ANNUAL REPORT 2015

McGill

CGP Centre of Genomics and Policy
Centre de génomique et politiques

Table of Contents

A Message from the Director

Dear Readers,

I am excited to share this year's Annual Report of the Centre of Genomics and Policy. We are pleased to showcase the work of our dedicated staff and to share their research interests with you. Once again, we have highlighted our Invited Scholars who have helped make this year exciting and fruitful.

The CGP has undergone some changes in December of this year with the departures of Rosario Isasi, after 13 years of dedicated stem cell research, and that of Dr. Nicole Palmour, our Executive Director. On behalf of the team, I would like to thank them both for their commitment and hard work. As of 2016, we are happy to announce that Ma'n H. Zawati will become the new Executive Director of our Centre.

We have had cause to celebrate this year with the successful defense by Anne-Marie Tassé of her PhD Thesis. Ma'n H. Zawati was recognized by McGill University through his receipt of the Queen Elizabeth II Diamond Jubilee Scholarship, as well as being named as a Royal Society of Canada "2015 Young Scientist". Last but not least, I was recipient of the Paul-André-Crépeau Medal from the Canadian Bar Association, Quebec Division, related to my contribution to the advancement of international aspects of private and comparative law.

This year's Annual Report again emphasizes the CGP's innovative research program. It details completed and ongoing research projects, profiles our Visiting Scholars, course offerings, and also joint projects with P3G-IPAC 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
McGill University

A Message from the Research Director

The year 2015 has seen the Centre continue to evolve and grow as a unique, international hub for research on the ethical, social, and policy issues of genetics and personalized medicine. I am extremely pleased by our success in obtaining funding on 5 new research projects in a year marked by austerity and cuts in research funding attesting to the creativity and grant writing skills of our researchers. The dynamism of our team is also manifest in the increasingly varied, multidisciplinary, and sophisticated methodologies now developed for our research projects while still keeping our traditional focus on the policy implication of emerging developments. I also note with great satisfaction the intense research activity undertaken by our group on the topic of cancer personalized medicine (7 funded projects). Given the devastating public health impact of this terrible disease and the great potential shown by personalized medicine to improve the clinical outcome for patients and at risk individual, it brings me comfort to see the CGP emerge as a natural leader of GELS research in this domain.

Prof. Yann Joly
Research Director

Centre of Genomics and Policy
McGill University

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, pediatrics, 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 @genomics_policy

Centre of Genomics and Policy

CGP TEAM 2015

PROFESSOR
KNOPPERS Bartha Maria - **Director**

ASSOCIATE PROFESSOR
JOLY Yann - **Research Director**

EXECUTIVE DIRECTOR
PALMOUR Nicole

ACADEMIC COORDINATOR
ZAWATI Ma'n H.

ACADEMIC ASSOCIATES
DOVE Edward S.
DYKE Stephanie O.M.
ISASI Rosario
KLEIDERMAN Erika
LÉVESQUE Emmanuelle
NGUENG FEZE Ida
NGUYEN Thu Minh
SALMAN Shahad
SÉNÉCAL Karine
TASSÉ Anne-Marie
THOROGOOD Adrian

ASSOCIATE MEMBERS
GOLD Richard
KIMMELMAN Jonathan

SCIENTIFIC CONSULTANT
LABERGE Claude

ELSI PEDIATRIC CONSULTANT
AVARD Denise

INVITED SCHOLARS
BORRY Pascal
GOURNA Elli
ROTHSTEIN Mark A.
STODDART Jennifer

RESEARCH ASSISTANTS
BESSO Annyck
BIRKO Stanislav
CINÀ Margherita
CHAN Benny
CHARLEBOIS Kathleen
CRIMI Laura
DALPÉ Gratien
DESCHÊNES-ST-PIERRE Constance
GAGNON Johannie
GRANADOS MORENO Palmira
HAGAN Julie
HÉTU Martin
LAGUIA Kristen
PACK Amy
PUZHKO Svetlana
RAHIMZADEH Vasiliki
SHUANG Shuang
SONG Lingqiao
ZHENG Yixiao

VISITING STUDENTS
RAGOUSSIS Vassilis
SHABANI Mahsa

PhD STUDENTS
BERTIER Gabrielle
SO Derek

COMMUNICATIONS
OLVERA Elena

ADMINISTRATORS
HOZYAN Rose-Marie
ROSSI Marisa
THORSEN Nadine

ARTICLING STUDENTS
PHILLIPS Mark
SAULNIER Katie

Invited Scholars

Pascal Borry

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

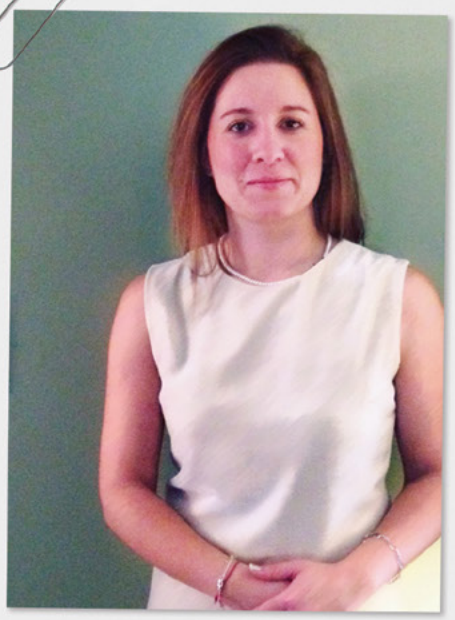
KU Leuven (Belgium)

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 testing and neonatal screening. In paticular, he is a co-PI with professor Knoppers in our EUCelLEX (FP7) project on stem cells and all therapies with a focus on umbilical cord banking and research use.



Elli Gourna

Department of Health Sciences

University of Leicester
(United Kingdom)

Elli Gourna is a PhD Candidate at the University of Leicester in the Department of Health Sciences under the supervision of Dr. Susan Wallace. She is the recipient of the College of Medical, Biological Sciences & Psychology PhD Studentship. Her dissertation investigates the attitudes of genetics professionals regarding clinical sequencing and incidental findings.

She has a Bachelor degree in Biology (University of Athens, Greece) and has two Masters of Sciences, one in Bioethics (University of Crete, Greece) and the other in Human Reproduction (University of Athens, Greece). She has worked as a scientific trainee in the National Bioethics Commission of Greece (Athens, Greece) and the Council of Europe Committee on Bioethics (Strasbourg, France).

Currently, she is completing her dissertation while coordinating the Data Sharing Lexicon Task Team for the Regulatory and Ethics Working Group of the Global Alliance for Genomics and Health.

Her main areas of interest are Bioethics, Medical and Public Health Ethics as well as ethical, legal, and social aspects of clinical sequencing and genetic/genomic tests (consent, data sharing, and ownership of genetic information). She is also particularly interested in comparative work i.e. cross-national and cross-state research as well as comparisons across backgrounds (e.g. professionals vs. lay people).

Mark A. Rothstein

Institute for Bioethics, Health Policy, and Law

University of Louisville
School of Medicine (United States)

Professor Mark A. Rothstein, J.D., is the Herbert F. Boehl Chair of Law and Medicine and the Director of the Institute for Bioethics, Health Policy, and Law at the University of Louisville School of Medicine. Professor Rothstein concentrates his research on bioethics, genetics, health privacy, and public health. He serves as Department Editor for Public Health Ethics of the American Journal of Public Health and also writes a regular column on bioethics for the Journal of Law, Medicine & Ethics.

Together with Professor Knoppers, they have undertaken a comparative legal analysis in twenty countries (including Australia, Brazil, China India, Israel, Mexico, Nigeria, South Africa, Taiwan, Uganda, etc.) revealing that the lack of international, regulatory harmonization impedes data sharing for translational research in genomics and related fields. The daunting task is to identify the applicable legal regime in each country and then to devise possible ways to harmonize the laws to enable international collaborative research while still giving effect to essential privacy projection (NIH grant).

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. With Professor Knoppers, she is involved in the "Draft Agenda: Advisory Expert Group for the Development of an OECD Draft Recommendation on Health Data Governance" and she co-Chairs its Advisory Expert Group.

Events 2015

P3G International Paediatric Platform "Think Tank"

(May 11 – 12)

In the Spring of 2015, a Think Tank focusing on "Re-contact in Biomedical Research: Implications of Attaining Majority" was organized by the P3G International Paediatric Platform in Montreal. The Think Tank brought together fourteen Paediatric experts to discuss the issue of re-contacting children in many different settings, including biobanks, longitudinal studies, clinical research, and newborn screening programs. All attendees contributed to a manuscript entitled "Attaining Majority in Biomedical Research: Re-contact for Consent?" consolidating the discussions brought forth during the Think Tank.

Summer Seminar Series

(June 12-September 15)

Each year, the CGP invites its members to present to the team and share their research findings (e.g. new publications, ongoing research results, etc). It is a great opportunity to both learn about each other's research projects and be acquainted with emergent issues in our field. Scholars from other institutions are also invited to present on their research. This year, our colleagues from the Research Group on Health and Law (Prof. Lara Khoury) and the Institute of Health and Social Policy (Prof. Daniel Weinstock) presented their work during our sessions.

Research Ethics Workshop Series

(Feb 4 - December 14)

Under the supervision of Ma'n H. Zawati, the interactive series of Research Ethics Workshops taking place in the 2015 academic year allowed participants to get acquainted with ethical issues present in research. Each two-hour workshop explored an important ethical aspect of the research process by allotting time for both background information and dynamic case-based group discussion. The following themes were presented: Introduction to Research Ethics Review, Recruitment and Informed Consent, Privacy and Confidentiality, Commercialization, Research Integrity, and also Return of Research Results and Incidental Findings.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COMPLETED RESEARCH PROJECTS
• A Research and Knowledge Network on Genetic Health Services and Policy: Building on the APOGEE-Net and CanGeneTest Experiences
• Translation Challenges, Science Policy and Stem Cell Research
• Protecting Privacy in Cloud-Based Genomics Research
• Quebec Training Network in Perinatal Research (QTNPR)
• International Stem Cell Forum Ethics Working Party (EWP)
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ANNUAL REPORT 2015

Completed Research Projects

PRINCIPAL INVESTIGATORS
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BLANCQUAERT I.R.
CASSISMAN Jean-Jacques
COLE David E.C.
DROUIN Régen
FOREST Jean-Claude
FOULKES William David
FRIEDMAN Jan M.
GAUDET Daniel
GIGUÈRE Yves
GODARD Beatrice
KNOPPERS Bartha Maria
LABERGE Anne-Marie
LABERGE Claude
LABREQUE Michel
LAFLAMME Nathalie
LAMOTHE Lise
LANDRY Réjean
LEDUC Nicole
LEGARE France
MARRA Carlo A.
MATHHIJS Gert
MITCHELL Grant A.
REINHARZ Daniel
ROUSSEAU François
SIMARD Jacques R.

ACADEMIC ASSOCIATES
SALMAN Shahad
ZAWATI Ma'n H.

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)

July 2010 – 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 has interested various stakeholders, including clinical researchers, health policy advisors, lawyers as well as technology and computer specialists. It promoted the research-to-practice transition and provided 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.

PRINCIPAL INVESTIGATOR
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CO-INVESTIGATOR
JOLY Yann

ACADEMIC ASSOCIATE
ISASI Rosario

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 was on the relationship between translation and commercialization pressure (including IP policies) and data access policies. We investigated current restrictions to access, as reflected in (for example) international stem cell banking policies, including restrictions to future IP claims, and compared them with existing open access policies (e.g., UK Stem Cell Initiative and the CIRM iPS biobank). This work included 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.

Protecting Privacy in Cloud-Based Genomics Research

Office of the Privacy Commissioner

April 2014 – March 2015

This project comprised 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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PHILLIPS Mark

ANNUAL REPORT 2015

Quebec Training Network in Perinatal Research (QTNPR)

Canadian Institutes of Health Research (CIHR)

April 2009 – May 2015

The QTNPR network created a multidisciplinary curriculum on the impact of environmental exposures on maternal and child health. The objectives of QTNPR were 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.

PRINCIPAL INVESTIGATOR
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GAGNON Robert
HATEM Marie
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MONNIER Patricia
MUCKLE Gina
MURPHY Bruce
TREMBLAY Yves
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PRINCIPAL INVESTIGATOR
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RESEARCH ASSISTANTS
GRANADOS MORENO Palmira
SO Derek

Reconciling Law and Ethics with Open Science in Biotechnology Research

Fonds de recherche du Québec - Santé (FRQS)

July 2011 – June 2015

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 investigated 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 used a combination of quantitative and qualitative research strategies that offered 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 facilitated comparisons and integration of our results. Our methods included comparative legal and ethical research (policy review, legal research), questionnaire analysis, and focus group interviews. To validate our findings, we engaged stakeholders at the annual meetings of two major organizations involved in research with open databases: The Public Population Project in Genomics and Society (P3G) and the International Cancer Genome Consortium (ICGC).

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ELLIOTT Paul
FERRETTI Vincent
FORTIER Isabel
HARRIS Jennifer
HVEEM Kristian
ILLIG Thomas
KNOPPERS Bartha Maria
OLLIER Bill
PEDERSEN Nancy
SPROSEN Tim
ZATLOUKAL Kurt

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TASSÉ Anne-Marie

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

The European Commission

December 2010 – November 2015

BioSHaRE-EU assembled a consortium of leading international researchers from all domains of biobanking science. These experts developed and applied methods and tools providing a foundation for an ambitious program of harmonization and standardization in European biobanks and major biomedical studies. This facilitated the full participation of European bioscience in the next phase of international aetiological research that demanded access to studies that have three 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 was 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 offered BioSHaRE its ethical expertise on issues of privacy and retrospective access to samples and data.


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CURRENT RESEARCH PROJECTS
• Access to Health Insurance in the Context of Personalized Medicine
• Réseau de médecine génétique appliquée (RMGA) Infrastructure
• From Banking to International Governance: Fostering Innovation in Stem Cell Research
• International Stem Cell Forum Ethics Working Party (EWP)
• Harmonizing Privacy Laws to Enable International Biobank Research
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Current Research Projects

Current Research Projects (cont' d)

PRINCIPAL INVESTIGATORS
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ACADEMIC ASSOCIATES
NGUENG FEZE Ida
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RESEARCH ASSISTANT
CRIMI Laura

Access to Health Insurance in the Context of Personalized Medicine

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

The Personalized Medicine Partnership for Cancer (PMPC) projects, led 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).

PRINCIPAL INVESTIGATOR
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BRAIS Bernard
JOLY Yann
KNOPPERS Bartha Maria
MICHAUD Jacques
PHILLIPS Michael
PUYMIRAT Jack
ROUSSEAU François
SIMARD Jacques
VÉZINA Hélène

ACADEMIC ASSOCIATE
SÉNÉCAL Karine

Réseau de médecine génétique appliquée (RMGA) Infrastructure

Fonds de Recherche du Québec - Santé (FRQS)
April 2008 – March 2016

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. The CGP is completing a consolidation of all the RMGA Statements of Principles in light of rapid developments in genomics at the provincial, national, and international levels.

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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International Stem Cell Forum Ethics Working Party (EWP)

International Stem Cell Forum, Medical Research Council (UK) / Canadian Institutes of Health Research (CIHR)

April 2012 – March 2016

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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KIM Ock-Joo
LAUNIS Veikko
LOMAX Geoffrey
MORRIS Clive
MURRAY Thomas
PENG Lee Hin
PERRY Margery
RAGER Bracha
RICHARDSON Genevra
SIPP Douglas
TANNER Klaus
WAHLSTROM Jan
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Harmonizing Privacy Laws to Enable International Biobank Research

National Institutes of Health (NIH)
September 2014 – July 2016

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 as well as the 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 2016 in two dedicated special issues in the Journal of Law, Medicine & Ethics.

ANNUAL REPORT 2015

PRINCIPAL INVESTIGATOR
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HOPPE Nils
KAYE Jane
KNOPPERS Bartha Maria
NYS Herman
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TOURNAY Virginie
ZATLOUKAL Kurt

ACADEMIC ASSOCIATE
ISASI Rosario

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.

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 – December 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.

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HÉTU Martin

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 GE3LS 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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Framework for Decision-Making for Rare Diseases

Canadian Institutes of Health Research (CIHR)
April 2013 – 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, economic factors and ethical principles while being consistent with the values of society at large.

ANNUAL REPORT 2015

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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

Fondation du cancer du sein de Québec / 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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Risk Stratification for Prevention and Early Detection of Breast Cancer: Development and Implementation of Communication Tools

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).

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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 2014 – 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.

ANNUAL REPORT 2015

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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.

Élaboration d'une stratégie de dissémination des connaissances sur les cancers familiaux dans le contexte des soins palliatifs fondée sur une analyse éthico-légale des points de vue des intervenants et des familles

Fonds de Recherche du Québec - Santé (FRQS) / Ministère de la Santé et des Services sociaux (MSSS)

May 2015 – April 2017

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This project aims to propose a strategy for the dissemination of knowledge in cancer genetics applied to the context of palliative care in order to help stakeholders address the needs of dying patients and their family members on issues related to their family history cancer, all in an appropriate legal and ethical framework.

To achieve this, three activities will be implemented and are aimed at:

1) identify with doctors and nurses in palliative care priority issues associated with family history of cancer in their work context as well as the barriers and facilitating factors to address, if any, ethically with the patient end of life and members of his family; 2) identify needs and concerns related to palliative care cancer patients about their family history and how to address them properly in the context of the end of life; 3) identify the legal and ethical guidelines applicable to the communication of family history of cancer in the family members of a patient in palliative care.

Ultimately, the goal is to develop knowledge dissemination activities, including a toolbox to ensure the dissemination and accessibility of information for healthcare professionals working in palliative care who have to deal with issues related to a family history of cancer.

ANNUAL REPORT 2015

Integrative Epigenomic Data Coordination Centre (EDCC) at McGill

Canadian Institutes of Health Research (CIHR)

January 2012 – December 2017

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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 Canadian Epigenetics, Environment and Health Research Consortium (CEEHRC) initiative and facilitate integration with the International Human Epigenome Consortium (IHEC). Protection of data confidentiality will be paramount, and all steps associated with data flow within the CEEHRC network will adhere to current IHEC policy through a reliance on two-tier classification of datasets, where data that cannot be aggregated to generate a dataset unique to an individual is made publicly accessible, while access to data associated with a unique (albeit not directly identifiable) person is controlled. A Centre-specific data access agreement has been developed to ensure that researchers adhere to standards of confidentiality and maintain good IT practices. Developments in the bioinformatics, IT security, scientific, and policy literature are monitored to ensure that the current classifications for "open" or "controlled" data continue to protect patients. Both the EMC and EDCC projects also involve the development of and support for a bioethics workgroup for the IHEC.

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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 (IHEC) has established an Epigenome Mapping Centre (EMC) at McGill University that applies epigenome mapping in order to understand interactions between environment and genome in human blood cells, interprets diseases impacting metabolism using tissue samples, and studies how epigenetic changes can alter function of the brain. The large-scale generation and sharing of human epigenome data presents challenges to the informed consent process that are managed first through the integration of existing cohort data with EMC McGill, using a special template developed in conjunction with the Public Project in Genomics (P3G), and subsequently by prospectively developing a model consent template that ensures all IHEC consent, policy, and ethics requirements are met. Throughout this, we will continue to actively participate in discussions on the development of a more comprehensive ethical policy framework at the IHEC level. Both the EMC and Epigenomic Data Coordination Centre (EDCC) projects also involve the development of and support for a bioethics workgroup for the IHEC.

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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 Quebec 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.

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 re-identification.

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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.

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Réseau en soins de santé personnalisés-Q-CROC

Fonds de partenariat pour un Québec innovant et en santé (FPQIS)
April 2014 – March 2019

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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A Syst-OMICS Approach to Ensuring Food Safety and Reducing the Economic Burden of Salmonellosis

Genome Quebec, Genome Canada
October 2015 – September 2019

Each year, approximately 88,000 people become sick from consuming fresh produce that is contaminated with Salmonella. The health impacts can vary between people suffering, from no ill effects to serious infection requiring medical care or even causing death. Salmonella infection is thought to cost the Canadian economy as much as $1 billion annually in terms of medical costs, work absenteeism, and economic losses (including that of the food and restaurant industries).

Using whole genome sequencing to identify the specific Salmonella strains that cause human disease, the team will develop natural bio-solutions to control the presence of Salmonella on fruits and vegetables. New tests will also be developed to quickly and efficiently detect the presence of Salmonella on fresh produces before they are sold to consumers. These new tools will allow public health officials to better determine the source of Salmonella illnesses so that contaminated foods can rapidly be removed from grocery stores and restaurants. An anticipatory governance approach will be used to conduct a regulatory assessment integrating a careful consideration of the evidentiary requirements, the economic, legal, ethical, regulatory, and global policy constraintsas well as the trade implications of supporting such a paradigm shift. More precisely, the CGP team will: 1) assess the viability and implementability of a novel genomic test for Salmonella that can determine the pathogenic status of a given isolate; and 2) assess the need to shift to a risk-based approach to food safety that classifies foodborne microbial adulterants on the basis of their pathogenicity, in contrast to the current regulatory practice of classifying a microbial adulterant based on species determination alone.

Research Awards

Canada Research Chair in Law and Medicine

Prof. Bartha Maria Knoppers, PhD

Holder of this Tier 1 Chair since the year 2001, the ensuing research program supports the full breath of CGP projects. In particular, it serves to ensure the update and maintenance of the HumGen database, the participation of trainees in national and international conferences and our Invited Scholars program. From 2013 to 2015, it also supported the Framework and policy work of the Regulatory and Ethics Working Group of the Global Alliance for Genomics and Health. The Chair will continue this work via the P3G-led Can-SHARE project.

Recherche translationnelle en médecine personnalisée, perspectives et enjeux pour le Québec

Fonds de Recherche du Québec - Santé (FRQS)

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

Designated as "Chercheur boursier niveau Junior 2" since July 2015, the awarded research grant will contribute to the development of a new type of infrastructure covering specific categories of diseases moving the translational domain closer to the clinic (eg. Q-CROC, Biobank Cohort of hospital ICM and Hepatopancreatobiliary (HPB) and Transplant Biobank Research at McGill). These facilities are used to conduct research, monitor patients in real time and inform therapeutic discoveries (choices) or treatments relevant to the patient's specific genetic profile. This research grant will allow the conception of legal and ethical policies needed to establish optimal translational research infrastructure for safe, patient-centered personalized medicine in Quebec.

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 and contribute to the learning that occurs. Such a 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

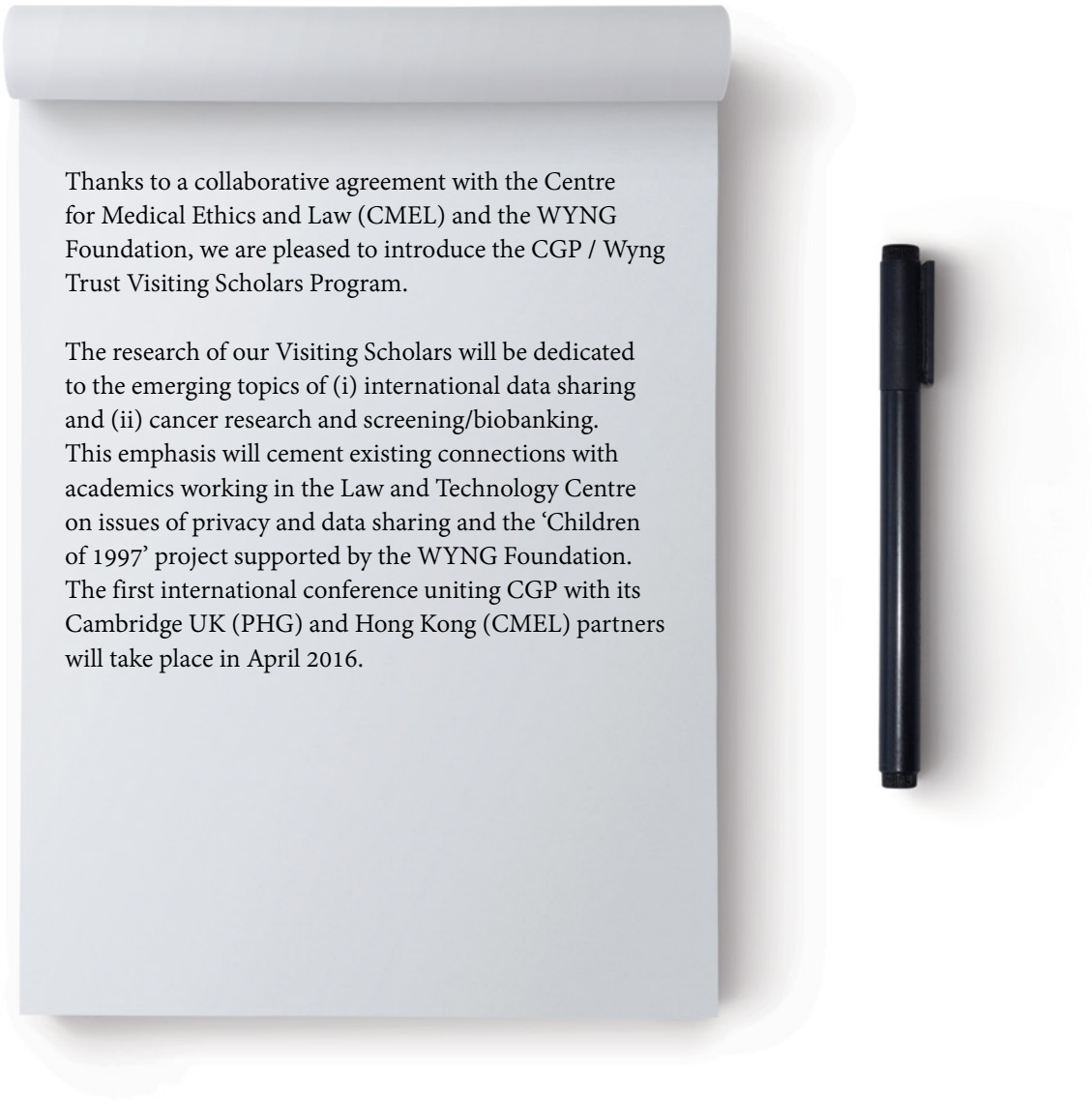
Instructor: Me. Ma'n H. Zawati, LL.B., LL.M.

The *Research Internship in Genomics and Policy* course aims at providing 1 to 2 graduate students in the Human Genetics program with an opportunity to do research on the ethico-legal and policy issues in human genetics. More specifically, graduate students will be 1) introduced to the ethical, legal, and policy issues in human genetics in both the research and clinical settings; and 2) familiarized with social science research methodologies, especially international comparative analysis of normative policy and legal instruments.

As an internship, these objectives will be achieved through active research under the supervision of a mentor working in the student's area of interest. Specific areas of research at the Centre of Genomics and Policy include but are not limited to: population genomics, biobanks, stem cells, reproductive technologies, pediatric genetic research, data protection, direct-to-consumer genetic testing, gene therapy, personalized medicine, and genetic counseling. Interested students are encouraged to explore the CGP website (www.genomicsandpolicy.org) to identify areas of interest. Undertaking an internship at the Centre of Genomics and Policy will allow students to benefit from a close collaboration with experts at the crossroads of the ethico-legal, medical, and policy fields.

The Center of Genomics and Policy and Wyng Trust Visiting Scholar Program(2015-2018)

Prof. Bartha Maria Knoppers, PhD



McGill CGP-CMEL Summer Internships

The CGP has proposed summer internships for two CMEL LLM students per year, providing one month supervision at CGP with appropriate mentorship and training anticipated to begin in the Summer of 2018.

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 to facilitate the sharing of clinical and research data.

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), MTAs/DTAs, commercialization, IP, confidentiality/privacy, research ethics and governance, and services. These tools are implemented through the following three modules:

- **Data Access Compliance (DAC)** - The DAC office services both international and national research projects.
  International: The DAC office 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
  National Canada: In 2015, the Canadian Partnership for Tomorrow Project (CPTP) opened its controlled access database and the IPAC runs it access office. (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, MTAs, etc.) for international and national research consortia and projects. In 2015, the IPAC provided 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 by 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:

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Ruth Chadwick, UK
Don Chalmers, Australia
Ellen Clayton, USA
Jantina de Vries, South Africa
Mats Hansson, Sweden
Nils Hoppe, Germany
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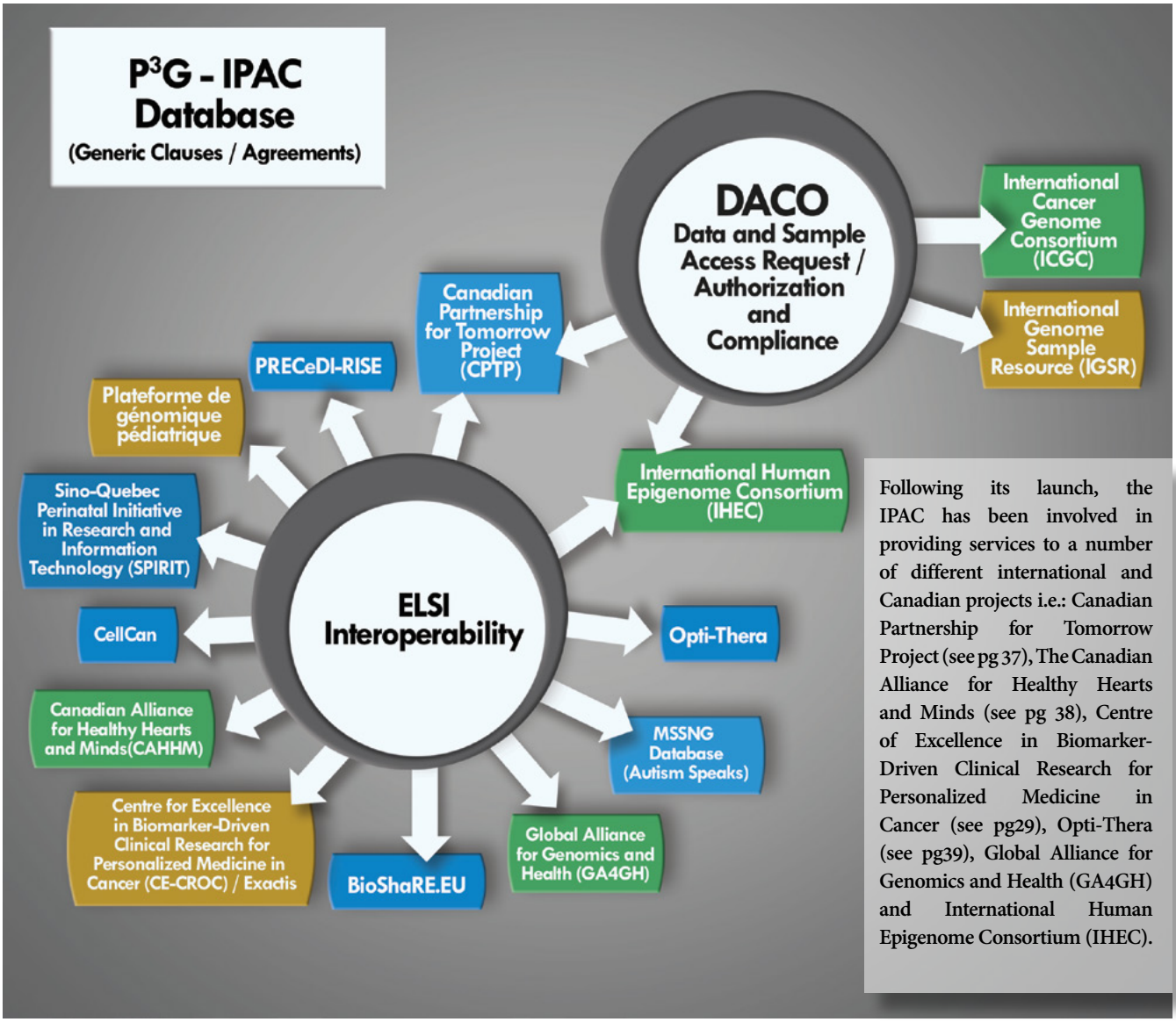

Following its launch, the IPAC has been involved in providing services to a number of different international and Canadian projects i.e.: Canadian Partnership for Tomorrow Project (see pg 37), The Canadian Alliance for Healthy Hearts and Minds (see pg 38), Centre of Excellence in Biomarker-Driven Clinical Research for Personalized Medicine in Cancer (see pg29), Opti-Thera (see pg39), 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 has organized and contributed to the Framework for Responsible Sharing of Genomic and Health Related Data, while providing 3 types of consent 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 and 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 the research community of high-resolution reference human epigenome maps for normal and disease cell types. 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 a Data Access Coordination Office (DACO services).

For more details please see www.p3g.org/ipac

CGP Centre of Genomics and Policy
Centre de génomique et politiques

and

IPAC

Collaborations

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

Ontario Institute for Cancer Research (OICR)

July 2009 – March 2017

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 (P^3G), 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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Canadian Partnership for Tomorrow Project (CPTP)

Canadian Partnership Against Cancer

April 2009 – March 2017

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, data sharing, and proposing governance structures for the CPTP.

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The Canadian Alliance for Healthy Hearts and Minds

Canadian Partnership Against Cancer 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.

ANNUAL REPORT

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Sino-Quebec 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-Quebec 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;
3) Consolidate infrastructures allowing the 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.

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; and 3) providing support to address 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).

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Can-SHARE

Genome Canada / Canadian Institutes of Health Research / Genome Quebec/ Genome British Columbia / Ontario Genomics Institute

July 2015 – June 2018

Despite decreasing sequencing costs in the wake of the Human Genome Project, wide scale data sharing is still a distant reality both in Canada and internationally. Ensuring interoperable policies and procedures across provinces in Canada and between jurisdictions remains a challenge, often due to socio-ethical and legal issues. Innovations in the biomedical sciences and in information technologies (IT) inspired Canadian leaders of the Global Alliance for Genomics and Health (GA4GH) to create Can-SHARE in amis of advancing the goals of the GA4GH within Canada and internationally. GA4GH's mission is to enable rapid progress in biomedicine by working to develop policies, tools ,and guidelines for harmonization while engaging stakeholders across disciplines (http://genomicsandhealth.org/). In this context, Can-SHARE will advance Canadian leadership by developing data access and sharing policy as well as more specifically tools in Canada, within the GA4GH and other international research consortia. The Can-SHARE team will support prominent Canadian leaders in GA4GH ensuring and enabling innovation in health care for Canadian patients in the decades to come.

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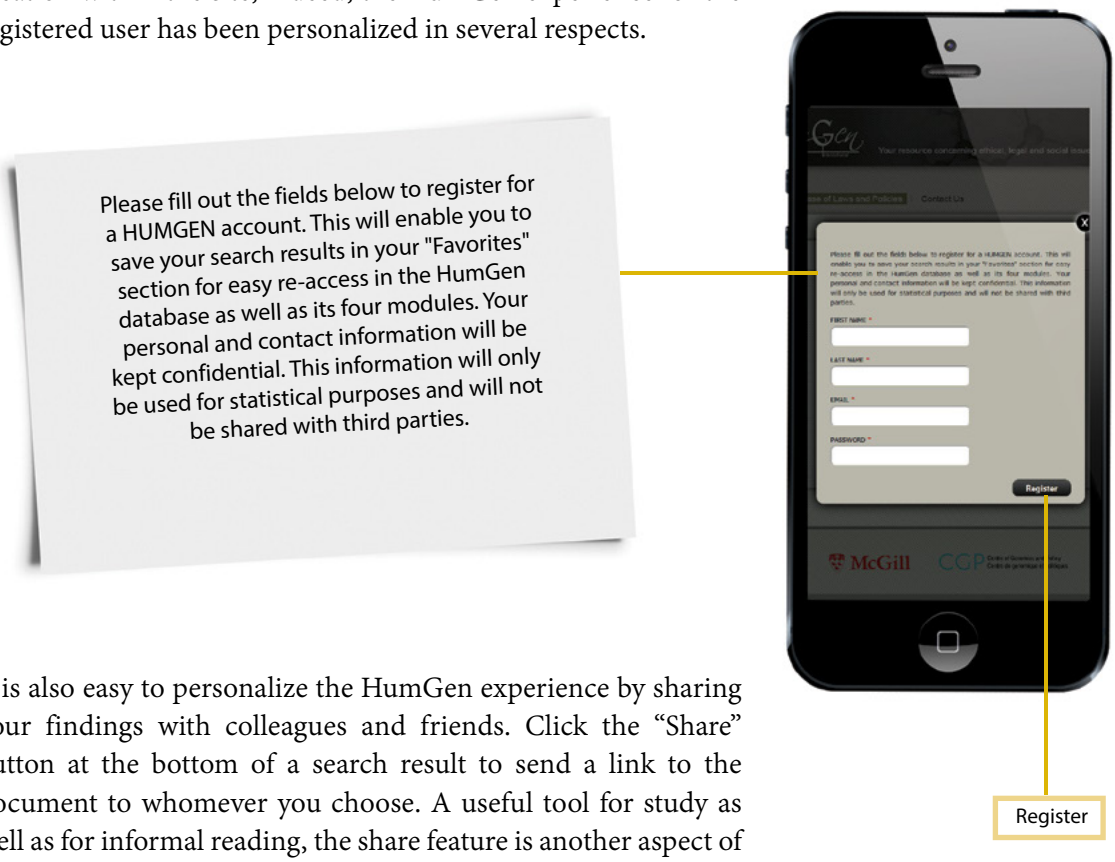
HumGen – Database

The optimized HumGen international database search engine promotes online access to widespread information on laws, policies, and guidelines in human genetic research. HumGen trivially searches through four modules making it easier for users to conduct research into ethical, legal, and social issues in human genetics while simultaneously personalizing the user's experience.

The optimized search engine is designed 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 superior 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 @genomics_policy.

Team Publications 2015

Book Chapters

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Zawati MH, Junker A, **Knoppers BM** & **Rahimzadeh V**, "Streamlining review of research involving humans: Canadian models" (2015) 52:8 Journal of Medical Genetics, 566.

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