiques majeurs et à condition de ne pouvoir être poursuivies par une méthode alternative d'efficacité comparable* » ;

- introduit une série de sanctions pénales visant à réprimer comme « crime contre l'espèce humaine » le clonage reproductif, puni de 30 ans de réclusion et à punir le clonage dit thérapeutique de 7 ans de réclusion au plus ;

- prévoit la création d'une Agence de la biomédecine qui devrait regrouper l'Établissement français des greffes, la Commission nationale de médecine et de biologie de la reproduction et du diagnostic prénatal et l'Agence de procréation de l'embryologie et de la génétique humaine ;

- permet l'extension des indications du diagnostic pré-implantatoire, permettant de sélectionner des embryons dont les caractéristiques permettraient, après la naissance, de soigner un frère aîné malade.

Panama/Government, *Que prohibe toda forma de clonacion humana y dicta otras disposiciones*, Panama, January 15, 2004.

Legislation that went even further, as it has prohibited not only the act of cloning (whether for reproductive, therapeutic or research purposes) but also criminalized the act of providing funds to finance those activities. The prohibition comprises funds from private and public sources, and is extended to investments and donations of funds directed to research, experiments and development on the prohibited activity.

United Kingdom Government, *Human Tissue Bill (modified version)*, London, June 29, 2004.

A bill to make provision with respect to activities involving human tissue; to make provision about the transfer of human remains from certain museum collections; and for connected purposes.

Be it enacted by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows[...]

Instituts de recherche en santé du Canada (IRSC), *Lignes directrices pour la protection de la vie privée et de la confidentialité dans la conception, la conduite et l'évaluation de la recherche en santé : pratiques exemplaires (consultation, version préliminaire)*, Ottawa, Avril 2004, http://www.cihr-irsc.gc.ca/f/about/draft_privacy_best_practice_guidelines_f.pdf (page consultée le : 6 juillet 2004).

Ces lignes directrices sur les pratiques exemplaires visent :

1. À guider les chercheurs en santé à travers le Canada en ce qui concerne les questions de protection de la vie privée, de confidentialité et de sécurité dans la conception et la conduite de la recherche en santé comprenant l'usage de renseignements personnels.
2. À outiller tous les comités d'éthique de la recherche et les établissements canadiens afin de leur permettre d'examiner et d'évaluer les aspects relatifs à la protection de la vie privée, à la confidentialité et à la sécurité dans la recherche en santé.
3. À favoriser l'adoption et l'application de pratiques exemplaires dans l'élaboration de lois et de politiques de protection de la vie privée, dans le but d'appuyer un cadre de politique plus cohérent et mieux harmonisé pour la protection de la vie privée dans la recherche en santé partout au Canada.[...]

Canadian Institutes of Health Research (CIHR), *Guidelines for Protecting Privacy and Confidentiality in the Design, Conduct and Evaluation of Health Research : best practices (consultation draft)*, Ottawa, April 2004, http://www.cihr-irsc.gc.ca/e/about/draft_privacy_best_practice_guidelines_e.pdf (date accessed : July 6, 2004).

These best practice guidelines are intended to:

1. Provide guidance for health researchers across Canada to address privacy, confidentiality and security concerns in the design and conduct of health research involving the use of personal information.
2. Provide a resource for Research Ethics Boards and institutions across Canada to use in reviewing and evaluating the privacy, confidentiality and security aspects of health research.
3. Promote the uptake and application of these best practice guidelines in the development of privacy laws or policy, toward the objective of supporting a more coherent and harmonized policy framework for protecting privacy in health research across Canada.[...]



The HumGen website will soon launch a "frequently asked questions" or FAQ section. It aims to provide accessible information on the ethical, legal and social implications of human genetics. In this issue of GenInfo, we present to you a sample of the questions that will be found in this section; the first, discusses the notion of informed consent in research involving human participants, and the second, the topic of population genetics.

Q How can the confidentiality of personal information and genetic data collected for research be protected ?

A Confidentiality is guaranteed both by applicable laws and also by the measures put in place by researchers. Among these measures, for example, it is possible to code or anonymise the information or biological samples (such as blood or tissue). It is also possible to establish procedures that control the access to and the circulation of personal information and genetic data.

Q What do you mean by "coding" a sample or data?

A A coded sample or data is identified by a specific code (for example a barcode), rather than by the name of the person who provided the sample (blood or tissue). It would become more difficult to identify a person from whom the sample was taken since the link between the two is protected by certain mechanisms.

Regulatory texts (such as the Tri-Council Policy Statement and other international texts) recommend that samples or personal and familial information should be coded in order to protect their confidentiality.

A coded sample is not anonymous, as it remains possible, in using the code, to identify or reveal the individual from whom the sample was taken.

Q What do you mean by "to anonymise" a sample or data?

A To anonymise a sample or data means to destroy the link that exists between the sample (blood or tissue) and the personal data (such as name or address) of the person from whom it was taken. It would become, therefore, highly unlikely to identify the person from which the sample originated. Imparting anonymity to samples is one way to protect their confidentiality. Anonymisation renders return of results to participants impossible.



Your Feedback

As we believe that information exchange is a two-way process, we would appreciate some feedback concerning your thoughts on this new format for the GenInfo Newsletter. The following is a brief survey; your input through this questionnaire 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. With the information that has appeared in GenInfo, have you taken any of the following measures after reading it? (Check all that apply)

You have :

Other

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



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