

ANNUAL REPORT 2016



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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. This year, our Invited Scholars joined us from Canada, the United Kingdom, the United States, China (Hong Kong), Belgium and Italy.

We have had cause to celebrate this year with the renewal of my Canada Research Chair in Law and Medicine (Tier 1, since 2001). In November of this year, I also became Fellow of the Royal Society of Canada. Furthermore, our Research Director, Prof. Yann Joly, received a Teaching Excellence Award from the Department of Human Genetics at McGill University's Faculty of Medicine.

This year's Annual Report again emphasizes the CGP's innovative research program. It details completed and ongoing research projects, profiles our Invited Scholars, course offerings, and also highlights joint projects with P³G-IPAC and the team's publications. Moreover, you will learn more about our Centre's work in promoting training in Canada and abroad through McGill Skillsets Program's Research Ethics Series, our Summer Seminar Series, and a biobanking ethics workshop in Amman, Jordan.

Through these features, we hope our work is accessible and helpful to all!

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

Bartha Maria Knoppers
Director
Centre of Genomics and Policy
McGill University

Message from the Research Director

Dear Readers,

The year 2016 has seen the Centre continue to advance and grow as a unique, international hub for research on the ethical, social, and policy issues of genomics and personalized health. In fact, members of the CGP have made several important contributions this year, with the publication of a number of articles on the ethical and legal issues of epigenetics, insurability risks in medical research, CRISPR/Cas9 and gene editing, DNA testing for family reunification, a gatekeeping function in personalized medicine, the sharing of health-related data and de-identification in very high profile journals such as Cell, Science, Nature Genetics, and The Lancet.

2016 has also seen the consolidation of the Réseau de Médecine Génétique Appliquée (RMGA)'s landmark policies in genetics and ethics into a single document, which covers issues related to consent, return of results, and the secondary use of data/samples from genomic research.

During 2016, the research of CGP members has also significantly supported the working groups of the Global Alliance for Genomics and Health (GA4GH). Likewise, important regulatory tools and policies were developed this year to guide international data sharing, which includes the GA4GH Accountability Policy and the Ethics Review Recognition policy finalized in early 2017. The latter aims to improve the consistency of ethics review of data intensive research, and in turn, to foster mutual recognition between ethics bodies.

I am also extremely pleased by our success in obtaining funding on 14 new research projects this year and by having had the opportunity to host 9 Invited Scholars, 4 students, 2 interns, and 2 articling law students. We look forward to collaborating with our research colleagues in upcoming national funding opportunities in 2017, where our team will continue to propose varied, multidisciplinary, and sophisticated methodologies to help in the implementation of novel science from research to the clinic.

Prof. Yann Joly

Research Director
Centre of Genomics and Policy
McGill University

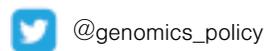
about

the Centre of Genomics and Policy

Located within the Genome Québec 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 and suscribe to our YouTube channel.



CENTRE OF GENOMICS AND POLICY

CGP TEAM

PROFESSOR

KNOPPERS Bartha Maria - *Director*

ASSOCIATE PROFESSOR

JOLY Yann - *Research Director*

EXECUTIVE DIRECTOR

ZAWATI Ma'n H.

ACADEMIC ASSOCIATES

DYKE Stephanie O.M.

HAGAN Julie

KLEIDERMAN Erika

LÉVESQUE Emmanuelle

NGUENG FEZE Ida

NGUYEN Minh Thu

PACK Amy

PHILLIPS Mark

SALMAN Shahad

SAULNIER Katie

SÉNÉCAL Karine

TASSÉ Anne-Marie

THOROGOOD Adrian

ASSOCIATE MEMBERS

BEREZA Eugene

GOLD Richard

KIMMELMAN Jonathan

SCIENTIFIC CONSULTANTS

AVARD Denise

LABERGE Claude

PhD STUDENTS

BERTIER Gabrielle

NOOHI Forough

RAHIMZADEH Vasiliki

SO Derek

INVITED SCHOLARS

BORRY Pascal

CLEMENT Chen

HAUSMAN Jean-Marc

ISASI Rosario

MESLIN Eric

STODDART Jennifer

UNIM Brigid

VEARS Danya

WALLACE Susan

RESEARCH ASSISTANTS

CAULFIELD Alison

CHARLEBOIS Kathleen

CINÀ Margherita

DALPÉ Gratien

DESCHÊNES-ST-PIERRE Constance

ESQUIVEL SADA Daphne

GAGNON Johannie

GAGNON Justin

GOODRIDGE Vinca

GRANADOS MORENO Palmira

HÉTU Martin

LAGUIA Kristen

LANG Michael

McLAUHLAN David

OLVERA Elena

PUZHKO Svetlana

SONG Lingqiao

TOURÉ Seydina

ZHANG Jian

ZHENG Yixiao

INTERNS

CHU Jordan

PUPAVAC Mihaela

ADMINISTRATORS

HOZYAN Rose-Marie

ROSSI Marisa

THORSEN Nadine

CENTRE OF GENOMICS AND POLICY CGP TEAM



BARTHA MARIA KNOPPERS

DIRECTOR



Bartha Maria Knoppers, PhD
(Comparative Medical Law),
Canada Research Chair
in Law and Medicine

Full Professor (PhD) and the Director of the Centre of Genomics and Policy, Faculty of Medicine, Department of Human Genetics, McGill University, Bartha Maria Knoppers holds four Doctorates Honoris Causa and is Fellow of the AAAS, the Hastings Centre (bioethics), the Canadian Academy of Health Sciences and the Royal Society of Canada. She is Officer of the Order of Canada and of Québec. She received the “Prix Montréal In Vivo: Secteur des sciences de la vie et des technologies de la santé” in 2012 and in 2013 was named “Champion of Genetics” by the Canadian Gene Cure Foundation. In 2014, she was named “Great Montrealer” (scientific Sector) by the Board of Trade of Metropolitan Montréal. In 2015, she received the Medal Paul-André Crépeau for her efforts in comparative medical law (Canadian Bar Association). She also chairs the Ethics Panel of the World Anti-Doping Agency (WADA). In 2016, her Canada Research Chair in Law and Medicine (CRC) was renewed for another seven years (Tier 1, since 2001).



YANN JOLY

RESEARCH DIRECTOR

Yann Joly, Ph.D. (DCL) Ad.E.: Lawyer Emeritus from the Québec Bar and Research Director of the Centre of Genomics and Policy (CGP). He is an Associate Professor at the Faculty of Medicine, Department of Human Genetics with a cross-appointment at the Biomedical Ethics Unit at McGill University. He is also a Research Fellow of the Fonds de Recherche du Québec-Santé (FRQS) and an Associate Researcher at the Centre de recherche en droit public at Université de Montréal. Prof. Joly chairs the Bioethics Workgroup of the International Human Epigenome Consortium (IHEC) and the UNESCO Human Variome Project (HVP) Standards Group. He is the Data Access Officer of the International Cancer Genome Consortium (ICGC) and a member of the Human Genome Organization (HUGO) Committee on Ethics, Law, and Society (CELS).

Ma'n H. Zawati (LL.B., LL.M.): Lawyer and the Executive Director of the Centre of Genomics and Policy at McGill University. He is also an Associate Member of the University's Biomedical Ethics Unit since 2013. His research focuses on the legal and ethical aspects of biobanking as well as the legal duties and liability of healthcare professionals in both the clinical and research settings. He has published numerous articles on issues such as access to genomic databases, the return of research results/incidental findings, the legal liability of physicians, and the closure of biobanks. Mr. Zawati has also presented on these topics in Canada and internationally. In 2014, the Young Bar Association of Montréal named him as one of its "Lawyer of the Year" awardees.



MA'N H. ZAWATI

EXECUTIVE DIRECTOR



STEPHANIE O.M. DYKE

ACADEMIC ASSOCIATE

Stephanie Dyke's research experience spans biochemistry (PhD, University of Cambridge), public perceptions of technology (MSc in Science Communication, DCU), bioethics and science policy. She has worked for a national bioethics advisory council, the Irish Council for Bioethics, as policy adviser at the Wellcome Trust Sanger Institute, and at the Francis Crick Institute in the UK. Stephanie served as a member of the International Cancer Genome Consortium Ethics and Policy Committee from 2009 to 2013. In 2013, she was awarded an Economic and Social Research Council Bright Ideas Fellowship by the Genomics Policy and Research Forum. Stephanie joined the Centre of Genomics and Policy at McGill University in April 2014. She is currently involved in ethics research focusing on data sharing policy with the International Human Epigenome Consortium and the Global Alliance for Genomics and Health. Stephanie is an invited lecturer in the Genetics, Ethics and Law course (HGEN 660) at McGill University, where she teaches ethics and science communication.

Julie Hagan has completed her undergraduate and master studies (B.Sc/M.Sc) in sociology at Université de Montréal. Currently a PhD candidate, she is interested in public participation, expertise, governance and interdisciplinarity. At the Centre of Genomics and Policy, she contributes her experience in qualitative research methodologies. She collaborates with Emmanuelle Lévesque on a research project studying the organizational dimensions of a risk stratification approach for breast cancer.



JULIE HAGAN

ACADEMIC ASSOCIATE

Erika Kleiderman is a lawyer and an Academic Associate at the Centre of Genomics and Policy (CGP). She holds a civil law degree (LL.B.) from the Université de Montréal, as well as a B.Sc. in Psychology from McGill University. She first joined the CGP as a research assistant in 2007, helping out with updating and maintaining the online database. Over the years, she has had the opportunity to work on various projects dealing with newborn screening, direct-to-consumer genetic testing, and return of results and incidental findings (from both a quantitative and qualitative perspective). Currently, she deals primarily with ethical, legal, and social implications related to privacy, confidentiality, and access to genetic information. Before joining the CGP, Erika was involved with a research lab at the Douglas Hospital dealing with the effects of sleep on children's academic performance. She carried out qualitative research, conducting focus groups with parents, teachers and children to develop an educational module to be incorporated and implemented into the elementary school curriculum as a means of educating children about the importance of sleep. Erika is also a member of the Montréal General Hospital's Research Ethics Board and the Jewish General Hospital's Research Ethics Committee.



**ERIKA
KLEIDERMAN**

ACADEMIC ASSOCIATE



**EMMANUELLE
LÉVESQUE**

ACADEMIC ASSOCIATE

Emmanuelle Lévesque is a lawyer and a member of the Québec Bar. She holds a Master of Laws (specializing in biotechnology, law and society) from the Université de Montréal and an LL.B. from Université Laval. Her masters thesis is an analysis of the protections offered by the Canadian Charter and the Québec Charter against genetic discrimination in the workplace. Emmanuelle works at the Centre of Genomics and Policy at McGill University. She specializes in questions concerning ethical and legal issues in health research, particularly in biomedical and genetic research. Over the past several years, she advises researchers about the ethical and legal issues raised by the deployment of their projects, especially about the development and the framework of biobanks. She works on projects conducted in Québec, in the rest of Canada and overseas. She published several publications and held conferences on different ethical and legal issues raised by research.



IDA NGUENG FEZE

ACADEMIC ASSOCIATE

Ida Ngueng Feze is an Academic Associate at the Centre of Genomics and Policy (CGP) at McGill University. Ms. Ngueng Feze's main research projects at the CGP include the legal, ethical and social issues related to the access and use of genetic data by third parties and genetic discrimination. She co-authored the first systematic review on the evidence of genetic discrimination in the context of life insurance published in BMC ethics in 2013. She also provides legal expertise on the legal and regulatory framework for the environmental applications of novel biotechnologies in contexts such as water governance and food safety. Her other areas of research include human rights, pharmacogenomics, research ethics, and the use of DNA testing in immigration processes. Ms. Ida Ngueng Feze Esq. is a lawyer admitted to practice in the State of New York. She holds a Bachelor of Arts degree (B.A.) in Law and Society with a Minor in Psychology from Ramapo College, a Juris Doctorate degree (J.D.) from Howard University School of Law, and an LL.M. in International Law from the Université de Montréal.

Minh Thu Nguyen holds a Master of Laws (LL.M.) degree in Health Law and Policy from the University of Toronto, a Civil Law (LL.B.) degree from the Université de Montréal, and a B.Sc. degree in Physical Therapy from McGill University. In 2009, she was a fellow in the Canadian Institute for Health Research training program in Health Law and Policy. During her Bachelor studies in law, she also spent time in France at the Université Panthéon d'Assas (Paris II) studying comparative law. Her work focuses primarily on the legal, social and ethical issues relating to stem cell research, cloning and regenerative medicine. She also has an interest in issues in reproductive health law, particularly, in the legal, ethical and social issues surrounding emerging reproductive technologies such as prenatal diagnosis and pre-implantation genetic diagnosis.

MINH THU NGUYEN

ACADEMIC ASSOCIATE

Amy Pack obtained a Master of Laws (LL.M.) in the field of Health Sciences from the University of Sherbrooke as well as a Bachelor of Sciences (B.Sc.) in Biology with a specialization in Human Genetics at McGill University. She is currently working at the Centre in collaboration with Ma'n Zawati, Executive Director, on a multitude of projects. Such projects involve research integrity, mobile health applications, electronic consent, physician legal obligations in the era of personalized medicine, and authorship attribution, to name a few. Moreover, Amy Pack helps organize and presents at the CGP's Summer Seminar Series as well as McGill Research Ethics Workshop Series. She is also the Coordinator of the HumGen international database search engine promoting online access to widespread information on laws, policies, and guidelines in human genetic research (<http://www.humgen.org/>). Amy Pack is a member of the McGill University Health Centre (MUHC) Research Ethics Board.



AMY PACK
ACADEMIC ASSOCIATE



**MARK
PHILLIPS**
ACADEMIC ASSOCIATE

Mark Phillips holds an LL.B. and a B.C.L. from McGill University's Faculty of Law, as well as a B.Sc. (Honours) in Computer Science from the University of Manitoba. His work at the Centre of Genomics and Policy is focused on comparative analyses of data protection, privacy, and cloud computing law and policy, particularly as they relate to bioinformatics. He is a former editor of both the McGill Journal of Law and Health and of the McGill Law Journal. His research interests also include computer-assisted legal research methodologies, mental health and disability, and law and social movements.



KATIE SAULNIER

ACADEMIC ASSOCIATE

Katie Saulnier graduated from Mount Allison University in 2010 with a Bachelor of Arts (Philosophy and English) focusing on ethics, and from the McGill Faculty of Law in May 2014 with a Bachelor of Civil Law (B.C.L.) and a Bachelor of Common Law (LL.B.). She was called to the Bar of the Law Society of Upper Canada in June 2016. Her previous research has involved the ethical implications of pop cultural depictions of reproduction and reproductive technology, policy problems with regard to rural access to healthcare for individuals living in poverty, and various questions of autonomy in law as it relates to gender. At the CGP, Katie is currently involved in policy development surrounding epigenetic research and data-sharing.

Karine Sénécal obtained a Master of Laws (option biotechnology, law, and society) from the Université de Montréal, and a Bachelors of Law from the Université du Québec à Montréal. Her Master's thesis addressed the legitimacy of a limited implementation of human germline gene therapy, from a human rights and research ethics perspective. Karine holds the title of Academic Associate at the Centre of Genomics and Policy at McGill University. Specializing in ethical, legal, and social issues arising in the domains of paediatric research and genetic research, Karine's work focuses on genetic testing and screening of minors, as well as paediatric biobanking.



KARINE SÉNÉCAL

ACADEMIC ASSOCIATE

Anne-Marie Tassé (LL.B., LL.M., M.A., LL.D.) is a lawyer specialised in health law and bioethics. She holds a Doctorate in Law (Université de Montréal), Master's degrees in Health Law (Université de Sherbrooke), and in Bioethics (Université de Montréal), and a Certificate in Health and Social Services Management (Université du Québec). Her work looks primarily at interactions between law and ethics, in the areas of international biomedical and genetic research. Specialised in international comparative law, she is the Executive Director of Public Population Project in Genomics and Society (P³G) and an Academic Associate at the Center of Genomics and Policy at McGill University. As such, she coordinates the legal and ethical aspects of more than 10 Canadian and international research projects. Author of more than 40 books, book chapters, peer-reviewed articles, policies and guidelines, her work is presented in Canada and abroad.



ANNE-MARIE
TASSÉ

ACADEMIC ASSOCIATE



ADRIAN
THOROGOOD

ACADEMIC ASSOCIATE

Adrian Thorogood (B.A./Sc, B.C.L./LL.B.) is a lawyer and Academic Associate at the Centre of Genomics and Policy. His research at the Centre focuses on health care professional responsibility in genetics, the privacy of health information, and the promotion of data sharing in genomic research. Adrian has a Bachelor's degree from McGill University with a double major in health economics and biomedical sciences. After completing his degree, he worked for a year as an epidemiology researcher and clinical trial coordinator at the Jewish General Hospital in Montréal. Adrian then pursued his joint common law - civil law degree at McGill University, graduating in 2013. He first joined the Centre of Genomics and Policy during his first year of law school. During his law studies, Adrian was also an editor-in-chief of the McGill Journal of Law and Health. He completed his articling at the Department of Finance Canada, where he had the opportunity to advise on a wide range of issues in legislative, constitutional, and aboriginal law, as well as international trade and financial sector regulation. He was called to the Ontario Bar in 2015.

INVITED SCHOLARS



PASCAL BORRY

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

Belgium

Pascal Borry is Associate Professor of Bioethics at the Centre for Biomedical Ethics and Law (University of Leuven, Belgium). His research focuses on the ethical and legal aspects of innovative genetic and genomic technologies, public health genomics, biobanking, and research on human tissue, pediatrics, and reproductive genetics. He is Programme Director of a Master of bioethics programme and coordinator of the Erasmus Mundus Master of Bioethics. He is member of the Flemish Commission on neonatal screening (2012-2017); the Belgian Consultative Committee on Bioethics (2014-2018); and the Superior Health Council (2014-2020), the Professional and Public Policy Committee (2009-2016) and of the Board (2012-2017) of the European Society of Human Genetics. In 2015, he received the prize of the Dutch Society for Bioethics and the Science Communication Award of the Royal Flemish Academy of Belgium for Science and the Arts. Invited scholar at the Centre for Genomics and Policy, his work examines the implications of whole genome sequencing in pediatrics, direct-to-consumer testing, and neonatal screening. He is a co-PI with Professor Knoppers in our EUCeLLEX (FP7) project on stem cell therapies and umbilical cord banking and in a bilateral Flanders-Québec project.

Dr. Clement Yongxi CHEN is a Postdoctoral Fellow at the Faculty of Law of the University of Hong Kong (HKU). He received his legal education at HKU (Ph.D.), University of Paris 1 Panthéon-Sorbonne (D.U. 3ième cycle “Le Droit en Europe” [postgraduate diploma], funded by a French Government Scholarship and Sun Yat-sen University (LL.M. and LL.B.). His research interests include freedom of information, privacy law, and comparative administrative law. He is also a Visiting Fellow at the Centre for Public Law of Sun Yat-sen University. Member of the International Media Lawyer Association and the Asian Privacy Scholar Network, he has participated in the drafting of China’s first local government rule on freedom of information as well as other local regulations concerning information rights. Currently publishing a book with Routledge on judicial review and freedom of information in China, he is also engaged in constructing legal information systems to provide free access to Chinese law and legal doctrine for the public, and has been awarded a national prize. His thesis has won the Intersentia Prize for the Best Ph.D. Thesis in Law at HKU.



CLEMENT CHEN

Faculty of Law,
University of Hong Kong

China



JEAN-MARC HAUSMAN

Faculty of Law,
University of Louvain

Belgium

Jean-Marc Hausman holds a Bachelor of Philosophy, a Master of Criminology, an Advanced Master in Human Rights and a Doctorate in Law. His dissertation analysed the legal and regulatory instruments (Belgian and international) related to the organization and the running of population-based biobanks set up for medical or scientific research purposes. Jean-Marc Hausman is an Assistant Professor at the University of Louvain (UCLouvain), where he teaches courses on “Civil Law”, “Ethics applied to Law”, “Introduction to Law”, and “Deontology of psychologists”. He is also a legal counsel for BWB – Biothèque Wallonie Bruxelles – which manages a virtual catalogue of biospecimens collected in hospitals, clinics, and laboratories. He works as a teaching assistant in legal history at the Université libre de Bruxelles (ULB). Jean-Marc Hausman has been appointed as an alternate member of the Federal Commission for Embryos (FCE) by the Belgian Senate.



ROSARIO ISASI

School of Medicine,
University of Miami

United States

Rosario Isasi, J.D., M.P.H., is a Research Assistant Professor at the Miller School of Medicine with appointments in the Dr. J. T. Macdonald Foundation Department of Human Genetics, the Institute for Bioethics and Health Policy, the John P. Hussman Institute for Human Genomics, and the Interdisciplinary Stem Cell Institute. Her expertise is in the area of comparative law and ethics regarding genomics and regenerative medicine. Ethics Advisor of the European Commission's European Human Pluripotent Stem Cell Registry (hPSCREG), member of the American Society for Human Genetics (ASHG) Task Force on "Gene Editing," Academic Secretary of the International Stem Cell Forum Ethics Working Party, and leader of the Governance Working Group of the International Stem Cell Banking Initiative (ISCBI). She contributed to the development of harmonized ELSI and educational tools for Canadian Blood Services' National Public Cord Blood Bank, the Centre for the Commercialization of Regenerative Medicine (CCRM), and the Bioethics Education Project of the Royal College of Physicians and Surgeons of Canada. With the CGP, she continues to collaborate in four projects related to stem cell research and regenerative cell therapy.

Eric M. Meslin is President and CEO of the Council of Canadian Academies, founding Director of the Indiana University Center for Bioethics, Professor of Medicine, of Medical & Molecular Genetics, of Bioethics and Law, of Public Health, and of Philosophy. He is also an Invited Scholar in the Department of History and Philosophy of Science at the University of Cambridge and at the Centre of Genomics and Policy. Prior to Indiana, he was Bioethics Research Director of the Ethical, Legal and Social Implications (ELSI) program at the U.S. National Human Genome Research Institute, and then Executive Director of the National Bioethics Advisory Commission appointed by then President Bill Clinton. In 2015 he was appointed Vice-Chair of the UK Biobank Ethics and Governance Council. Among his honours, Dr. Meslin is a Fellow of the Canadian Academy of Health Sciences and a Chevalier de L'Ordre Nationale du Mérite (Knight of the National Order of Merit) for his contributions to French bioethics policy. His work as an Invited Scholar in the CGP focuses on projects related to regenerative medicine.



ERIC MESLIN

Council of Canadian Academies

Canada

Jennifer Stoddart was awarded an honorary doctorate in 2013 by the University of Ottawa and again in 2015 by McGill University. In June 2011, the Québec Bar awarded her the distinctions of Avocat émérite and Mérite Christine-Tourigny. She was appointed Officer of the Order of Canada in December 2015, for her international leadership in privacy rights and for her exemplary public service as the privacy commissioner of Canada (2003-2010). In her role as commissioner, she gave an annual report to Parliament about privacy trends and results of privacy audits of government departments. She represented Canada at the annual International Conference on Privacy and Personal Data Protection. She 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.



JENNIFER STODDART

**Centre of Genomics and Policy,
McGill University**

Canada



BRIGID UNIM

**Department of Public Health
and Infectious Diseases**

Sapienza University

Italy

Brigid Unim is a PhD fellow at the Department of Public Health and Infectious Diseases - Sapienza University of Rome, Course Coordinator: Prof. Stefano D’Amelio. She is currently attending the first year of her course. Brigid Unim has been collaborating in different areas of research at the Department of Public Health and Infectious Diseases, such as health education and health promotion; epidemiology and prevention of chronic diseases; epidemiology and prevention of infectious diseases; infectious disease surveillance and statistical analysis.



DANYA VEARS

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

Belgium

Danya Vears commenced her position with CBMER in June 2015. She is currently working as a postdoctoral researcher on a collaborative project with the Centre of Genomics and Policy exploring the ethical and legal challenges of whole genome sequencing in children under the supervision of Prof. Pascal Borry. Prior to this, Danya completed her PhD at the University of Melbourne, Australia. Her thesis was entitled *Genetic carrier testing in children: perspectives of parents and genetic health professionals*. In 2009, she obtained her Master of Genetic Counselling at the University of Melbourne. Prior to this, she worked as a senior research assistant at the Epilepsy Research Centre for eight years, exploring the genetic basis of epilepsy.

Dr. Susan E. Wallace is an Honorary Lecturer of Population and Public Health Sciences in the Department of Health Science, University of Leicester, UK. She is also an Invited Scholar at the Centre of Genomics and Policy, McGill University, Montréal, Canada, and at the Centre for Health, Law, and Emerging Technologies (HeLEX), Nuffield Department of Population Health, University of Oxford, UK. Her research interests include the legal and policy implications of population-based and disease-based longitudinal cohort studies and biobanks; the ethical issues surrounding the collection, use, linking, and sharing of research data across international borders; and research ethics review. Currently, she is a member of the Ethics and Governance Council of UK Biobank and the Scientific Advisory Boards of ELIXIR and the University of Leicester's EXCEED study. She also sits on the International Cancer Genome Consortium (ICGC) Ethics and Governance Committee and the ICGC UK Prostate Project Oversight Group. She was a member of the Nuffield Council on Bioethics Working Party on Biological and Health Data. She actively contributes to the work of tasks teams in the Global Alliance for Genomics and Health.



SUSAN WALLACE

Department of Health Sciences,
University of Leicester

United Kingdom

PhD STUDENTS



**GABRIELLE
BERTIER**

“**Clinical implementation of Next-Generation Sequencing in pediatrics: A multidisciplinary analysis of policy implications**”

My thesis project analyses the current use of Next-Generation Sequencing technologies in the clinic. Focusing on France and Quebec, I am analyzing the ethical, legal, social and policy implications of the use of such technologies, in pediatric patients with undiagnosed rare diseases and relapse or refractory cancers.

Supervisor: Yann Joly, Centre of Genomics and Policy, McGill University.

Co-Supervisor: Anne Cambon-Thomsen, UMR 1027, Inserm, Université Toulouse III - Paul Sabatier.

“**The Role for Images of Human Genomic Engineering in Assessing Societal Views Relevant to Policy**”

By analyzing the longstanding cultural repository of images concerning the selection of human traits, my thesis project aims to develop a theory of the socio-cultural influences on various communities’ beliefs and values toward the use of gene editing technology.

Supervisor: Yann Joly, Centre of Genomics and Policy, McGill University.

Co-Supervisor: Rob Sladek, Department of Human Genetics, McGill University



DEREK SO



**VASILIKI
RAHIMZADEH**

“**Evaluating the gap between research ethics review governance and data sharing for pediatric genomics in Canada**”

My dissertation aims to characterize the relationship between research ethics review processes (in terms of time and cost), and data sharing practices for six, large-scale genomic projects involving children across Canada.

Supervisors: Bartha M. Knoppers, Centre of Genomics and Policy, McGill University and Gillian Bartlett, Department of Family Medicine, McGill University.

MASTER STUDENT

“**Genomic Medicine in International Health: The Role of International Open Science Genomic Projects**”

My thesis aimed to document the impact of international open science genomic projects’ innovation policies on research and development in genomics, capacity building and access to genomic medicine in developing countries.

Supervisors: Centre of Genomics and Policy, McGill University.

Co-Supervisor: Konstantia Koutouki, Faculty of Law, Université de Montréal.



**MARTIN
HÉTU**

EVENTS 2016



SUMMER SEMINAR SERIES

(June 29 - September 22)

Each year, the CGP invites its members and Invited Scholars 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 emerging issues in different fields.

JORDAN WORKSHOP

(December 21 - 22)



Ma'n H. Zawati led a two-day training workshop for members of the Institutional Review Board of the King Hussein Cancer Centre (KHCC) in Amman, Jordan. The session focused on the ethical and legal issues faced by cancer-specific biobanks. The meeting was attended by the CEO, COO, CMO of the KHCC, the IRB members of the institution as well as the Heads of the Hospital Departments.

RESEARCH ETHICS WORKSHOP SERIES

(January 25 - December 14)

The interactive series of the McGill Skillsets Research Ethics Workshops that took place in the 2016 academic year allowed participants (students, Faculty and staff) 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: informed consent, privacy and confidentiality, commercialization, research integrity, authorship and also data sharing.

COMPLETED RESEARCH PROJECTS

Access to Health Insurance in the
Context of Personalized Medicine **23**

Réseau de médecine génétique
appliquée (RMGA) Infrastructure **23**

From Banking to International
Governance: Fostering Innovation
in Stem Cell Research **24**

International Stem Cell Forum
Ethics Working Party (EWP) **25**

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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, and develop new diagnostic tests as well as improved therapies. The CGP led the sub-project on “Insurance and Personalized Medicine”, which aimed 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 Québec. Our main objectives included: 1) analyzing the normative insurance framework in Québec; 2) reviewing insurance proposition form requirements; and 3) analyzing consent forms (for diagnostic tests in clinical and research contexts).

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Réseau de médecine génétique appliquée (RMGA) Infrastructure

April 2008 – March 2016

The RMGA is a Québec 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 Québec population. The Network has 350 members representing the majority of human genetics researchers in Québec. The RMGA included a Legal and Socio-Ethical Issues Infrastructure at the CGP that considered issues arising from the research activities of the RMGA members and provided ELSI guidance on emerging issues. In 2016, the CGP consolidated a decade of RMGA policies into a prospective *Statement of Principles*.

From Banking to International Governance:

Fostering Innovation in Stem Cell Research

October 2011 – March 2016

International initiatives are addressing the harmonization and standardization of stem cell research and banking (e.g. International Society for Stem Cell Research (ISSCR) and the International Stem Cell Banking Initiative (ISCBI)). Until recently, 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, we assessed if they could thrive by applying the lessons learned in biobanking generally. We examined the current national and international SC banking landscapes 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 also developed “international governance models” and a “Points to Consider” for a wide range of stakeholders (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 built capacity by training and mentoring future ELSI researchers.

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We developed “international governance models” and a “Points to Consider” for a wide range of stakeholders.

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International Stem Cell Forum Ethics Working Party (EWP)

April 2012 – March 2016

Scientific collaboration is a key aspect of the globalization of research and 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 was 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 was chaired by Prof. Bartha Maria Knoppers and its Secretariat housed at the CGP in the Genome Québec / McGill University Innovation Centre. In 2016-2017, Rosario will become Chair.

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

Harmonizing Privacy Laws to Enable International Biobank Research

September 2014 – July 2016

This project compared and analyzed national and international privacy frameworks applicable to genomic databases and biobanks. A series of articles were prepared on the privacy frameworks in place in 21 countries.

Each article surveyed the privacy instruments as well as the legal and policy materials in place in a given jurisdiction, and provided a legal analysis and critical evaluation of those instruments and materials. The general political and research contexts of the country or region were introduced and a description of its biobanking ecosystem was provided. This was then followed by a comprehensive description of the legal and regulatory privacy framework applicable to genomic databases/biobanks in the country or region. Each article concluded with a critical evaluation of the national privacy framework as it related to genomic research privacy, security, and governance. The project had an International Advisory Board (IAB) consisting of three internationally recognized scholars who provided oversight and guidance of the project throughout its development and advancement. The series of articles were published in 2016 in two dedicated special issues in the *Journal of Law, Medicine & Ethics*.

The series of articles were published in 2016 in two dedicated special issues in the *Journal of Law, Medicine & Ethics*. In addition, the CGP in collaboration with P³G, the Institute for Bioethics, Health Policy and Law of the University of Louisville, and the International Society for Biological and Environmental Repositories held the International Biobanking Summit V in 2016 where the team presented the results of the analysis of different national legal approaches to privacy and biobanking as well as the challenges to the international harmonization of privacy laws and the protection and sharing of personal data.

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Cell-based Regenerative Medicine:

New Challenges for EU Legislation and Governance (EUCeLEX)

October 2013 – September 2016

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The aim of this project was to collect and analyze the current European legislation on the therapeutic use of somatic cells and to bridge it with the research infrastructure capacity building. The project was based on a 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 was to examine and enhance the understanding and interpretation of national, regional, and international legal and ethical issues surrounding umbilical cord blood (UCB) research and to provide recommendations. This was 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 provided the Commission with 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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Le séquençage du génome entier :

un « bulletin » génétique pour chaque enfant?

January 2014 – December 2016

The project’s main objective was to study the legal and ethical issues that arise from the use of whole-genome sequencing (WGS) in minors. Our results contributed to: 1) the development of two policies on the use of WGS in minors – one for the research setting and the other for the clinical setting; and 2) the elaboration of a prospective analysis detailing the implications associated with the eventual use of WGS in paediatrics within the realm of direct-to-consumer (DTC) testing and neonatal screening.

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Enhanced CARE for RARE Genetic Diseases in 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.

Framework for Decision-Making for Rare Diseases

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.

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Innovative Chemogenomic Tools to Improve Outcome in Acute Myeloid Leukemia

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 (PERSPECTIVE)

April 2013 – March 2017

The project is designed to significantly extend the benefits of the current high-quality population breast cancer screening programs, 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

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

April 2014 – March 2017

In Canada, Immigration, Refugees, and Citizenship Canada (IRCC) representatives increasingly resort to DNA testing to confirm biological filiations in the realm of immigration sponsorship possibly leading to genetic discrimination and the biologization of the concept of family. In collaboration with the Canadian Council for Refugees, this project proposes a multidisciplinary analysis 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.

This analysis resulted in three articles and a workshop which was organized with the participation of representatives of IRCC, the Canadian Human Rights Commission, international experts, and practicing lawyers to identify common issues and reflect on potential avenues for reform to be considered by Canadian policymakers and other stakeholders.

Regenerative Cell Therapy Network (RCTN)

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 centres 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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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

May 2015 – April 2017

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 of 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 patients 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.

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Treatment of Patients with Corneal Limbal Stem Cell Deficiencies Using Cultured Epithelial Corneal Autografts

September 2016 – October 2017

This project will complete our clinical trial and allow us to seek Health Canada approval for a new modality of treatment for corneal limbal stem cell deficiency (“LSCD”) using cell therapy. LSCD is a severe disease caused by damage or depletion of the corneal stem cells in the limbal region of the eye following trauma/disease. The epithelial tissue of the cornea can no longer regenerate resulting in chronic inflammation, conjunctivalization, and vision loss. To treat LSCD patients, we developed a tissue engineering technique involving massive expansion of epithelial cells in vitro to produce epithelial sheets for autologous transplantation (cultured epithelial corneal autografts –“CECA”). After twenty-five years of experience with skin substitutes using cultured epithelial autografts (“CEA”) on burn patients, we successfully demonstrated the effectiveness of CECA (pre-clinical studies in animal models), reconstructed human corneas in vitro (CECA), and initiated a clinical trial of a new treatment for which Health Canada approval will be sought with the help of the Centre of Genomics and Policy. Our team of scientific researchers, clinicians, and ethical/legal experts – with extra funding support from CHU de Québec Hospital Foundation, the FRQS, ThéCell Network – will be the first in Canada to offer CECA treatment for unilaterally blind or vision impaired patients suffering from LSCD.

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Integrative Epigenomic Data Coordination Centre (EDCC) at McGill

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 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. As part of CGP’s collaboration, 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.

Multidimensional Epigenomics Mapping Centre (EMC) at McGill

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 and Society (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

April 2009 – March 2017

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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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.

GE³LS Network in Genomics and Personalized Health

April 2016 – March 2018

The 2012 Genome Canada large-scale applied research project competition, genomics and personalized health (GAPH), funded 17 projects. Each project integrates technology assessment and social science and humanities research under the banner of the signature genome canada GE³LS initiative (i.e. genomics and its ethical, environmental, economic, legal and social aspects).

In 2016, Genome Canada announced funding for a network to bring together GE³LS researchers from all 17 projects. The network will enable the projects to share best practices; improve and prime future collaborative research; accelerate the progress to market of gaph technologies; and maximize the impact of investment in the gaph projects.

The network will address four priority GE³LS themes: research ethics review; health economics and health technology assessment; knowledge transfer and implementation in health systems for 'omics technologies; and intellectual property and commercialization.

This \$2 million initiative is designed to accelerate the translation of research results into practical applications in healthcare for the benefit of Canadians. The government of Canada, through Genome Canada, is investing \$1 million in the network, with the balance of funding to be secured from co-funders.

Objectives for each network theme were outlined by GE³LS and science representatives from each of the 17 projects at a workshop in April 2015. A network management team (network co-leads and theme leads) will monitor progress on each objective.

By identifying and directing research to overarching issues that emerge from the GE³LS components of the 17 projects, the network will accelerate their common goal of transforming research results into practical applications adopted by health systems for the benefit of patients.

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

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 such research.

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

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Réseau en soins de santé personnalisés-Q-CROC

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.

Predisposition, Prediction et Prevention du Cancer du Sein (PREVENTION)

April 2016 – March 2019

Evidence suggests that the majority of breast cancers develop in a small proportion of women with susceptibility to the disease. The identification of these is a determining factor in the effectiveness of prevention. Currently, high-risk women are mainly identified on the basis of a family history of cancer and screening for mutations in BRCA1 and BRCA2 genes. However, recent breakthroughs in genomics have led to the identification of a large number of genetic variations associated with breast cancer. These include variations/rare mutations in new genes or predisposition/rare mutations in novel susceptibility genes, conferring a range of moderate to high risks, as well as common variations (SNPs) associated with the risks of cancer <1.5 times the risk of the general population. Knowing that SNPs act multiplicatively, they can be combined into a polygenic risk profile in order to stratify women, with or without family history, according to their individual risk. A much more accurate risk prediction could be obtained by combining data from all genetic variations (frequent and rare) with other recognized risk factors. It is imperative to conduct studies using large international cohorts in order to obtain reliable estimates of individual risk in order to improve models of prediction of risk of breast cancer/risk prediction models and better adapted therapies, facilitating the identification of women who can benefit the most (substantially) from the approaches of prevention, reduction of risk and of the best adapted therapy/treatments. This is why two major projects were set up: PERSPECTIVE, led by the Québec team, and BRIDGES, funded by the European Commission-Horizon 2020 (09/2015-08/2020), of which Université Laval is a partner without funding. Professor Simard's participation was decisive and the results of PERSPECTIVE will be very useful for the realization of several BRIDGES objectives. The funding of the MEIE for the project will come at a pivotal time, permitting the consolidation of the leadership of the Québec team in the BRIDGES project, which will be all the more critical since the financing of PERSPECTIVE will end in March 2017. Our results will improve targeted disease prevention in the context of oncogenetic/ oncogenic clinics and the breast cancer screening program in Québec.

Fondation du cancer du sein
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l'Économie, de la Science
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A Syst-OMICS Approach to Ensuring Food Safety and Reducing the Economic Burden of Salmonellosis

October 2015 – September 2019

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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 constraints as 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.

Programme de Recherche et d'Innovation Sur les Maladies rarES (PRISMES)

April 2016 – March 2020

In a framework of scientific collaboration, the Centre of Genomics and Policy (CGP) will oversee and prepare the ethical documents required for initial approval by the Research Ethics Committee of CHU of the Québec-Université de Laval. Subsequently, the CGP will provide support on ethical and legal issues, including changes/modifications to ethical documents or preparation of documents arising from the evolution of the research Program and the initiation of new collaborators with groups of international research.

How the early environment interacts with prenatal adversity and genetic susceptibility to moderate the risk for anxious and depressive disorders from infancy to early adolescence - the moderating effect of maternal care and the mediating effect of temperament

April 2016 – March 2021

The precocious and chronic course of depression makes it the disease with the leading cause of disability, an effect marked by a 2-fold difference in the rate for girls and women as of early adolescence. Arguably what is missing is not a list of risk factors, but rather a precise knowledge of how factors interact to predict those at higher risk. For instance, differences by gender in the response to stress are well documented in early emotional development, but evidence is needed in older children and adults. Genetic differences in susceptibility to prenatal events are also important. Likewise, early maternal care might be a significant positive or negative influence on the effect of prenatal, gender and genetic risk. The project gives the opportunity to collaborate in four prolific international longitudinal cohorts to communicate, share and reproduce models and findings about early factors in the prediction of early age psychopathology. The cohorts in Canada (Maternal Adversity, Vulnerability and Neurodevelopment), the United Kingdom (Avon Longitudinal Study of Parents and Children), the Netherlands (Generation- Rotterdam) and Singapore (Growing Up in Singapore Towards Health Outcomes) include and share measures of genes, maternal care, child psychopathology, and data of a sensitive nature with different consent forms, measures, access approaches, laws and regulations. The role of the CGP will be to act as a collaborator-consultant, supporting the project with analysis, reflections and recommendations that pertain to the ethics and legality of: 1. Safeguarding child genomic data, 2. Sharing data across four national jurisdictions, 3. Maintaining standards of international IRB, and 4. Issues of consent and the need to re-contact for child data as subjects become adults.

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Research Advancement through Cohort Cataloguing and Harmonization (ReACH)

April 2016 – March 2021

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More and more Canadians are affected by chronic diseases such as cancer, cardiovascular disease, chronic obstructive lung disease, diabetes, and mental illnesses. Many of these conditions have their origins in early life (conception, pregnancy, infancy, and childhood). Numerous outstanding Canadian pregnancy and birth cohort studies have been implemented to explore hypotheses related to the Developmental Origins of Health and Disease (DOHaD).

The Research Advancement through Cohort Cataloguing and Harmonization (ReACH) initiative was formerly established in 2016 to provide the Canadian research community with the means to leverage and carry out leading-edge collaborative research. The ReACH initiative will provide resources in the form of a comprehensive web-based catalogue and a harmonization platform to optimize and expand the use of Canadian pregnancy and birth cohorts data and biological samples. Ultimately, the ReACH initiative will enhance the capacity for collaborative and cross-disciplinary research (outputs generated faster and at a lower cost); expand research perspectives (leverage national and international collaborations); improve quality of research practices; and foster the development of innovative and reliable evidence-based research on the Developmental Origins of Health and Disease.

Sino-Canada HeLTI: A Multifaceted Community-Family- Mother-Child Intervention Study for the Prevention of Childhood Obesity (SChELTI)

April 2016 – March 2021

The epidemics of obesity and metabolic syndrome related disorders are a major public health concern. Increasing evidence points to the role of early life adverse factors in the developmental origins of the vulnerability to such metabolic disorders. Reducing the risk of overweight and obesity (OWO) from early life stages will produce substantial benefits to decrease population burdens of metabolic diseases. However, current intervention measures remain insufficient to halt the increasing OWO epidemics. Building on our strengths in large birth cohort studies, clinical trials and studies on developmental programming of metabolic disorders, our transdisciplinary Sino-Canadian team will conduct a community-based multi-centre cluster-randomized controlled trial to test the effect of an evidence-based and multi-faceted early life-course community family-mother-child interventions package incorporated into the routine pre-conception, prenatal and child care systems on childhood OWO rates in 1-6 years old children in China. The mechanisms (microbiome, epigenetics, micro RNAs) that may underline the development of OWO will be explored, as well as the impacts of the intervention. The research program will for the first time evaluate an integrated intervention package from pre-conception and early pregnancy into childhood on OWO rates. The findings will produce a scalable community-based intervention package that may be recommended for implementation at regional and national level to reduce the risk of OWO and metabolic syndrome related disorders in China.

The CGP develops appropriate policies and tools to facilitate the use of the cohorts included in this project. More specifically, the CGP develops the governance framework as well as the data access and biospecimen sharing policy. The tools created by the CGP will aim to facilitate policy interoperability and access authorizations as well as streamline the ethical and legal aspects of international collaborative research. Furthermore, the CGP offers to SChELTI researchers ongoing ethics and policy support throughout the project.

Canadian Institutes of
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/ The National Natural
Science Foundation of
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The gender specific effects of prenatal adversity on the development of anxious and depressive psychopathology in early adolescence – the moderating effect of genes and early maternal care

April 2016 – March 2021

There is a considerable amount of evidence for gender dimorphic effects of prenatal stress. Gender effects have been found on the placenta, the fetus, the infant and the child, although inconsistently. Girls may be more susceptible to the effects of fetal adversity on fearful temperament, emotional reactivity and internalizing problems increasing their risk for the development of affective problems. Very little research has directly examined whether gender differences in the effect of fetal adversity are maintained in the prediction of anxious and depressive psychopathology in older children. A landmark study reports that maternal prenatal depression is associated with an increased risk of depressive symptoms in 18 year-old offspring in females. Although inconsistent findings can be explained by multiple factors (including for example variations in the measurement of prenatal stress exposure), this study suggests the need to carefully consider how gender and prenatal adversity interact in a longitudinal design, and to consider the role of genotype and the postnatal environment. Accordingly, gender considerations will be approached as follows: (1) carefully examination of gender-based age-specific trends in the developmental of anxious and depressive psychopathology from preschool age to pre-adolescent age; (2) the moderation of gender effects for anxious and depressive psychopathology by genetic susceptibility; (3) the role of early maternal care; and, (4) early temperamental signals of vulnerability to anxious and depressive psychopathology.

The CGP's role is to design the guidelines for the ethics and legality of: (i) the safeguarding of genomic data from children; (ii) the sharing across four national jurisdictions of biologic data; (iii) the maintenance of standards by international IRB's; and, (iv) the consent for use of data from children as subjects become adults.

RESEARCH AWARDS

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 (GA4GH). The Chair will work on establishing models for data access that take into account the different levels of data sensitivity and use in order to streamline the process and reduce delays.

CANADA RESEARCH CHAIR IN LAW AND MEDICINE

Prof. Bartha Maria Knoppers, PhD



Canada Research
Chairs

Chaires de recherche
du Canada

Canada

**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 University). 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 Québec.

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, paediatric 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 Centre of
Genomics and Policy

and WYNG TRUST
Visiting Scholar Program
(2016-2019)

Prof. Bartha Maria Knoppers, PhD

Thanks to a collaborative agreement with the Centre for Medical Ethics and Law of the University of Hong Kong (CMEL) and the WYNG Foundation, we are pleased to introduce the CGP / Wyng Trust Visiting Scholars Program.

The research of our Visiting Scholars will be dedicated to the emerging topics of (i) international data sharing and (ii) cancer research and screening/biobanking. This emphasis will cement existing connections with academics working in the Law and Technology Centre on issues of privacy and data sharing and the 'Children of 1997' project supported by the WYNG Foundation. The first international conference uniting CGP with its Cambridge UK (PHG Foundation) and Hong Kong (CMEL) partners will take place in April 2017. This conference entitled "Who Owns your Body?" will discuss issues of property rights in human bodies, tissue, and data as well as matters on human organ transplantation.

The CGP would like to thank the WYNG Foundation for this award.

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.

Developed in collaboration with the Centre of Genomics and Policy (CGP), the Public Population Project in Genomics and Society (P³G)'s International Policy interoperability and data Access Clearinghouse (IPAC) offers a “one-stop” service for national and international collaborative research projects. It provides services to assist international researchers in meeting ethical and legal regulatory requirements governing genetic/genomic their collaborative, international projects. The IPAC provides four main types of services:

Generic Clauses/Agreements Database

This tool is useful to both international and national projects. The Database offers templates, as well as approximately 180 generic clauses for 6 different types of ELSI-related documents.

Data Access Compliance (DAC)

The DAC office services both international and national research projects. It receives and reviews data access applications for access to controlled datasets, in conformity with the goals and policies of the project.

ELSI Interoperability Screening

This service creates a wide range of customized tools (consent forms, data access policies, material/data transfer agreements, re-contact, return of results, publications and intellectual property policies, etc.) to foster the interoperability of international and national research consortia and projects.

DataTrust (DT)

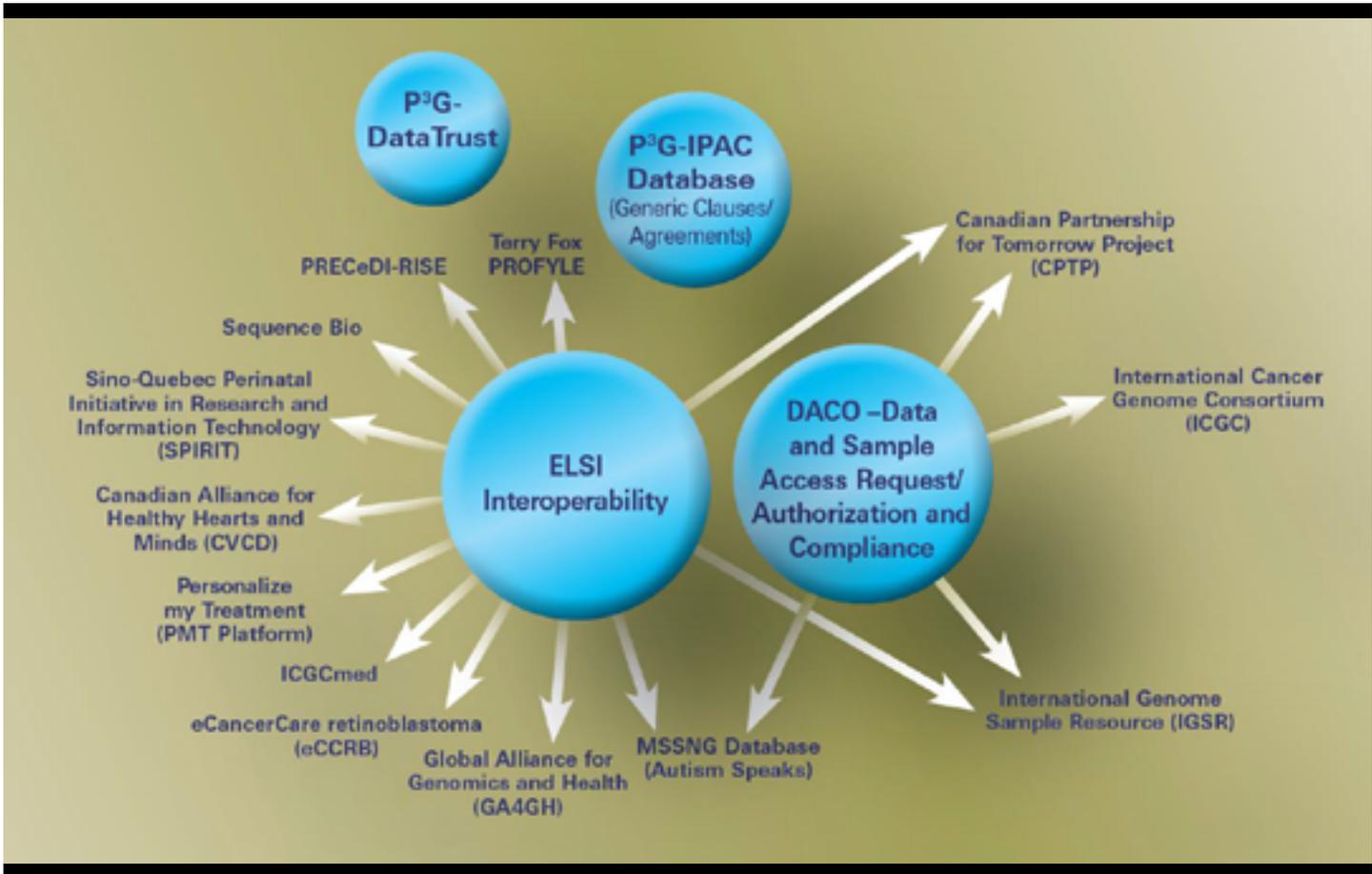
This service supports the process of re-contacting participants and returning individual-level results in translational research projects, when appropriate. The DataTrust provides a separate, independent gatekeeping function for the final verification of ethical or legal requirements prior to any return.

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 IPAC receives a request requiring a country/region-specific expertise.

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Ellen Clayton, USA
Jantina de Vries, South Africa
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Nils Hoppe, Germany
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Pedro Rondot Radío, Argentina
Emmanuelle Rial-Sebbag, France
Sharon Terry, USA
Susan Wallace, UK
John Wilbanks, USA



In 2016, the P³G-IPAC has been involved in providing services to a number of different international and Canadian projects, including: Canadian Partnership for Tomorrow Project (see pg 50), The Canadian Alliance for Healthy Hearts and Minds (see pg 51), Centre of Excellence in Biomarker-Driven Clinical Research for Personalized Medicine in Cancer (see pg 37), Opti-Thera (see pg 52).

CGP & P³G<IPAC

COLLABORATIONS

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

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 (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.

Canadian Partnership for Tomorrow Project (CPTP)

April 2009 – March 2017

The Canadian Partnership for Tomorrow Project (CPTP) enrolls 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 (P³G), 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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Cancer Research (OICR)

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The Canadian Alliance for Healthy Hearts and Minds

April 2013 – March 2017

The Canadian Alliance for Healthy Hearts and Minds (CAHHM) is a landmark national research study aimed at understanding the causes, contextual risk factors, and the development of chronic diseases such as heart disease, stroke, dementia, and cancer. The study collects information from participants who answer a series of questionnaires about their health, diet, physical activity engagement, access to health services, community environment, and cultural experience, provide blood samples and their physical measurements (weight, height, and blood pressure), and undergo a magnetic resonance imaging scan. The information collected by the CAHHM project will be added to the Canadian Partnership for Tomorrow Project to build a major tool for Canadian health research that can be used by National and International scientists for future investigations. From 2013-2017, the approximate number of participants aged 35-69 from across Canada for CAHHM will be approximately 10,500. In 2016, P³G, CGP, and the Policy Research Program continued to work with the research team of the CAHHM to answer queries and consult on ethical/legal issues.

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

April 2014 – March 2017

The Sino-Québec Perinatal Initiative in Research and Information Technology (SPIRIT) was created to promote collaboration in epidemiological and fundamental research concerning the intrauterine determinants of health and child development as well as research on perinatology health services in Shanghai and in Québec. SPIRIT intends to set forth updated guidelines, health policies, and transfer activities in the clinical setting.

In order to achieve this, the Centre of Genomics and Policy and P³G work in the development of a governance framework to harmonize the use, sharing, and management of health-related data and biological samples as well as in the drafting of an ethical and legal framework that allows access to Québec medical and hospital data for research and monitoring purposes. This collaboration is expected to reinforce strategic positioning of our academic and industrial partners in Québec, China, and internationally by accentuating access to new markets/expertise and by developing harmonized products adapted to perinatal research.

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

April 2014 – May 2016

The OPTI-THERA project aims to 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 conducted research concerning: the legal aspects surrounding insurance and the use of genetic information and examined the role of a trusted third party within a personalized medicine context.

Collaborating closely on this project, the Population Project in Genomics and Society (P³G) reviewed and amended the project's consent forms; provided ongoing ethics support (i.e. ethics approval); and developed policies and procedures regarding the clinical assessment and gate keeping functions.

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HumGen-Database

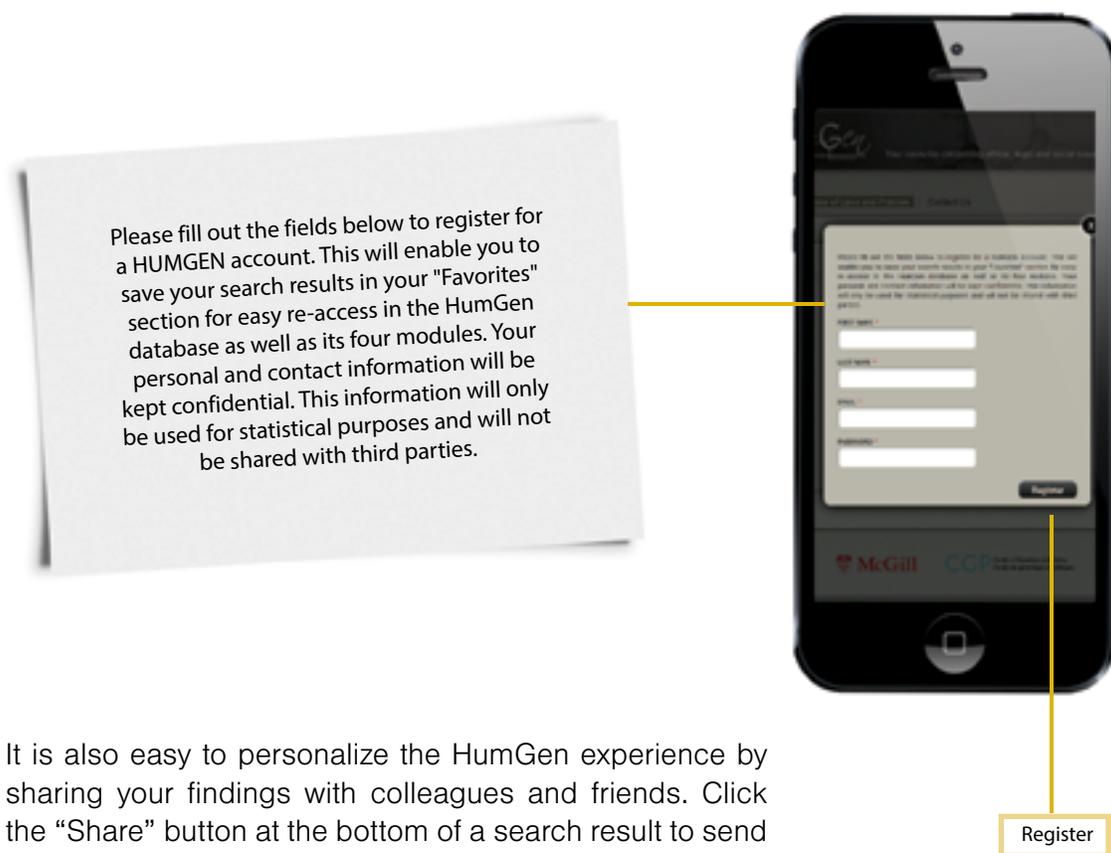
<http://www.humgen.org>



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 and suscribe to our YouTube channel.

 @genomics_policy

 Centre of Genomics and Policy

TEAM PUBLICATIONS 2016

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