ANNUAL REPORT 2014

McGill

CGP Centre of Genomics and Policy
Centre de génomique et politiques

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A Message from the Director

Dear Readers,

This year's Annual Report showcases the work of the CGP, its people, and values. In addition, we have highlighted our invited scholars, who have helped make this year exciting and fruitful.

The CGP has had some cause to celebrate this year with the promotion of our Research Director, Yann Joly to Associate Professor in the Department of Human Genetics, McGill University, the recognition of our Academic Coordinator, Ma'n Zawati as "Lawyer of the Year" by the Young Bar Association of Montreal, and last but not least, the induction of myself, its Director, into the Academy of Great Montrealers.

This year's Annual Report emphasizes the CGP's innovative research program and the dedicated research and support staff. The Report details completed and ongoing research projects, profiles of visiting scholars, course offerings and the team's publications. Through these features and our user-friendly format, we hope our work is accessible to the lay reader and relevant to researchers, professionals, policy-makers, and students.

We trust you will enjoy getting to know the CGP, its people, and our work.

Bartha Maria Knoppers
Director
Centre of Genomics and Policy

About the Centre of Genomics and Policy

Located within the Genome Quebec Innovation Centre at McGill University, the CGP works at the crossroads of law, medicine, and public policy. Applying a multidisciplinary perspective and collaborating with national and international partners, the CGP analyzes the socio-ethical and legal norms influencing the promotion, prevention and protection of human health.

Currently, the CGP's research covers six areas of genomics and policy: stem cell research and therapies, paediatrics, privacy, cancer, intellectual property, and biobanks (population genetics). These domains are approached using three guiding foundations: internationalization, policy development and knowledge transfer. First, the CGP promotes internationalization by undertaking comparative analyses of policies and guidelines around the world. Second, the CGP actively participates in the creation of international consortia thereby promoting multidisciplinary policymaking. Finally, via the HumGen law and policy database, the CGP encourages knowledge transfer.

Don't forget to follow us on Twitter @GenomicsPolicy

Centre of Genomics and Policy

CGP TEAM 2014

PROFESSOR
KNOPPERS Bartha Maria - **Director**

ASSOCIATE PROFESSOR
JOLY Yann - **Research Director**

EXECUTIVE DIRECTOR
PALMOUR Nicole

ACADEMIC COORDINATOR
ZAWATI Ma'n H.

ACADEMIC ASSOCIATES
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DYKE Stephanie O.M.
ISASI Rosario
LÉVESQUE Emmanuelle
MILIUS Djims
NGUENG-FEZE Ida
NGUYEN Thu Minh
SÉNÉCAL Karine
TASSÉ Anne Marie

ASSOCIATE MEMBERS
GOLD Richard
KIMMELMAN Jonathan

SCIENTIFIC CONSULTANT
LABERGE Claude

ELSI PAEDIATRIC CONSULTANT
AVARD Denise

INVITED SCHOLARS
BORRY Pascal
MESLIN Eric
SECKO David
STODDART Jennifer

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BESSO Annyck
BIRKO Stanislav
CHARLEBOIS Kathleen
COHEN Eliza
CRIMI Laura
DALPÉ Gratien
DUPUIS Marie-Andrée
ESQUIVEL SADA Daphne
GAGNON Johannie
GRANADOS MORENO Palmira
HAGAN Julie
HÉTU Martin
MALLETTE Ariane
OSIEN Gladys
PACK Amy
PELLEGRINO Chelsea
PHILLIPS Mark
RAHIMZADEH Vaso
SALMAN Shahad
SAULNIER Katie
SHUANG Shuang
THOROGOOD Adrian
VARDATSIKOS George

Ph.D. STUDENTS
BERTIER Gabrielle
SO Derek

COMMUNICATIONS
OLVERA Elena

ADMINISTRATORS
HOZYAN Rose-Marie
ROSSI Marisa
THORSEN Nadine

INTERNS
KLEIDERMAN Erika
NYCUM Gillian

Invited Scholars

Pascal Borry

Centre for Biomedical Ethics and Law,
Department of Public Health and Primary Care

KU Leuven (Belgium)

Pascal Borry is Assistant Professor of Bioethics at the Centre for Biomedical Ethics and Law (University of KU Leuven, Belgium).

His teaching is focused on fundamental and applied research in bioethics while his research activities are concentrated on the ethical, legal and social implications of genetics and genomics. Pascal Borry is involved in various national and international research projects including such projects as GENEBANC (Genetic bio and dataBanking: Confidentiality and protection of data. Towards a European harmonisation and policy), ENGAGE (European network of genomic and genetic epidemiology), EUROGENTEST, Public Health Genomics II, EUCellex (Cell-based regenerative medicine: new challenges for EU legislation and governance), PACITA (Parliaments and civil society in technology assessment), and the Marie Curie project on the Ethical, Legal and Social aspects of direct-to-consumer genetic testing.

He has published in more than 90 international peer reviewed journals on topics such as direct to consumer genetic testing, public health genomics, biobanking, research on human tissue, genetic testing, preconception screening and neonatal screening. He has also published on the relationship between empirical and normative approaches in bioethics.

In 2006, he received the 'Professor Roger Borghgraef' triennial prize for his research publications in biomedical ethics. He was a visiting scholar at the Case Western Reserve University, the Université de Montréal, McGill University, and the VU Medical Center, Amsterdam. His work with the CGP involved examining the implications associated with the eventual use of whole genome sequencing in paediatrics, direct-to-consumer (DTC) testing and neonatal screening.

Eric Meslin

Center for Bioethics

Indiana University (United States)

Eric Meslin is founding Director of the Indiana University Center for Bioethics which celebrated its 10th anniversary in 2011. He is also Associate Dean for Bioethics in the Indiana University School of Medicine, and is Professor of Medicine; of Medical & Molecular Genetics; of Public Health; of Bioethics and Law; and of Philosophy. In 2012, he was appointed as Indiana University's first endowed Professor of Bioethics.

Born in Canada, Dr. Meslin has a B.A. from York University (Toronto), and an M.A. and Ph.D. from Georgetown University. Prior to coming to Indiana, he was director of bioethics research in the ELSI program at the National Human Genome Research Institute (1996-98), and Executive Director of the U.S. National Bioethics Advisory Commission (1998-2001) appointed by President Bill Clinton. He has held academic positions at the University of Toronto (1988-96); as Visiting Fellow at Green College, University of Oxford (1994-95); and as Professor-at-Large at the University of Western Australia (2008-2010). In 2007, he was appointed Chevalier de L'Order Nationale du Mérite (Knight of the National Order of Merit) by the French Ambassador to the United States for contributions to French bioethics policy. During 2012-2013 he was on sabbatical leave as the Pierre de Fermat Chaire d'Excellence at the Université de Toulouse, Paul Sabatier III, France.

Dr. Meslin has more than 150 published articles and book chapters on various topics in bioethics and science, is a co-editor of the Cambridge University Press Bioethics and Law Series. While an invited scholar at the Centre of Genomics and Policy he was engaged with Dr. Knoppers in developing the concept of international ethics review equivalency or "Safe Harbour".

David M. Secko

Department of Journalism

Concordia University (Canada)

Dr. David Secko is an Associate Professor in the Department of Journalism at Concordia University (Montréal). His amazement at the speed at which an amoeba could crawl, led him to a Ph.D. (2004) from the University of British Columbia (UBC) that focused on the soil amoeba Dictyostelium discoideum. However, upon finishing his Ph.D., he started writing about science and completed a Masters of Journalism at UBC. Dave's journalism has been published in The Scientist magazine, Vancouver's Tyee, the New Scientist, Reader's Digest (Canada), Concordia Magazine and Canadian Medical Association Journal.

Dave also studies science journalism as a scholar and is the leader of the Concordia Science Journalism Project (www.csjp.ca). In Dave's research he experiments with the roles of the public, experts and journalists in the democratic governance of biotechnology. Examples of his recent articles include a qualitative metasynthesis of the experiences of science journalists (Science Communication 34, 2: 241-282) and the definition models of science journalism (Journalism Practice 7(1), 62-80). Dave won a University Research Award for his research contributions in 2011, the Dean's Award for excellence as a new scholar in 2010 and was awarded the Hal Straight Gold Medal in Journalism from UBC's School of Journalism in 2006. He is proud to have been a visiting scholar at the Centre of Genomics and Policy, McGill University (2013-14) exploring journalistic representations of genomic research.

Jennifer Stoddart

Centre of Genomics and Policy

McGill University (Canada)

Jennifer Stoddart was the sixth Privacy Commissioner of Canada.

Stoddart studied Quebec social history and received a Master of Arts in history from the Université du Québec à Montréal. In 1980 she received a licence in civil law from McGill University; she was admitted to the bar in 1981. She was awarded an honourary doctorate by the University of Ottawa in 2013 and is an advocate emeritus of the Quebec Bar.

On December 1, 2003, Stoddart was appointed Canada's Privacy Commissioner by the Governor in Council for a seven-year term. In December 2010, she was reappointed for a three-year term, which ended in December 2013.

In her role as commissioner she gave an annual report to Parliament about privacy trends and results of investigations, including privacy audits of government departments. Her 2013 report drew attention to privacy problems with the Canada Revenue Agency. She represented Canada at the annual International Conference on Privacy and Personal Data Protection. In 2008, she drew international headlines when she announced an investigation into the privacy policies of Facebook, which resulted in the social media site instituting privacy protections for its users.

Stoddart continues to explore her interests in personal data protection at the Centre of Genomics and Policy as an invited scholar.


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COMPLETED RESEARCH PROJECTS
• A Haplotype Map of the Human Genome-Biomedical Tool for Genetic Research in Canada
• A Prospective Study to Identify and Validate Biomarkers of Therapeutic Resistance in Colorectal Metastic Cancer (Q-CROC)
• A Research and Knowledge Network on Genetic Health Services and Policy: Building on the APOGEE-Net and CanGeneTest Experiences
• A Review of Approaches Considering Social, Ethical, and Legal Issues in Health Technology Assessment
• An Ethical and Legal Framework for The Canadian Breast Cancer Alliance "National Retrospective Tissue Microarray Resource for Breast Cancer"
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Completed Research Projects

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GABOURY Louis
KNOPPERS Bartha Maria
MULLER William
NEPVEU Alain
PARK Morag
SIEGEL Peter
URSINI-SIEGEL Josie

ACADEMIC ASSOCIATE
PALMOUR Nicole

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BESSO Annyck

Next Generation Predictive Signatures for Breast Cancer

Genome Quebec

January 2011 – January 2014

The project proposes to adapt a prognostic gene signature test to the Genome Quebec platform in order to develop and validate a "made in Quebec" clinical test for ER positive breast cancer patients. The ELSI portion of this project, for which the Centre of Genomics and Policy has primary responsibility, revolves around the barriers associated with the adoption of new technologies into clinical practice. A policy and literature review of the ethical, legal and knowledge translation research and a systematic review of health technology assessments and the ELSI (both explicit and implicit) purportedly raised by prognostic gene signature technologies was performed. A qualitative study of clinical care providers on the barriers for the use of genetic testing in their practice was completed. The work will culminate in a discussion paper on barriers to uptake of new genetic technologies, including educational and any other barriers that arise from the qualitative study.

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HÉTU Martin

Recherche sur les maladies rares : Vie privée « bon gré mal gré »?

Fonds de recherche du Québec-Santé / Réseau de médecine génétique appliquée du Québec

April 2013 – March 2014

Research on rare diseases raises special issues regarding privacy and confidentiality, notably due to the low number of people affected by each of these rare diseases such that indirect identification of participants often remains possible despite the usual measures of protection. Moreover, research on rare diseases requires concerted action and transnational (and even international) data sharing. This fact may exacerbate concerns related to the protection of privacy and confidentiality. The goal of this pilot-project is to examine whether the legal and ethical rules on protection of privacy and confidentiality can be a barrier to research on rare diseases and to provide, if needed, practical solutions to rectify the situation. This involves an analysis of provincial laws, and national and international policy and guidelines on the protection of privacy and confidentiality of human research participants, as well as a literature review. These analyses culminated in the production of a green paper, i.e., a prospective report containing a set of proposals to be discussed for the development of a policy. This green paper informed policymakers, researchers and REB on the specific issues of research on rare diseases and outline the strategic measures (legislative, normative or administrative) that could be implemented to not impede research in this area.

From the Lab to the Clinic: ELS Issues in Cancer Stem Cell Research

Cancer Stem Cell Consortium (CSCC)

May 2010 – April 2014

From the Lab to the Clinic: ELS Issues in Cancer Stem Cell Research is a project key to a larger Cancer Stem Cell Consortium (CSCC) funded initiative that aims to identify, characterize and develop methods of destroying leukemia stem cells (LSC).This latter research project involves three key phases of the innovation process: 1) the use of a large tissue bank (basic research); 2) the engagement of industry partners (commercialization); and 3) the development of valuable therapeutics (translation) for patients with intractable leukemia. The ELS initiative led by HeaLS Research Director Timothy Caulfield explores the ethical, legal, social and policy issues affiliated with each realm of research associated with the innovative process. The team will be investigating ELS challenges that characterize tissue banking and the commercialization process, in addition to those associated with the marketing of therapies. This latter component is being done through the lens of medical tourism.

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SCHIMMER Aaron
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SIPP Douglas
WANG Jean
WILLISON Donald
WOLF Susan

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BEAK Carla

Centre for Commercialization of Regenerative Medicine ("CCRM") Ethics and Policy Unit

Centres of Excellence for Commercialization and Research (CECR)

May 2012 - April 2014

CCRM is a Canadian, non-profit organization supporting the development of foundational technologies that accelerate the commercialization of stem cell and biomaterials-based products and therapies. CCRM is supported by the Centres of Excellence for Commercialization and Research (CECR) Program. The CCRM Ethics and Policy Unit is housed at the Center of Genomics and Policy, McGill University. The overall objective of the Ethics and Policy Unit is to provide gold standard policies on Socio-Ethical and Legal Issues (ELSI) related to commercialization for CCRM core activities as well as on communication strategies.

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The Terry Fox New Frontiers Program Project in Genomic Determinants of Childhood Leukemia

Canadian Institutes of Health Research (CIHR) / Terry Fox Foundation

June 2010 – June 2014

This project aims to examine whole-genome sequence variations from a sample of childhood acute lymphoblastic leukemia (ALL) patients with the following aims: 1) to identify novel sequence and structural variants in childhood ALL genomes; 2) to explore changes in gene expression associated with ALL by examining the transcriptome and allelic expression; 3) to assess the impact of selected genes on disease susceptibility and disease outcomes and investigate the functional significance of these genes in vitro; and 4) to translate the genetic discoveries into appropriate health care policy and services. These findings will ultimately lead to the development of powerful research and clinical tools that could improve detection, diagnosis and treatment of childhood leukemia.

The CGP aims to identify ethical, legal, and social issues (ELSI) in the return of paediatric research results. More specifically, our Centre is reviewing the ELSI implications of Genome-wide re-sequencing results on children and parents. This involves an analysis of international and national policy statements, the obligations and needs of researchers and health professionals regarding the return of research results, and the needs of families and their children. This analysis culminated in the production of a comprehensive discussion document. The development of the discussion document also involved literature and policy review, interviews with healthcare providers and families, and collaboration with various stakeholders.

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HILL Janet
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BIRKO Stanislav

Applied Metagenomics of the Watershed Microbiome

Genome British Columbia / Genome Canada

July 2011 – June 2014

Water quality is primarily assessed at the tap using coliform bacterial species as indicators of microbial pollution, a paradigm which reflects an anthropocentric focus on drinking water and human health. Metagenomics is a "culture-independent" method for analysis of multiple microbial genomes, for example, in drinking water. Importantly, water safety and genomics together create a highly volatile postgenomics innovation trajectory for metagenomics applications in public health and ecosystem health.

This study comprises three stages. First, we will identify the metagenomics stakeholders for water safety in consultation with the water and metagenomics experts and through metagenomics and water safety document analyses and interviews. Second, the issues associated with a new watershed test that may impact each stakeholder group will be identified through complementary social science methodologies including document analyses, literature reviews, surveys, focus groups, and interviews. Third, we will hold a multi-stakeholder workshop to present, negotiate, and validate the identified social, legal, ethical and policy issues in the form of a "points-to-consider" document to inform prospective policy.

Design and Evaluation of Electronic Consent and Governance Processes for Clinical Research

Canadian Institutes of Health Research (CIHR)

February 2011 – July 2014

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The objective of this study is to create Canadian recommendations and other resources for electronic consent for future research use of data and biological materials. Informed consent crystallizes the primary duty to inform and protect research participants. Providing consent is based on the right of research participants to exercise full autonomy in decisions affecting their health and personal privacy. As technologies in medical research improve and research questions become increasingly complex, there is a need to recruit new participants as well as use previously-collected data and biological materials to increase statistical power and minimize the burden on research populations. This application addresses the need for guidance in the use of research data and biological materials to answer questions that were not planned or known at the time of collection.

This guidance will provide recommendations for the use of data and biological materials that have already been collected and provide recommendations and a model electronic consent process for data and biological materials that will be collected in the future.

Specifically we will: 1) evaluate the feasibility of creating a digital governance system in Canada by identifying the legal and ethical issues relating to the use of an electronic approach to consent for future research use of data and biological materials; and 2) draft an Electronic Consent Technical Report with actionable recommendations, and validate it with pertinent stakeholders (ethics boards, patient organizations, etc.).

The Cartography of Intestinal Microbial Communities in a NHP Model System

Genome Quebec

June 2010 – September 2014

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RESEARCH ASSISTANT
VARDATSIKOS George

The scientific objectives of this project are to evaluate in a nonhuman primate (NHP; vervet monkey) model differences in the microbiome of the gastro-intestinal tract at different locations, determine whether stool is a relevant material for microbiome studies, and assess how age, sex, genetics and diet influence the diversity of the microbiome at points along the gastrointestinal tract. Microbiome based therapies, namely fecal transplantation (FT) therapeutics, are thought to hold great potential for treatment of a number of disorders. However, potential FT based therapeutics raise GE^{3}LS issues that are unique to microbiome research and implementation. The project aims to investigate the regulatory hurdles of FT based therapies, namely: 1) How would FT based therapeutics, as they are currently prepared and administered, be treated under Canadian and International legislative and regulatory regimes? 2) What are the legislative, regulatory, and local administrative hurdles that both current and anticipated FT based therapeutics face in Canada and Internationally?

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Towards Systems Medicine for Fatty Liver Disease

Fonds de recherche du Québec-Santé

April 2012 – September 2014

This project focuses on three questions relating to a disease-specific biobank:
1) Given its current ethical framework, can the liver biobank re-contact research participants for updates to enrich the quality of the bank? If so, what measures will need to be taken to meet Canadian and international ethical standards?
2) How can a policy to return incidental findings be developed that takes advantage of a double-coding system of privacy protection but is streamlined and efficient?
3) What is the scientific, ethical, legal, and policy framework applicable to the return of results in the context of a personalized medicine biobank project?

PRINCIPAL INVESTIGATOR
JOLY Yann

ACADEMIC ASSOCIATE
NGUENG-FEZE Ida

L'encadrement juridique des tests d'ADN dans le contexte du processus de parrainage des membres de la famille des immigrants Canadiens

Fondation du Barreau du Québec

January 2014 – December 2014

In Canada, Citizenship and Immigration Canada (CIC) representatives increasingly resort to DNA testing to confirm biological filiations in the realm of immigration sponsorship, specifically concerning immigrants originating from Africa, Asia, and the Caribbean. This project proposes a Canadian-specific analysis to: 1) determine the legal and ethical issues arising from the use of DNA testing in the context of immigration sponsorship in Canada; and 2) propose a legislative and political reform in response to this emerging problematic.


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CURRENT RESEARCH PROJECTS
• Biobank Standardisation and Harmonisation for Research Excellence in the European Union (BioSHaRE-EU)
• Framework for decision-making for rare diseases
• From Banking to International Governance: Fostering Innovation in Stem Cell
• Integrative Epigenomic Data Coordination Centre (EDCC) at McGill
McGill
CGP
Centre of Genomics and Policy

Current Research Projects

Current Research Projects

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FOULKES William David
FRIEDMAN Jan M.
GAUDET Daniel
GIGUÈRE Yves
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KNOPPERS Bartha Maria
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LABERGE Claude
LABREQUE Michel
LAFLAMME Nathalie
LAMOTHE Lise
LANDRY Réjean
LEDUC Nicole
LEGARE France
MARRA Carlo A.
MATHHIJS Gert
MITCHELL Grant A.
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A Research and Knowledge Network on Genetic Health Services and Policy: Building on the APOGEE-Net and CanGeneTest Experiences

Canadian Institutes of Health Research (CIHR)
November 2008 – March 2015

Consent has long been considered as the crystallization of the researcher's duty to inform research participants. Indeed, providing consent is based on the right of participants to exercise full autonomy in decisions affecting their personal privacy. That being said, as the number of participants recruited in large-scale longitudinal studies grows, obtaining and maintaining consents will become increasingly onerous and complex. Hence, research studies are gradually using interactive, electronic media for consent procedures which are seen as more accurate, dynamic, and cost-effective. It is unclear, however, how and under what conditions such an approach will satisfy the legal and ethical requirements related to consent. Outcomes from this research will interest various stakeholders, including clinical researchers, health policy advisors, lawyers as well as technology and computer specialists. It will promote the research-to-practice transition and provide preliminary data and guidelines for the legal and ethical design, implementation, and approval of projects using e-consent procedures. More generally, the future use of e-consent will likely require that decision-makers provide guidelines and rules specifically addressing the role of new technologies in this field, thereby impacting the research, ethical, and legal fields.

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ELSI STANDING COMMITTEE CHAIR
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Canadian Partnership for Tomorrow Project (CPTP)

Canadian Partnership Against Cancer
April 2009 – March 2015

The Canadian Partnership for Tomorrow Project (CPTP) enrols 300,000 Canadians between the ages of 35 and 69 years, who agree to be followed for their adult lifetime, to explore how genetics, environment, lifestyle, and behavior interact and contribute to the development of cancer and other chronic diseases. This pan-Canadian Project has five participating Cohorts (Atlantic PATH, CARTaGENE, Ontario Health Study, Alberta Tomorrow Project, BC Generations Project).

Hosted at the Public Population Project in Genomics and Society (P^3G), the ELSI Standing Committee builds the ELSI infrastructure of the CPTP platform. The goals are to bring together ELSI experts from each cohort and develop relevant policies, documents, and procedures that are needed either by the CPTP or by a specific cohort and to ensure the conformity of the platform with legislation and ethics guidelines so as to prospectively guide the cohorts. The ELSI Standing Committee mandate is broad. It ranges from developing interoperable recruitment, access policies, and procedures to dealing with ethical issues surrounding consent, privacy, and data sharing, and proposing governance structures for the CPTP.

Réseau de médecine génétique appliquée (RMGA) Infrastructure

Fonds de Recherche du Québec-Santé

June 2010 – March 2015

The RMGA is a network of multi- and trans-disciplinary researchers. Its objective is to support and develop basic and applied human genetic research by creating, managing, and promoting scientific infrastructures and knowledge transfer through health services and interventions for the benefit of the Quebec population. The Network has close to 350 members representing the majority of human genetics researchers in Quebec. The RMGA includes a Legal and Socio-Ethical Issues Infrastructure at the CGP that considers issues arising from the research activities of the RMGA members and provides ELSI guidance on emerging issues.

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Translation Challenges, Science Policy and Stem Cell Research

Stem Cell Network

October 2011 – March 2015

Intellectual property (IP) is perceived as playing an important role in the commercialization process and the role of patents in particular has received a considerable amount of attention in the literature (Golden 2010). Our focus in this phase will be on the relationship between translation and commercialization pressure (including IP policies) and data access policies. We will investigate current restrictions to access, as reflected in (for example) international stem cell banking policies, including restrictions to future IP claims, and compare them with existing open access policies (e.g., UK Stem Cell Initiative and the CIRM iPS biobank). This work will include an analysis of whether certain commercialization policies, and concomitant IP approaches (such as restrictive patenting practices) do in fact conflict with emerging open access approaches and policies, as reflected, for example, in the UK Stem Cell Bank.

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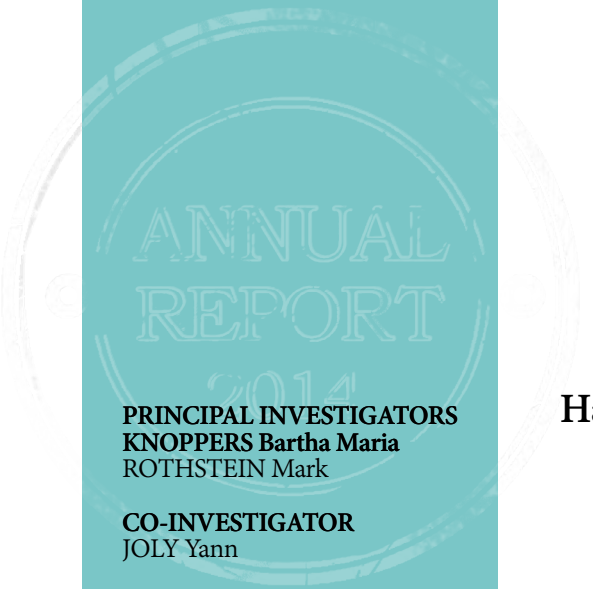
Protecting Privacy in Cloud-Based Genomics Research

Office of the Privacy Commissioner
April 2014 – March 2015

This project comprises three synergistic research objectives:
1) Identifying the existing environment and gaps in the Canadian legal and policy framework applicable to the use of cloud computing for genomic research;
2) Documenting and analyzing the policies currently used by several significant cloud providers to address privacy issues; and
3) Developing tools and strategic recommendations to assist Canadian policymakers fill the policy gaps and guide Canadian privacy professionals and genomics researchers in developing privacy-enabled cloud-based genomics research.



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Harmonizing Privacy Laws to Enable International Biobank Research

National Institutes of Health (NIH)
October 2014 – March 2015

This project aims to compare and analyze national and international privacy frameworks applicable to genomic databases and biobanks. A series of articles will be prepared on the privacy frameworks in place in a wide sample of countries and regions. Each article will survey the privacy instruments and legal and policy materials in place in a given jurisdiction, and will provide a legal analysis and critical evaluation of those instruments and materials. The general political and research contexts of the country or region will be introduced, and a description of its biobanking ecosystem will be provided. This will be followed by a comprehensive description of the legal and regulatory privacy framework applicable to genomic databases / biobanks in the country or region. Each article will conclude with a critical evaluation of the national privacy framework as it relates to genomic research privacy, security, and governance. The project will have an International Advisory Board (IAB) consisting of three internationally recognized scholars to provide oversight and guidance of the project throughout its development and advancement. The series of articles will be published in two dedicated special issues in the Journal of Law, Medicine & Ethics.

Quebec Training Network in Perinatal Research (QTNPR)

Canadian Institutes of Health Research (CIHR)
April 2009 – May 2015

The QTNPR network is creating a multidisciplinary curriculum on the impact of environmental exposures on maternal and child health. The objectives of QTNPR are to 1) provide trainees the knowledge, skills, and values that will allow them to address the complex interdisciplinary challenges of the current reproductive and perinatal health environment; 2) integrate into a single training network several research groups with complementary expertise in reproductive, perinatal, and infant health research; 3) link state-of-the-art, discipline specific teaching to crosscutting core competencies in the form of a transdisciplinary training grid; and 4) establish and maintain national and international partnerships with relevant complementary training programs.

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International Stem Cell Forum Ethics Working Party (EWP)

International Stem Cell Forum,
Medical Research Council (UK) / Canadian Institutes of Health Research (CIHR)
April 2012 – May 2015

Scientific collaboration is a key aspect of the globalization of research. It is essential for the feasibility of any international collaborative project such as the International Stem Cell Forum (ISCF). The ISCF is composed of twenty-one partners and research funding institutions from around the world. It faces the challenge of conflicting regulatory and policy approaches regarding the exchange of materials and data adopted by its various health ministries. The divergent policy frameworks and governing regulations affect the permissibility of conducting stem cell research, (i.e., procurement, derivation, banking, distribution and use of stem cell lines) affecting collaboration at the national and international levels.

The Ethics Working Party (EWP) initiative was set up on behalf of the International Stem Cell Forum by its Canadian member organization, the CIHR, and is now supported by the Canadian Stem Cell Network. The EWP is comprised of independent experts in the area, appointed by each of the Forum's member organizations. It is chaired by Dr. Bartha Maria Knoppers and its Secretariat is housed at the CGP in the Genome Quebec / McGill University Innovation Centre.

The primary purpose of the Ethics Working Party is to assist member countries to undertake stem cell research within a transparent and well-considered ethical framework. The EWP seeks to identify prospective strategies to foster the scientific and ethical integrity of research in a global context.

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International Cancer Genome Consortium / Data Access Compliance Office (DACO)

Ontario Institute for Cancer Research (OICR)

July 2009 – May 2015

The International Cancer Genome Consortium (ICGC) has been organized to launch and coordinate a large number of national cancer research projects that have the common aim of elucidating the genomic changes present in many forms of cancers that contribute to the burden of disease in people throughout the world.

Hosted at The Public Population Project in Genomics and Society (P³G), the DACO is responsible for the handling of requests for access to controlled data collected by the ICGC. It reports to both the Data Coordination Centre and the International Data Access Committee. Its objectives are to facilitate ethical, efficient, and responsible transfer of controlled data to members of the scientific community who agree to the Consortium terms and objectives.

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Biobank Standardisation and Harmonisation for Research Excellence in the European Union (BioSHaRE-EU)

The European Commission

December 2010 – June 2015

BioSHaRE-EU has assembled a consortium of leading international researchers from all domains of biobanking science. These experts are working to develop and apply methods and tools that will provide a foundation for an ambitious program of harmonization and standardization in European biobanks and major biomedical studies. This facilitates the full participation of European bioscience in the next phase of international aetiological research that demands access to studies that have 3 complementary characteristics: 1) participants must be comprehensively assessed not only for genotype, but also for phenotype; 2) measurement quality must be high; and 3) because no single study will provide adequate numbers of subjects for certain questions, biobanks must therefore be harmonized and standardized so that studies can pool biobank data in valid and effective ways. The CGP is involved in the development of ethical, legal, and social guidance in order to harmonize the treatment of environmental risk and personal life-style data in and from different European biobanks. The CGP also offers BioSHaRE its ethical expertise on issues of privacy and retrospective access to samples and data.

Reconciling Law and Ethics with Open Science in Biotechnology Research

Fonds de recherche du Québec-Santé
July 2011 – June 2015

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Do the current ethical and legal policies applicable to research with genomic databases sufficiently account for the new reality of open biotechnology? How could the current policy framework be improved to facilitate the transition to a more transparent, collaborative research context? Our research will investigate the impact of open biotechnology on research ethics and legal policies with a particular focus placed on informed consent (scope of consent, privacy, data ownership) to large open database projects. We will use a combination of quantitative and qualitative research strategies that will offer complementary applied legal and ethical data on the impact of open biotechnology on the governance of genomic research.

The use of a common research methodology in all streams of the project will facilitate comparisons and integration of our results. Our methods will include comparative legal and ethical research (policy review, legal research), questionnaire analysis, and focus group interviews. To validate our findings, we will engage stakeholders at the annual meetings of two major organizations involved in research with open databases: The Public Population Project in Genomics and Society (P^3G) and the International Cancer Genome Consortium (ICGC).

Access to Health Insurance in the Context of Personalized Medicine

Ministère des finances et de l'économie / Partenariat pour la médecine personalisée en cancer / Caprion Protéome Inc
November 2013 – January 2016

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The Personalized Medicine Partnership for Cancer (PMPC) projects, lead by Caprion Proteome, are expected to have a measurable impact on clinical diagnosis and therapeutic management of various cancers as well as on the efficiency and costs of the healthcare system by developing an integrated clinical platform to validate new biomarkers, develop new diagnostic tests as well as improved therapies. The CGP is leading the sub-project "Insurance and personalized medicine", which aims to account for the legislative, regulatory, and normative changes needed to maximize societal benefits related to the use of genetic data in clinical cancer research in Quebec. Our main objectives include: 1) analyzing the normative insurance framework in Quebec; 2) reviewing insurance proposition form requirements; and 3) analyzing consent forms (for diagnostic tests in clinical and research contexts).

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From Banking to International Governance: Fostering Innovation in Stem Cell Research

Stem Cell Network / Networks of Centres of Excellence (NCE)
October 2011 – March 2016

International initiatives are emerging to address harmonization and standardization processes for Stem Cell Research and banking (e.g. International Society for Stem Cell Research (ISSCR) and the International Stem Cell Banking Initiative (ISCBI)). Until recently however, these efforts adopted an 'embryo-centric' approach, leaving behind other timely and promising sources (e.g. induced pluripotent stem (iPS) cells, cells derived from placentas, etc.).
While certain socio-ethical and legal (ELSI) concerns are specific to the nature of Stem Cell Banks, can they thrive by applying the lessons learned in biobanking generally? To answer this, we will examine the current national and international SC banking landscape against the biobanking models for human tissues generally, with a view to evaluating existing governance, commercialization and regulatory frameworks and to proposing policy recommendations to increase the upstream understanding of the factors which encourage or hinder SC translation. We will develop "international governance models" and a "Points to Consider" thereby providing a wide range of stakeholders and receptors (e.g., researchers, SC bankers, policy-makers and the general public) with analyses, strategies, and solutions for moving towards translational SC research within Canada and on the global stage. Furthermore, we will build capacity by training and mentoring future ELSI researchers.

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Le séquençage du génome entier : un « bulletin » génétique pour chaque enfant?

Ministère de l'enseignement supérieur, de la recherche, de la science et de la technologie (MESRST)
January 2014 – September 2016

The project's main objective is to study the legal and ethical issues that arise from the use of Whole Genome Sequencing (WGS) in minors. Our results will contribute to: 1) developing two policies on the use of WGS in minors – one for the research setting and the other for the clinical setting; and 2) elaborating a prospective analysis detailing the implications associated to the eventual use of WGS in paediatrics within the realm of direct-to-consumer (DTC) testing and neonatal screening.

Cell-based Regenerative Medicine: New Challenges for EU Legislation and Governance (EUCelLex)

European Commission / INSERM

October 2013 – September 2016

The aim of this project is to collect and analyze facts and figures to assess the current legislation on the therapeutic use of somatic cells, and to bridge it with the research infrastructure capacity building. The project is based on a coherent consortium of experts in the fields of cell therapies, cell banks and translational biomedicine, having strong expertise in law and / or in governance issues to provide evidence about the contemporary practices around cells and design a picture of the "market" and its distribution between the public and private sector. The CGP's role in the project is to examine and enhance the understanding and interpretation of national, regional, and international legal and ethical issues surrounding umbilical cord blood (UCB) research and provide recommendations. This is a critical and logical step towards building a robust implementation process for the ethical and legal frameworks governing UCB research, banking and clinical applications in Europe, so as to harness its potential for novel therapeutic applications. The project will thus help the Commission in the regulatory choices covering the use of human cells for therapeutic purposes and to foster the innovation potential of related research activities.

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Framework for Decision-Making for Rare Diseases

Canadian Institutes of Health Research (CIHR)

February 2012 – March 2017

As our understanding of diseases and how to treat them evolves, so too must our decision-making procedures for providing fair and cost effective treatments for those living with an illness. Today, one area of policy and decision making in particular lags behind: that for treating rare diseases. At present there is no policy framework to help decision makers navigate the complex factors involved when making decisions about paying for orphan drugs. This project brings together a multidisciplinary team of experts in matters relating to treatment for rare diseases, and will incorporate input from the public and key stakeholders to develop such a framework. It will facilitate priority setting for orphan drug treatment decisions constrained by a limited budget that considers the relevant developmental, clinical, and economic factors and ethical principles, as well as being consistent with the values of society at large.

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Enhanced CARE for RARE Genetic Diseases in Canada

Genome Canada
April 2013 – March 2017

CARE for RARE is a collaborative pan-Canadian project configured to improve the diagnosis and treatment of rare diseases. Powerful new DNA sequencing methods such as whole-genome (WGS) and whole-exome sequencing (WES) will be used to discover 60 new genes, each of which causes a rare disease. The identification of new genes provides useful biological information, giving us insight into cellular pathways significant in human health. It is hoped that the research will lead to the implementation of WES as an effective and reliable diagnostic tool for clinical use.

However, in order to facilitate the integration of WES into the clinical setting, the GE^{3}LS component of this study, which will be conducted at the Centre of Genomics and Policy, will include: 1) the drafting of clinical exome trial consent forms; 2) a qualitative analysis of the clinical utility of WES as a diagnostic tool for patients with rare diseases (from the patients' and clinicians' point of view); 3) the drafting of a national position statement and best practices outlining professional and ethical standards for the reporting of incidental findings found using WES; and 4) the development of clinical integration tools for use by clinics offering exome sequencing to patients with rare diseases.

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Innovative Chemogenomic Tools to Improve Outcome in Acute Myeloid Leukemia

Genome Canada
April 2013 – March 2017

This project intends to implement two novel tests in the healthcare system: 1) a chemogenomic model for the development of a prognostic test in Acute Myeloid Leukemia (AML); and 2) an integrated detection kit for Minimal Residual Disease (MRD). Our first objective is to highlight the strengths and weaknesses of Canadian federal and provincial regulatory test approval models. To this end, we will undertake a comparative analysis of US and EU models. Our second objective is to develop recommendations based on an ethical and legal analysis of the duty to inform in the context of lab directors (i.e., whether these directors are under an obligation to inform treating physicians of clinically-valuable information resulting from AML research).

Personalized Risk Stratification for the Prevention and Early Detection of Breast Cancer

Quebec Breast Cancer Foundation, Genome Canada, Genome Quebec / Canadian Institutes of Health Research (CIHR) / Ministère de l'enseignement supérieur, de la recherche, de la science et de la technologie du Québec (MESRST)

April 2013 – March 2017

The project is designed to significantly extend the benefits of the current high-quality population screening program, particularly for younger women (35 to 49) by implementing a risk stratification approach targeting screening at an identifiable subset of women with relatively high risk of breast cancer (BC) who are missed by the current standard age-based screening program. This personalized risk-based approach to breast cancer screening will detect cancers at an earlier stage. Significant socio-economic and health benefits will be achieved since a woman's survival prospects will be increased and the burden of disease and costs of treatment will be reduced.

Knowledge of the genetic basis of BC and its risk factors will allow stratification of individuals into different risk groups for screening and personalized follow-up with appropriate preventive and clinical measures. However, a strategic approach is needed to facilitate the acceptance and adoption of risk-based stratification BC screening models in clinical settings, healthcare services and policies. At the end of our project we will deliver a web-based risk stratification and communication toolbox for use by health professionals and women to facilitate the implementation of a personalized risk-based approach in BC screening and management.

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Pistes de réformes législatives en matière de parrainage familial: un consensus à établir sur les tests d'ADN dans les dossiers d'immigration

Fonds de Recherche du Québec- Société et Culture

April 2013 – March 2017

In Canada, Citizenship and Immigration Canada (CIC) representatives increasingly resort to DNA testing to confirm biological filiations in the realm of immigration sponsorship possibly leading to genetic discrimination as documented in Canadian case law. In collaboration with the Canadian Council for Refugees and Immigration Canada, this project proposes a multidisciplinary analysis (qualitative research, systematic review, and consensus conference) to: 1) determine the social, cultural, and ethical issues associated with the use of DNA testing in the family sponsorship process; and 2) propose a legislative and political reform in response to this emerging problematic.

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The Canadian Alliance for Healthy Hearts and Minds

Canadian Partnership Against Cancer and Heart and Stroke Foundation

April 2013 – March 2017

The Canadian Alliance for Healthy Hearts and Minds is a project that aims to build on the Canadian Partnership for Tomorrow Project (CPTP), a pan-Canadian research platform, by expanding efforts to identify the early root causes that lead to chronic diseases of the brain, the heart and the cardiovascular system. To do so, the Alliance will gather detailed information from about 10,000 Canadian participants on their environments, lifestyle and behaviors that could affect their cardiovascular health. Participants will also be assessed by magnetic resonance imaging (MRI) of the brain, blood vessels, heart and liver. Adding this to the health and biological information assembled over many years within CPTP will allow researchers to explore how these factors contribute to the development of chronic disease leading to heart failure and dementia. In partnership with the Public Population Project in Genomics and Society (P^3G), the Centre of Genomics and Policy will support the project in its development of consent forms and policies.

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Risk Stratification for Prevention and Early Detection of Breast Cancer: Development and Implementation of Communication Tools

La fondation du cancer du sein du Québec

April 2013 – March 2017

The goal of this project is to develop an integrated information campaign that aims to sensitize the population to the importance of considering family history to fight effectively against breast cancer. The campaign also aims to better equip health professionals to evaluate the risk of breast cancer on the basis of family history. This campaign will be realized through a rigorous process that will partner diverse professional and community associations.

Information and sensitization tools will be developed and compiled into information toolkits. These toolkits will respond to three needs: to effectively collect, use, and share information on family history of breast cancer. The tools will allow users, for example, to answer the following questions: From whom should I obtain information? What kind of medical information do I need? How can I obtain this information from my family? With whom should I share the information I gather on breast cancer risk?

The team includes experts in genetics, epidemiology, public health, psychosocial evaluation, ethics, and public law (CGP).

Sino-Québec Perinatal Initiative in Research and Information Technology (SPIRIT)

Ministère de l'Enseignement supérieur, de la recherche, de la science et de la technologie (MESRST)

April 2014 – March 2017

The Sino-Québec Perinatal Initiative in Research and Information Technology (SPIRIT) was created to fulfill three main objectives: 1) Promote collaboration in epidemiological and fundamental research concerning the intra-uterine determinants of health and child development as well as research on perinatology health services in Shanghai and in Quebec; 2) Reinforce strategic positioning of our academic and industrial partners in Quebec, China, and internationally by accentuating access to new markets/expertise and by developing harmonized products adapted to perinatal research; and 3) Consolidate infrastructures allowing transfer and application of knowledge among users and partners, ultimately reinforcing China-Quebec collaborations.

By doing so, SPIRIT will set forth updated guidelines, health policies, and transfer activities in the clinical setting.

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Regenerative Cell Therapy Network (RCTN)

Networks of Centres of Excellence (NCE)

May 2014 – April 2017

The goal of the Regenerative Cell Therapy Network (RCTN) will be to standardize RCT by sharing the data generated at each participating center, by accelerating the implementation of novel cell therapy applications, and by reducing operational costs, consequently enabling more rapid technological advances. The RCTN will also promote the implementation of innovative cell therapy approaches in patients by disseminating knowledge to: 1) clinical centers with the expertise to identify suitable patients and administer the cells; 2) industrial partners to further develop and commercialize cell therapy strategies; and 3) patients to discuss treatment opportunities and implications. The RCTN will enable Canadian investigators to share information and engage with scientific collaborators, cell therapy organizations, and regulatory bodies from around the globe. Through RCTN's unique collaborative approach with non-profit organizations, the knowledge capacity and access of patients to cutting-edge care will be enhanced.

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Integrative Epigenomic Data Coordination Centre (EDCC) at McGill

Canadian Institutes of Health Research (CIHR)
January 2012 – December 2017

This project proposes an integrative Epigenomic Data Coordination Centre (EDCC) at McGill, which will be a national hub to support data collection, processing, storage, and dissemination for projects funded under the CEEHRC initiative and facilitate integration with the IHEC.
The outcome will include data pipelines and tools using standardized formats and vocabularies for verification, validation, and analyses across the CEEHRC network. The EDCC McGill will also develop a framework that leverages Compute Canada national resources to support large scale processing, sharing, and visualization of epigenomics data. The platform will enable epigenetic researchers on a national level to query and exploit this valuable resource.

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Multidimensional Epigenomics Mapping Centre (EMC) at McGill

Canadian Institutes of Health Research (CIHR)
January 2012 – December 2017

To join global efforts (The International Human Epigenome Consortium), we will establish an Epigenome Mapping Centre (EMC) at McGill University that builds upon a high-throughput sequencing infrastructure with a critical mass of expertise and technology available to contribute significantly in deciphering the functional code of the human genome. Our work is internationally coordinated and will support research initiatives across the Canadian research community. We apply epigenome mapping to understand interactions between environment and genome in human blood cells, to interpret diseases impacting metabolism using tissue samples and to study how epigenetic changes can alter function of the brain. EMC McGill is a national hub housing a critical mass of epigenomics expertise supported by state-of-the-art genomics infrastructure. Our integrated operation also includes a legal and ethics component.
It will contribute to Canadian leadership in epigenome research in biomedicine.

Réseau en soins de santé personnalisés-Q-CROC

Fonds de partenariat pour un Québec innovant et en santé (FPQIS)

April 2009 – March 2018

This project aims to broaden and deepen the existing Q-CROC Network which has developed internationally recognized expertise in designing and executing biopsy-driven studies to identify biomarkers in metastatic cancers. Moreover, it will use a program in which all new cancer patients are asked to consent to having their primary tumor biobanked and profiled, to having their entire clinical course anonymously recorded, and to being re-contacted for additional studies. Consistent with its prospective population-based approach, the new trans-national global network will help generate the large scale of profiled patient numbers and build an enormous biological and clinically annotated database.

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ThéCell (Réseau de thérapie cellulaire et tissulaire) : enjeux socio-éthiques et juridiques des thérapies cellulaires et tissulaires

Fonds de recherche du Québec-Santé (FRQS)

April 2009 – March 2018

Created in 2009, the Cell and Tissue Therapy Network (ThéCell) brings together some 50 researchers in order to facilitate Phase 1 and 2 clinical studies aimed at making advanced cell therapy publicly accessible by enhancing and developing technological platforms established through Québec universities and their partners. ThéCell is a lever and catalyst in mobilizing and coordinating use of and access to infrastructure and highly qualified personnel in the field of cell and tissue therapy. As the Socio-Ethical and Legal Platform, our role is to provide ad hoc consultation to researchers and clinicians on ethical and regulatory issues related to cell and tissue therapies. We provide assistance with drafting consent forms and research protocols for research ethics approval and Health Canada clinical trial applications.

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Optimisation des approches thérapeutiques en soins personnalisés de première ligne (OPTI-THERA)

Ministère des Finances, de l'Économie et de la Recherche (MFER)

April 2014 – March 2018

The OPTI-THERA project will implement Optimized Therapeutic drug responses and Optimized Theranostics strategies through the creation of a Knowledge and Information Integrating Node (KIIN). The Centre of Genomics and Policy will conduct research concerning: 1) the legal aspects surrounding insurance and the use of genetic information; 2) the role of a trusted third party; 3) the conflict of interest issues in public-private partnerships for personalized medicine. Collaborating closely on this project, the Population Projects in Genomics and Society (P^3G) will: 1) review and amend of the project's consent forms; 2) provide ongoing ethics support (i.e., ethics approval); and 3) develop policies and procedures (re. clinical assessment and gate keeping functions).

PRINCIPAL INVESTIGATOR
STEIN Lincoln

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SHAH Sohrab
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DOVE Edward S.
PALMOUR Nicole

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CHARLEBOIS Kathleen
PHILLIPS Mark

The Cancer Genome Collaboratory

Natural Sciences and Engineering Research Council of Canada (NSERC)

April 2014- March 2018

This project will greatly accelerate research for effective cancer treatments by making available to the world research community an unprecedented collection of more than 25,000 cancer genomes. The project will store the data in a powerful cloud computing environment in which researchers will be able to search for common patterns in cancer genomes that are associated with tumor biology and translate this information into new diagnostic tests, prognostic tools, and therapies. From the perspective of law, ethics, and the protection of personal health information, this project has four major deliverables: 1) A comprehensive review of current ELSI practices in Genomic Cloud Computing; 2) An International Code of Conduct for Genomic Cloud Computing; 3) Harmonized templates for consent / confidentiality / access for Genomic Cloud Computing; and 4) Software protocols that will allow researchers to perform secure computations across the controlled tier without risk of donor de-identification.

CE in Biomarker-Driven Clinical Research for Personalized Medicine in Cancer (Exactis)

Networks of Centres of Excellence (NCE)

April 2014- March 2019

The objective of the project is to create and expand a biomedical ecosystem that overcomes the major rate-limiting steps involved in realizing and expanding biomarker-driven clinical research for personalized medicine in cancer. This will be achieved through: 1) ready access to an enormous collection of engaged patients, their tumors, and clinical data collected in a prospective and longitudinal manner that conforms to the highest standards of ethics and quality; and 2) an advanced program in serial biopsies of metastatic tumors that defines the molecular signature of resistance to new targeted agents allowing the industry to modify the drug or add combinations to overcome or avoid resistance and greatly expand the clinical benefit to patients. The Centre of Genomics and Policy will provide a review of the ethical and legal issues while ensuring that: 1) the consent form respects the federal and provincial legal requirements (on re-use of samples, governance, confidentiality, data-sharing, e-consent, risks, etc.); and 2) is compliant with the various ethical policies and guidelines pertaining to storage of data and samples, (access, re-contact). Finally, we will analyze the legal liability of health professionals undertaking research.

PRINCIPAL INVESTIGATOR
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GELMON Karen
JOLY Yann
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OZA Amit
SAAD Fred

ACADEMIC ASSOCIATE
ZAWATI Ma'n H.

RESEARCH ASSISTANT
BERTLER Gabrielle

Courses

HGEN-660B - GENETICS, ETHICS AND LAW

Instructor: Prof. Yann Joly, PhD (DCL), Ad.E.

The objectives of this course are to: 1) introduce students to legal, ethical, and policy scholarship in genetics and related "omics" disciplines; 2) promote interdisciplinary collaboration and debate as a means of enriching scientific practices; 3) enable students to develop analytical research skills and to identify and critically evaluate the legal, ethical and policy issues that arise in genetic research and in clinical genetics.

The classes will be taught in seminar style, complemented by thematic class discussions and case studies. Themes covered in this course include, but are not limited to: genetic testing, genetic counseling, personalized medicine, privacy and confidentiality, population genetics, regenerative medicine, commercialization and intellectual property, genetic discrimination, and genetic analysis of social and behavioral traits. Through class lectures, case studies and discussions on a series of selected readings, students will be asked to reflect on the complex relationships between science, law, and ethics. Each member of the class will participate in and contribute to the learning that occurs. Such collaborative learning experience will be reflected in the way that the course is structured and the student's work is evaluated.

HGEN-674 -RESEARCH INTERNSHIP IN GENOMICS AND POLICY

Instructor: Me. Ma'n H. Zawati, LL.B., LL.M.

The objectives of this course are to: 1) introduce students to legal, ethical, and policy scholarship in genetics and related "omics" disciplines; 2) promote interdisciplinary collaboration and debate as a means of enriching scientific practices; 3) enable students to develop analytical research skills and to identify and critically evaluate the legal, ethical and policy issues that arise in genetic research and in clinical genetics.

The classes will be taught in seminar style, complemented by thematic class discussions and case studies. Themes covered in this course include, but are not limited to: genetic testing, genetic counseling, personalized medicine, privacy and confidentiality, population genetics, regenerative medicine, commercialization and intellectual property, genetic discrimination, and genetic analysis of social and behavioral traits. Through class lectures, case studies and discussions on a series of selected readings, students will be asked to reflect on the complex relationships between science, law, and ethics. Each member of the class will participate in and contribute to the learning that occurs. Such collaborative learning experience will be reflected in the way that the course is structured and the student's work is evaluated.

P³G International Policy interoperability and Data Access Clearinghouse (IPAC)

In the context of its Genomics and Policy Research Program, the Centre of Genomics and Policy (CGP) identified an absence of international mechanisms to support researchers in ensuring ethical and legal interoperability. In addition, the multiplicity and diversity of laws, standards and policies on sharing and accessing genetic and medical data represent major hurdles to international collaboration. To address this gap, a partnership formed by the CGP with the Population Project in Genomics and Society (P³G) launched the IPAC (International Policy interoperability and data Access Clearinghouse) in January 2014 (http://www.p3g.org/ipac). This resource aims to promote the interoperability of international norms and facilitates via it services the sharing of clinical and research data.

The IPAC offers a "one-stop" service for national and international collaborative research projects, and provides interoperability services to assist international researchers in meeting ethical and legal regulatory requirements governing genetic / genomic research in their home countries. IPAC services and tools include, but are not limited to: consent, access (data / samples), MTA's / DTA's, commercialization, IP, confidentiality / privacy, research ethics and governance, and services are implemented through the following three modules:

•Data Access Compliance Office (DACO) - The DACO services both international and national research projects. International: The DACO has processed over 200 data access requests and approved 132 projects—from both the public and private sectors around the world—for the Canadian-led, International Cancer Genome Consortium Canadian: In 2015, the Canadian Partnership for Tomorrow Project (CPTP) will open its controlled access database and the IPAC will run its DACO. (http://www.p3g.org/daco-review-data-and-samples-access-requestauthorization-and-compliance)

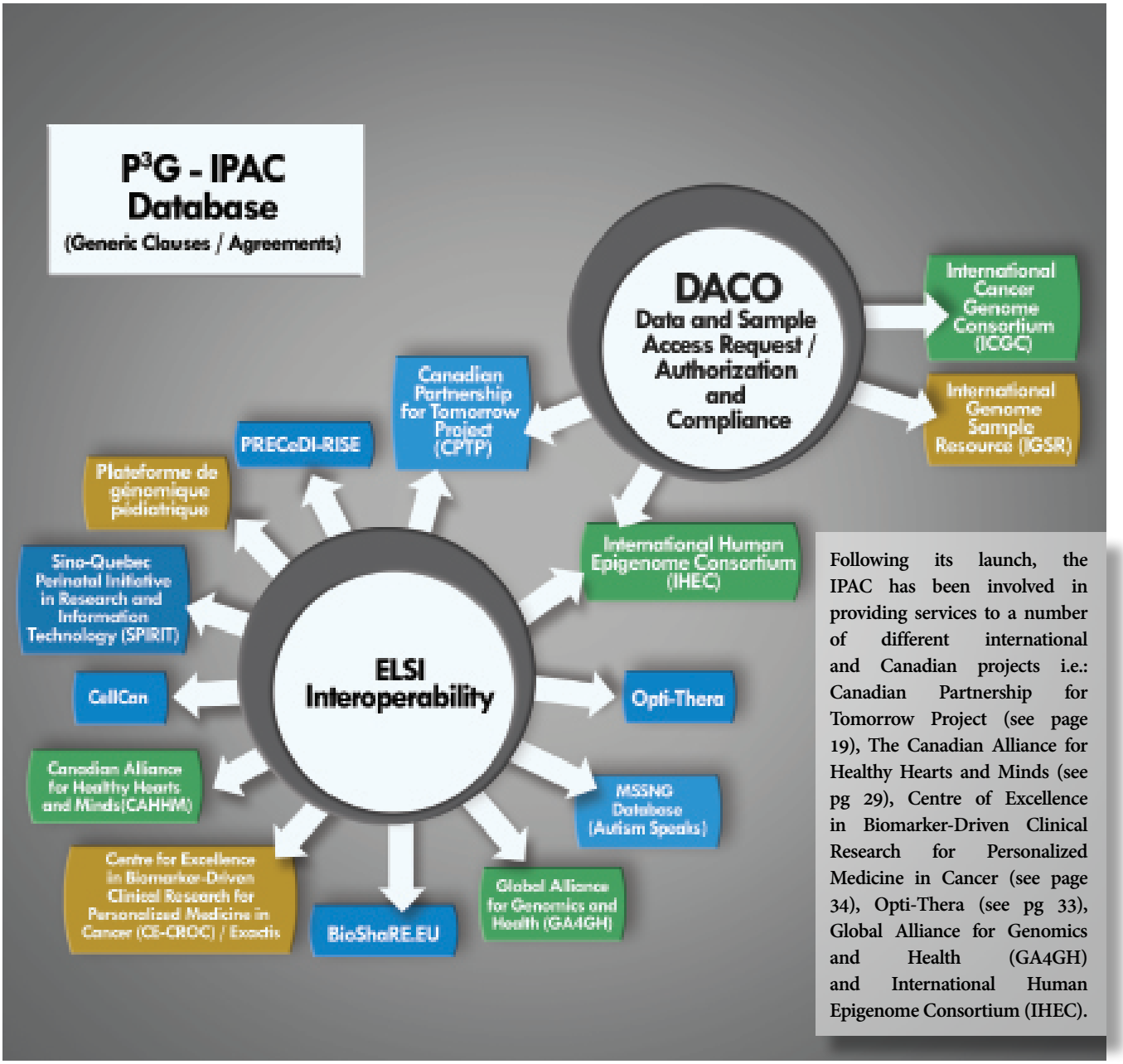
•ELSI Interoperability Screening - This service has created a wide range of customized tools (consent forms, data access policies, MTA's, etc.) for international and national research consortia and projects. In 2015, the IPAC foresees providing interoperability screening and access services / tools to the 1000 Genomes Project, the International Neuroblastoma Risk Group Database and the 10,000 Autism Genome Sequencing Project (http://www.p3g.org/datasample-collection-elsi-interoperability).

•Generic Clauses / Agreements Database – This tool is applicable to international and national projects. The Database offers approximately 180 generic clauses for 6 different types of GE³LS-related documents and was instrumental in the publication of the P³G Generic Access Agreement and its model form. It includes the Consent Tools provided to the Global Alliance for Genomics and Health (GA4GH) Framework for Responsible Sharing of Genomic and Health Related Data (http://www.p3g.org/resources/ipac).

International Advisory Board Members:
The International Advisory Board is a group of international experts involved in providing guidance on several aspects of IPAC activities, including consulting on queries if the P³G-IPAC receives a request requiring a country / region specific expertise.

Current members of the advisory board:

Hadi Abderrahim, Qatar
Ruth Chadwick, UK
Don Chalmers, Australia
Ellen Clayton, USA
Jantina de Vries, South Africa
Mats Hansson, Sweden
Nils Hoppe, Germany
Chingli Hu, China
Kazuto Kato, Japan
Jane Kaye, UK
Jean McEwen, USA
Pedro Rondot Radío, Argentina
Emmanuelle Sebbag, France
Sharon Terry, USA
Susan Wallace, UK
John Wilbanks, USA



Following its launch, the IPAC has been involved in providing services to a number of different international and Canadian projects i.e.: Canadian Partnership for Tomorrow Project (see page 19), The Canadian Alliance for Healthy Hearts and Minds (see pg 29), Centre of Excellence in Biomarker-Driven Clinical Research for Personalized Medicine in Cancer (see page 34), Opti-Thera (see pg 33), Global Alliance for Genomics and Health (GA4GH) and International Human Epigenome Consortium (IHEC).

Global Alliance for Genomics and Health (GA4GH) - The Global Alliance for Genomics and Health (GA4GH) is an international coalition, enabling the sharing of genomic and clinical data. The Regulatory and Ethics Working Group (REWG) of the GA4GH, is supported by IPAC in its policy work and organized and contributed to the Framework for Responsible Sharing of Genomic and Health Related Data, as well as providing 3 types of consent tools and data sharing tools. The first, on Legacy Consent and International Data Sharing, covers situations where researchers already have data collected using older "legacy" consents. The second, on Clauses for International Data Sharing addresses situations where researchers wish to add clauses on international data sharing to actual consents. The third, a Generic International Data Sharing Prospective Consent Form, provides a generic template for new, prospective studies.

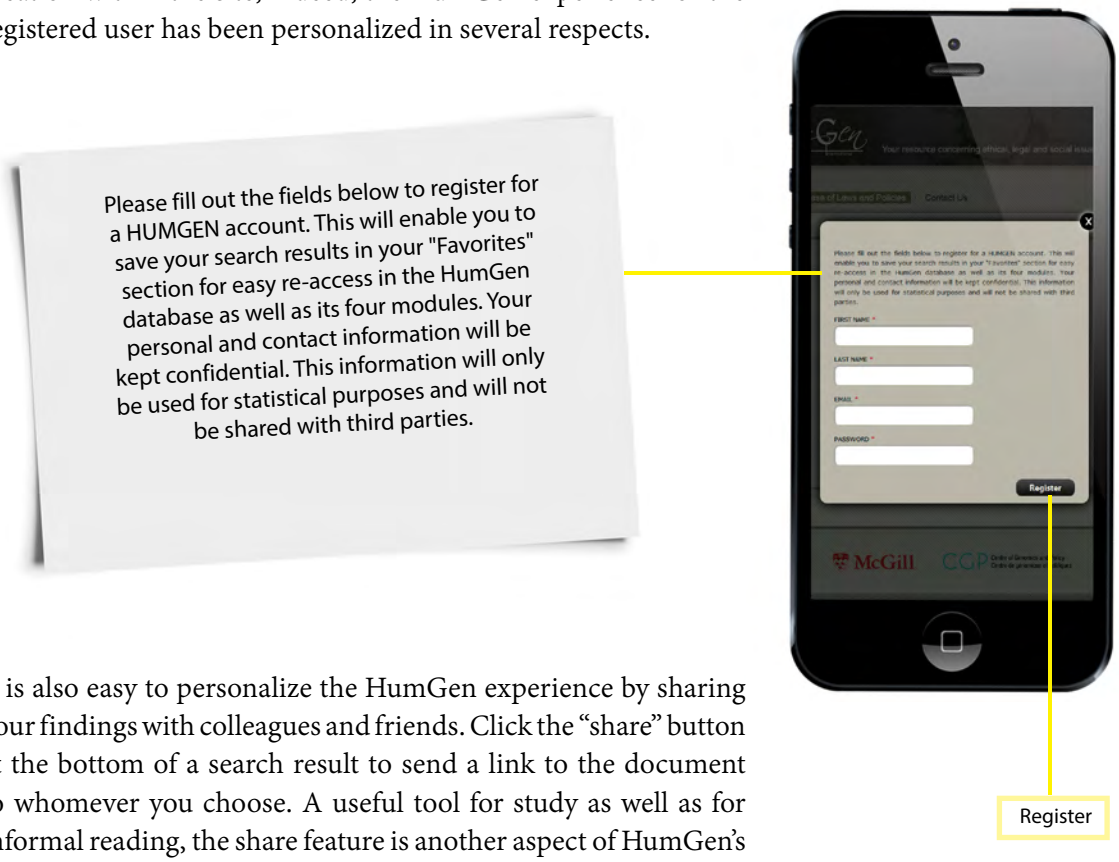
International Human Epigenome Consortium (IHEC) - The International Human Epigenome Consortium (IHEC) is a global consortium with the primary goal of providing free access to high-resolution reference human epigenome maps for normal and disease cell types to the research community. Participating projects improve epigenomic technologies, investigate epigenetic regulation in disease processes, and explore broader gene-environment interactions in human health. IHEC facilitates communication among the members and offers a forum for coordination, with the objective of avoiding redundant research efforts, implementing high data quality standards, and thus maximizing efficiency among the scientists working to understand, treat, and prevent diseases. The IPAC is involved in assisting the development of project consent forms; data sharing policies and guidelines; as well as setting up Data Access Compliance Office (DACO services).

HumGen – Database

In 2012, the Centre for Genomics and Policy optimized its HumGen international database search engine to promote online access to information on laws, policies, and guidelines in human genetics research. This year, the HumGen website has undergone a makeover to optimize searches through four modules in order to make it easier for users to conduct research into ethical, legal and social issues in human genetics, and to personalize the user's experience at the same time.

The newly-optimized search engine has been redesigned to facilitate access to normative documents (laws, policies and guidelines), and to word and phrase searches. Search results are displayed in four subsections of international, national, provincial, and regional documents, giving a sense of socio-geographical context to the findings. HumGen's new search functions make research easier to conduct, organize and follow international developments.

Registration is also open. It enables you, the user, to create and save a personalized favourites list. This function is useful for when you want to bookmark especially interesting results, or when you want to return to certain documents at a later date. The list is your creation within the site; indeed, the HumGen experience for the registered user has been personalized in several respects.



It is also easy to personalize the HumGen experience by sharing your findings with colleagues and friends. Click the "share" button at the bottom of a search result to send a link to the document to whomever you choose. A useful tool for study as well as for informal reading, the share feature is another aspect of HumGen's evolving role in ELSI research.

HumGen has been built to serve multiple audiences. The search engine is a streamlined research tool for researchers, professionals, policymakers, and students alike. We hope the new HumGen search engine will assist you in exploring the world of ethics in human genetics research.

Don't forget to follow us on Twitter @GenomicsPolicy.

Team Publications 2014

Book

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