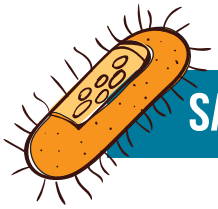
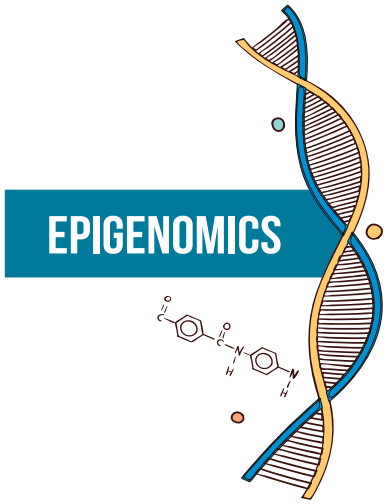


SALMONELLA

ANNUAL REPORT 2017

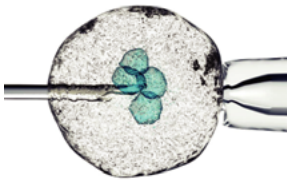


EPIGENOMICS

PEDIATRICS

PERSONALIZED MEDICINE

CANCER



REGENERATIVE MEDICINE

RARE DISEASES

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CGP Centre of Genomics and Policy
Centre de génomique et politiques

McGill

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Message from the DIRECTOR

Dear Readers,

I am pleased to share the 2017 Annual Report of the Centre of Genomics and Policy. This report highlights the work of our dedicated staff, and shares their research interests with you. Once again, we present our Invited Scholars who made this year exciting and fruitful. Our Invited Scholars joined us from Canada, the United States, the United Kingdom, the Netherlands, and Italy.

In November of this year, I became Fellow of the Royal Society of Canada, and gave the prestigious Galton Lecture in the United Kingdom. Furthermore, our Research Director, Prof. Yann Joly, was named Fellow of the Canadian Academy of Health Sciences.

This year's Annual Report 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. During 2017, the research of CGP members significantly supported efforts by the Global Alliance for Genomics and Health (GA4GH) to develop regulatory and ethics policies and tools that enable international data sharing. CGP Members contributed to an Ethics Review Recognition Policy and to a data sharing guidance for sequencing in pediatric and dementia research contexts, as well as a Mobile Health App Consent Inventory, an international survey of participants' data sharing attitudes (YourDNAYourSay.org), and an Automatable Discovery and Access Matrix. In addition, they helped to launch GA4GH:CONNECT, a new phase of the organization, and an accompanying 5 year Strategic Plan for collaboration across the international genomics community.

Moreover, you will learn about our Centre's work in promoting training in Canada through the McGill Skillsets Program's Research Ethics Series, our Summer Seminar Series, and through our multitude of workshops. The Centre has also hosted a public engagement event, which included a presentation by Senator Jim Cowan.

Through this report, 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,

For the Centre, the year 2017 has provided a unique opportunity to redefine our strategic research priorities in light of the most recent scientific developments in artificial inteligence (AI), genomics and related fields. The CGP was asked to contribute a substantial number of applications in the context of the 2017 Large-Scale Applied Research Project (LSARP) Competition: Genomics and Precision Health of Genome Canada, to demonstrate the high opinion of the community towards the ingenuity, quality and relevance of our work. Fortunately, the time spent on grant applications did not affect the high productivity of our team, which includes four students. Together, we published a total of 47 articles in high profile journals such as PLOS ONE, Nature Regenerative Medicine, Nature Neuroscience, and the New England Journal of Medicine, to name a few. We were also pleased to welcome a new post-doctoral researcher Charles Dupras, B.Sc., M.Sc., Ph.D., who was awarded a three-year fellowship (2017-2020) by the Canadian Institutes of Health Research (CIHR), for pursuing his research on the translation of emerging knowledge in epigenetics.

With a new year upon us, we look forward to expanding our collaborations with our research colleagues in Canada and abroad, while working towards including a greater diversity of participants in our research. It goes without saying that our team will continue to propose varied, multidisciplinary, and sophisticated methodologies to help in the implementation of novel science from research to the clinic.

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.

@genomics_policy

Centre of Genomics and Policy

CGP TEAM

PROFESSOR
KNOPPERS Bartha Maria - DIRECTOR

ASSOCIATE PROFESSOR
JOLY Yann - RESEARCH DIRECTOR

EXECUTIVE DIRECTOR
ZAWATI Ma'n H.

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GRANADOS-MORENO Palmira
HAGAN Julie
KLEIDERMAN Erika
LÉVESQUE Emmanuelle
NGUENG FEZE Ida
NGUYEN Minh Thu
PACK Amy
PHILLIPS Mark
SAULNIER Katie
SÉNÉCAL Karine
SONG Lingqiao
TASSÉ Anne-Marie
THOROGOOD Adrian

ASSOCIATE MEMBERS
BEREZA Eugene
GOLD Richard
KIMMELMAN Jonathan

SCIENTIFIC CONSULTANTS
AVARD Denise
LABERGE Claude

POST DOCTORAL FELLOW
DUPRAS Charles

PHD STUDENTS
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NOOHI Forough
RAHIMZADEH Vasiliki
SO Derek

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ISASI Rosario
ISSA Amalia
STODDART Jennifer
UNIM Brigid
van den IJSSEL Dalisa
van DUIJN Cornelia
YOTOVA Rumiana

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BOILY Audrey
CARON Roxanne
CAULFIELD Alison
GOODRIDGE Vinca
LAGUIA Kristen
LANG Michael
McLAUCHLAN David
OLVERA Elena
PINKESZ Miriam
TOURÉ Seydina

INTERNS
JIAO Yue
VARGAS Karla Manzano

ADMINISTRATORS
HOZYAN Rose-Marie
THORSEN Nadine

CGP DIRECTORS

BARTHA MARIA KNOPPERS

DIRECTOR

(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 is the Canada Research Chair in Law and Medicine (CRC) and holds four Doctorates Honoris Causa. She is Fellow of the AAAS, the Hastings Centre (bioethics), the Canadian Academy of Health Sciences and the Royal Society of Canada, and 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, and 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), and co-chairs the Ethics and Regulatory Foundational Workstream of the Global Alliance for Genomics and Health (GA4GH).

RESEARCH DIRECTOR

YANN JOLY

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). In 2016 he was awarded a teaching award, and in 2017 he became a Fellow of the Canadian Academy of Health Sciences (CAHS).

EXECUTIVE DIRECTOR

MA'N H. ZAWATI

Ma'n H. Zawati (LL.B., LL.M.): is a 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 health care 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 presented on these topics in Canada and internationally. In 2014, the Young Bar Association of Montreal named him as a "Lawyer of the Year" awardee. In 2015, he received the Queen Elizabeth Jubilee Scholarship and was chosen by the Royal Society of Canada as a Young Investigator of the Year.

ACADEMIC ASSOCIATES

GRATIEN DALPÉ

Gratien Dalpé completed his undergraduate and master studies (B.Sc/M.Sc) in biochemistry at the University of Sherbrooke. He holds a doctorate degree (Ph.D.) in molecular biology from the University of Montreal. He later worked as a post-doctoral fellow and research associate at the Samuel Lunenfeld Research Institute in Toronto. During his career, he uncovered new molecular signalling networks regulating the development and degeneration of the nervous system. With an interest in law and bioethics, he later obtained his LL.B. in civil law at the University of Montreal and joined the Centre of Genomics and Policy as an academic associate in 2017. His current work involves research translation, genomic medicine, genetic discrimination and the participation of vulnerable persons in research.

STEPHANIE O.M. DYKE

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, and as policy adviser at the Wellcome Trust Sanger Institute, as well as 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 the same year, 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 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.

PALMIRA GRANADOS

Palmira Granados is a Mexican lawyer specialized in intellectual property and information technologies, and a Doctor of Civil Law candidate at the Faculty of Law at McGill University, under the supervision of Professor Richard Gold. Her interests focus on the intersection of intellectual property, ethics, human genetic information, health, and technology. She joined the Centre of Genomics and Policy (CGP) in 2013. Her work focuses on the social, ethical, and legal aspects of research and development involving human genetic information and technology. Before joining the CGP, she became a member of the International Expert Group of the Innovation Partnership, of the New Researchers Group of VALGEN, and of the Centre for Intellectual Property and Policy of McGill University. Prior to Montreal, she obtained her law degree from la Escuela Libre de Derecho in Mexico and her LL.M from the Faculty of Law at the University of Toronto. She practiced law with a Mexican leading law firm in the area of intellectual property and information technology and was responsible for teaching the course Law and Public Policy at the Instituto Tecnologico Autonomo de Mexico. She has also been closely involved with the Free Software Foundation and the Creative Commons Mexico.

JULIE HAGAN

Julie Hagan has completed her undergraduate and master studies (B.Sc/M.Sc) in sociology at the Université de Montréal. Currently a PhD candidate, she is interested in public participation, the role of 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 the PERSPECTIVE project studying the organizational dimensions of a risk stratification approach to breast cancer screening.

ERIKA KLEIDERMAN

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 was called to the Quebec Bar in 2014. Currently, her research deals with the ethical, legal, and social implications surrounding access to data and genetic information, regulation of stem cells and regenerative technologies, biobanking, and paediatrics. Erika is the Coordinator of the Canadian International Data Sharing Initiative (Can-SHARE) and has also been actively involved in the development of controlled data and biosample access documentation and operating procedures for the Canadian Partnership for Tomorrow Project (CPTP). 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 McGill University Health Centre Research Ethics Board.

EMMANUELLE LÉVESQUE

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 master's thesis is an analysis of the protections offered by the Canadian Charter and the Québec Charter against genetic discrimination in the workplace. At the CGP, she specializes in questions concerning ethical and legal issues in health research, particularly in biomedical, cancer 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, including the PERSPECTIVE project on risk stratification in breast cancer screening. She has published several publications and held conferences on different ethical and legal issues raised by research.

IDA NGUENG FEZE

Ida Ngueng Feze, JD, LLM, is an Academic Associate at the Centre of Genomics and Policy (CGP) at McGill University. Her research focuses on the ethical, legal, and social issues (ELSI) related to health and environmental applications of genomic technologies. Ms Ngueng Feze has conducted several studies on the use of genetic information by third parties and co-authored the first systematic review on the evidence of genetic discrimination in the context of life insurance published in 2013. She has provided training and presented at conferences in Canada and abroad before various stakeholders including patients associations, health professionals, and members of the Canadian Human Rights Tribunal. She is a guest lecturer at Laval University and the University of Montreal. She is a member of the New York Bar and is currently serving on the Board of the Réseau Rose (Resources in Ongogenetics for Support and Education). She holds a Master's degree (LL.M.) in International Law from the Université de Montréal, a Juris Doctorate degree (J.D.) from Howard University School of Law, a certificate in Chinese Law from the China University of Political Science and Law, and a Bachelor of Arts degree (B.A.) in Law and Society with a Minor in Psychology from Ramapo College in New Jersey.

MINH THU NGUYEN

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 Bachelor of Science (B.Sc.) degree in Physical Therapy from McGill University. She was a fellow of the Canadian Institute for Health Research - Health Law and Policy Program (2009) and coordinator of the P3G International Paediatric Research Programme (2012-2013). She has managed the ELSI Platform for the ThéCell Network (stem cell therapies) and has been involved in several Stem Cell Network funded projects dealing with the regulation of cell and tissue therapies in Canada. She has worked on the development of model consent forms for rare disease research projects such as FORGE and CARE for RARE (pan-Canadian) and PRISMES (Quebec). Her work focuses on the socio-ethical and legal aspects of paediatric genetic research, rare disease research, cell/tissue therapy and regenerative medicine. She also has an interest in reproductive health law, particularly issues surrounding emerging reproductive technologies, such as prenatal diagnosis and pre-implantation genetic diagnosis.

AMY PACK

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. Her projects include research integrity, mobile health applications, electronic consent, physician legal obligations in the era of personalized medicine, and authorship attribution. Amy Pack also organizes and presents at the CGP's Summer Seminar Series as well as McGill Research Ethics Workshop Series. She is the Coordinator of the HumGen international database search engine promoting online access to widespread information on laws, policies, and guidelines in human genetic research (www.humgen.org/). Amy Pack is a member of the McGill University Health Centre (MUHC) Research Ethics Board.

MARK PHILLIPS

Mark Phillips works in comparative privacy and data protection law, particularly where it intersects with health data sharing. His academic background is in law and computer science. He holds degrees in IT and in law, and is a practicing member of the Quebec Bar Association. He works at the Centre of Genomics and Policy at McGill University as an Academic Associate, and is the co-chair of the Data Protection Task Team of the Global Alliance for Genomics and Health's Research and Ethics Work Stream. His comparative legal research focuses on topics including cloud computing, the identifiability of personal data, bioinformatics, and open data.

KATIE SAULNIER

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 Ontario in June 2016. At the CGP, Katie is currently involved in research into the ethical, legal and social issues surrounding epigenetics and data sharing. Her other research interests include the ethical implications of depictions of reproduction and reproductive technologies in speculative fiction, issues with conceptions of autonomy in laws affecting women and Indigenous communities, and neurodiversity and disability theory as they relate to the field of genomics.

KARINE SÉNÉCAL

Karine Sénécal holds a Master's degree in Law (Biotechnologies and Society) from the Université de Montréal and a Bachelor of Laws from the Université du Québec à Montréal. Her master's thesis focused on the legitimacy of a restricted application of germline gene therapy, from a human rights perspective and research ethics. Her thesis was published by the editor Themis, in 2007. Karine is an Academic Associate at the CGP at McGill University. She specializes in comparative law and policies, as well as in the analysis of the ethical, legal, and social implications surrounding genomic research and modern medicine. Her main areas of research are paediatric research, genetic testing and screening of minors as well as on the governance and ethics interoperability of paediatric biobanks and databases (including access, use and sharing). Karine is a coordinator of the Paediatric Task Team of the Global Alliance for Genomics Health, a consultant for the Public Population Projects Genomics (P^3G), and a member of the Quebec Network of Applied Genetics (RMGA). She sits on committees for the assessment of issues raised by biomedical technologies or on public health questions. She is author and co-author of more than 40 publications, including books or book chapters, peer-reviewed articles and policies.

LINGQIAO SONG

Lingqiao Song acquired a B.Sc in Biology and Master Degree of Civil Law at the Chinese Academy of Social Science in China. In 2015, she completed her second Masters degree of international business law at the University of Montreal and was awarded "Dean's Award: Best Overall Academic Achievement". In 2016, she was admitted as a Chinese Lawyer and is working as a legal consultant for Anran Law firm (China). Currently, she is pursuing her Ph.D. degree focusing on data sharing in Chinese biobanks at the Faculty of Law, McGill University. She is also a member of the Institutional Review Board of Faculty of Medicine, McGill University, and is the assistant to the Data Access Officer of the International Cancer Genome Consortium. At the Centre of Genomics and Policy, Lingqiao is working with Prof. Yann Joly and Ms. Ida Ngueng Feze on projects regarding Ethical, Legal, Social Issues (ELSI) of gene technology, policy approaches to address genetic discrimination, global data sharing of biobanks, and regulatory framework of microbiological genetic testing.

ANNE-MARIE TASSÉ

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 the Public Population Project in Genomics and Society (P3G) and an Academic Associate at the Center of Genomics and Policy (McGill University). As such, she coordinates the legal and ethical aspects of Canadian and international research projects. Author of more than 45 books, book chapters, peer-reviewed articles, policies and guidelines, her work is presented in Canada and abroad.

ADRIAN THOROGOOD

Adrian Thorogood (B.A.&Sc., B.C.L./ LL.B.) is a lawyer and Academic Associate at the Centre of Genomics and Policy. He manages the Regulatory and Ethics Work Stream of the Global Alliance for Genomics and Health. This consortium frames policy and establishes technical standards to accelerate the global sharing of genomic and health related data. Adrian manages the development of policies addressing consent, privacy and security, data access, and research oversight that enable responsible data sharing between countries, institutions, and sectors. Adrian's legal research focuses on how genomic sequencing platforms, information and networking technologies, open science practices, and patient empowerment movements are disrupting biomedical research and health care. He focuses on the duties and liabilities of health professionals, and the privacy, confidentiality, and "ownership" of genomic and health data. Adrian is also a jurist on a hospital research ethics board, and a member of the MSSNG Autism genome database access committee. He completed his law degree at McGill, articled at the Department of Finance Canada, and was called to the Ontario bar in 2015. Before entering law, Adrian obtained a Bachelor's degree from McGill University with a double major in health economics and biomedical sciences, and worked as an epidemiology researcher and clinical trial coordinator.

INVITED SCHOLARS

ROSARIO ISASI

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 to 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, 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.

AMALIA ISSA

Amalia M. Issa is an internationally renowned scientist in the field of personalized genomic medicine (precision medicine). Dr. Issa was one of the first scientists to develop a unique area of translational research focused on precision medicine applications, and how they will be translated and integrated into clinical practice and health systems. She undertook some of the earliest studies of the societal and policy implications of pharmacogenomics, and continues to be engaged in leading a multidisciplinary collaborative effort to investigate and address important questions to build and develop the science of personalized genomic healthcare delivery. Dr. Issa founded the Personalized Medicine & Targeted TherapeuticsTM Center in 2001, as one of the very first centers focused on pharmacogenomics and personalized medicine. The mission of the center is to develop the evidence base for, inform decision-making about and accelerate knowledge translation of personalized medicine applications into meaningful health outcomes. She is also currently a Full Professor at the University of the Health Sciences in Health Policy and Public Health and Pharmaceutical Sciences. Dr. Issa holds leadership positions in several professional associations and national and international scientific advisory committees, and has received many awards and honours for her work. She is excited to be collaborating on several projects of mutual interest at the CGP, as well as with the Global Alliance for Genomics & Health.

JENNIFER STODDART

Jennifer Stoddart was awarded an honourary 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 Advisory Expert Group that developed the 2017 OECD Recommendation on Health Data Governance and she co-Chaired its Advisory Expert Group.

BRIGID UNIM

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. 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, newborn screening and prevention of chronic diseases; epidemiology and prevention of infectious diseases; infectious disease surveillance and statistical analysis.

DALISA van den IJSSEL

Dalisa van den IJssel is a PhD fellow at the Department of public health, VU medical Centre in the Netherlands. Her PhD research started in 2015 and concerns informed decision making in prenatal screening. Her background in cognitive psychology is combined with knowledge about clinical genetics to find out how to optimize conditions for pregnant women that make the decision whether or not to screen for Down syndrome, Edwards syndrome or Patau syndrome. The research combines qualitative interviews, quantitative online questionnaires, eye-tracking and literature research.

CORNELIA van DUIJN

Cornelia van Duijn is a professor of Genetic Epidemiology at the Department of Epidemiology of the Erasmus University Medical Center. She is involved as a principle investigator in three large-scale population- and family-based studies: the Erasmus Rucphen Family (ERF) study, the Rotterdam study and Generation R. Her work focuses on omics research in neurodegenerative disorders including Alzheimer's disease, Parkinson's disease, Creutzfeldt–Jakob disease and open angle glaucoma. She is a leader in several international genome wide association consortia including CHARGE (Cohorts for Heart & Aging Research in Genome Epidemiology), IGAP (International Genetics of Alzheimer Disease Project (IGAP), ADSP (Alzheimer Disease Sequencing Project) and IGGC (International Genetics of Glaucoma Consortium). Over the years, she served on various scientific committees, including the International Society for Genetic Epidemiology (IGES), the American and the European Society for Human Genetics (ASHG, ESHG). She founded the MSc and PhD program in Genetic Epidemiology of the Erasmus University Medical Center of which she is the scientific director. Since 2014, she is a member of the Royal Netherlands Academy of Arts and Sciences.

RUMIANA YOTOVA

Dr. Yotova is an international lawyer and a lecturer in the University of Cambridge Law Faculty and at Lucy Cavendish College, where she teaches international law, investment law and EU external relations, and coaches the Cambridge Jessup team. She practices as a Door Tenant at Thomas More Chambers. Rumiana completed her PhD in Cambridge under the supervision of Prof. James Crawford and assisted him with cases as his Research Associate. Prior to this, she spent time at the Secretariat of the Permanent Court of Arbitration, the European Commission in Brussels and the International Tribunal for the Law of the Sea. Rumiana did her Magister Juris at the University of Sofia, an LL.M Advanced in International Law at Leiden University and was awarded the Hague Academy Diploma in International Law cum laude. She was a founder and editor-in-chief of the Cambridge Journal of International and Comparative Law (now Cambridge International Law Journal). Dr. Yotova is a fellow at the Lauterpacht Centre for International Law, a member of the Centre for European Legal Studies and the Cambridge Centre for Law, Medicine and Life Sciences. She was a Visiting Professor at McGill in 2017.

POST-DOC FELLOW

CHARLES DUPRAS

Charles Dupras, B.Sc., M.Sc., Ph.D. is a postdoctoral fellow at the Center of Genomics and Policy (CGP) at McGill University. He completed a master's degree in molecular biology at INRS-Institut Armand-Frappier, then completed a doctoral degree in bioethics at the University of Montreal. He was recently awarded a three-year fellowship (2017-2020) by the Canadian Institutes of Health Research (CIHR), for pursuing his research on the translation of emerging knowledge in epigenetics.

Epigenetics is an emerging field of study focusing on the biological mechanisms responsible for regulating gene expression. Epigenetic modifications have been associated with physico-chemical (e.g., pollutants) and psychosocial (e.g., family context, social adversity) environments to which people are exposed during their development, and with the development of many diseases later in life. Charles is interested by the ethical, legal and social implications of epigenetics. He examines, among other things, the impact of epigenetics on nature vs nurture representations, and questions of environmental and social justice.

Charles is exploring Canadian laws and public policies potentially applicable to – or to be amended to accommodate – recent findings about epigenetic mechanisms, such as DNA methylation. The main objective is to ensure that Canadian regulations, such as the recent Genetic Non-Discrimination Act (2017), or existing guidelines for the ethical conduct of genetic research (e.g., data sharing and protection of privacy), apply consistently and justifiably to epigenetic information.

Other ongoing projects include empirical studies of the ethical and social acceptability of implementing non-invasive prenatal testing (NIPT) in Canada. Charles sits on the Executive Committee of the new Canadian Journal of Bioethics. He is also an active member of the Bioethics Workgroup of the International Human Epigenome Consortium (IHEC).

PhD STUDENTS

GABRIELLE BERTIER

"Clinical Implementation of Next-Generation Sequencing in Pediatrics: A Multidisciplinary Analysis of Policy Implications"

This thesis project analyses the current use of Next-Generation Sequencing (NGS) technologies in the clinic. Focusing on France and Quebec, it examines the ethical, legal, social and policy implications of the use of NGS 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, Insem Université Toulouse III – Paul Sabatier.

DEREK SO

"The Role for Images of Human Genomic Engineering in Assessing Societal Views Relevant to Policy"

Recent advances in gene editing technology have renewed a longstanding bioethical debate about making heritable genetic modifications in humans. For many decades, various communities have envisaged different scenarios for the intentional selection of human traits, producing a repository of images which continue to evoke strong moral responses and to shape popular, bioethical and literary discourses alike. Studying this body of thought can help us to develop policy on gene editing by learning more about the ways people tend to conceptualize the human genome, genetic disorders, and the act of genetic modification. The aim of this thesis is to provide a theory accounting for these schemata, in order to help clarify the socio-cultural influences on stakeholder values toward gene editing. To this end, reviews of both academic and popular discourse will be performed, as well as surveys aimed at eliciting the views of different stakeholders, and a discussion paper to disseminate the resulting framework.

Supervisor: Yann Joly, Centre of Genomics and Policy, McGill University.
Co-Supervisor: Rob Sladek, Department of Human Genetics, McGill University.

VASILIKI RAHIMZADEH

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

Biomedical research since sequencing the human genome has become increasingly data-intensive that requires collaboration often across disciplinary and geographic borders. Delivering on the promises of precision/genomic medicine rests largely on making sound statistical associations between the human genome and disease. This requires that genomic and associated clinical data are shared widely and securely, including data involving children. Sparse policy attention has been paid, however, to the specific ethical-legal protections associated with such sharing in pediatric populations, nor what impact they might have on research collaboration. This PhD thesis adopts policy Delphi methods to examine the relationship between research ethics review policy and genomic data sharing for collaborative studies involving children across Canada (www.projectpedigree.org).

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

FOROUGH NOOHI

"Promoting Responsible Governance of Mitochondrial Replacement Therapy in Canada"

Today, more than ever, the progress of scientific technologies continues to push legal and ethical boundaries. At the center of the controversy surrounding the regulation of scientific advancements is human gene editing and more specifically the manipulation of human embryos and the human germline. Mitochondrial Replacement Therapy (MRT), a type of in vitro fertilization that aims to prevent the transmission of mitochondrial diseases to future generations, is considered a criminal offence in Canada. This PhD thesis aims to address important issues in debating the legitimacy of this controversial technique in Canada.

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

EVENTS AT THE CGP 2017

SUMMER SEMINAR SERIES

(June 7 – September 7, 2017)

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. This year, some of the topics ranged from precision medicine, informed consent and informed decision making, re-identification and privacy solutions, risk stratification, regulatory considerations for novel microbiological tests for Salmonella, remedies for exclusion, dependence, and exploitation in Dementia Research, bridging stem cell-based research and medicine, legal and ethical benefits and challenges to the harmonization of data access agreements, and open science in medical biotech in North America, to name but a few.

RESEARCH ETHICS SERIES

(January - April 2017)

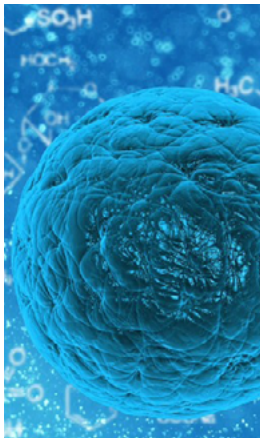
The interactive series of the McGill Skillset Research Ethics Workshops that took place in the 2017 academic year allowed participants (students, Faculty and staff) to get acquainted with ethical issues present in research. Each two-hour workshop explored an important ethical aspect of the research process by allotting time for both background information and dynamic case-based group discussion. The following themes were presented: research integrity (presented by Amy Pack), commercialization (presented by Palmira Granados-Moreno), and authorship (presented by Ma'n Zawati).

- **"Research Integrity" -Amy Pack** (January, 2017)
- **"Commercialization" -Palmira Granados** (February, 2017)
- **"Authorship" -Ma'n Zawati** (April 2017)

STEM CELL NETWORK

BARTHA MARIA KNOPPERS, ERIKA KLEIDERMAN, MINH THU NGUYEN AND FOROUGH NOOHI

1. **Mitochondrial Replacement Therapy (MRT) WORKSHOP** (March 24, 2017)
2. **Research Aspects of the Assisted Human Reproduction Act: Time for Revision?** (June 23, 2017)
3. **Preimplantation Genetic Diagnosis (PGD) and Screening (PGS) WORKSHOP** (August 25, 2017)
4. **Consensus Statement** (Presentation by Professor Knoppers at the Till & McCulloch Meeting) (November 7, 2017)



PREVENTING GENETIC DISCRIMINATION:

AN EVOLVING LEGAL LANDSCAPE

KEYNOTE SPEAKER: SENATOR JIM COWAN

There is significant public concern over genetic discrimination, which in turn affects participation rates in genomic research and the use of clinical genetics services. In response, many countries have adopted laws and policies to address this issue, such as the United States Genetic Nondiscrimination Act (GINA). The Canadian government adopted Bill S-201 “An act to prohibit and prevent genetic discrimination”, after a long legislative process. Bill-201 is the first Canadian law specifically prohibiting genetic discrimination and the use of genetic test results to conclude contracts of goods and services. This seminar provided an overview of Bill S-201 and situated the changing Canadian landscape within the broader international normative context on genetic discrimination. The CGP was honored to name hosted Senator Jim Cowan as the Keynote speaker at that event.

GUEST SPEAKERS AT THE CGP

MARCH 27

DR. RUMIANA YOTOVA,
AFFILIATED LECTURER
University of Cambridge Law Faculty, Fellow and Director of Studies at Lucy Cavendish College
"The Right to Science and Data-Sharing"

MARCH 27

ANDREA BOGGIO,
ASSOCIATE PROFESSOR,
History and Social Sciences Faculty, University of Bryant
"History/Evolution of Article 27 (UDHR, 1948)"

JUNE 7

CORNELIA VAN DUIJN, (MRT)
Department of Epidemiology, Erasmus University Medical Centre (Netherlands)
"Translating genomic findings to precision medicine using metabolomics and organ-on-chip models"

JUNE 15

DALISA VAN DEN IJSSEL
Department of Public Health, VU Medical Centre (Netherlands)
"Informed consent versus informed decision making"

JULY 13

ERIC RACINE & IRCM NEUROETHICS TEAM
Institut de Recherches cliniques de Montréal
"An overview of the Neuroethics Research Unit current projects"

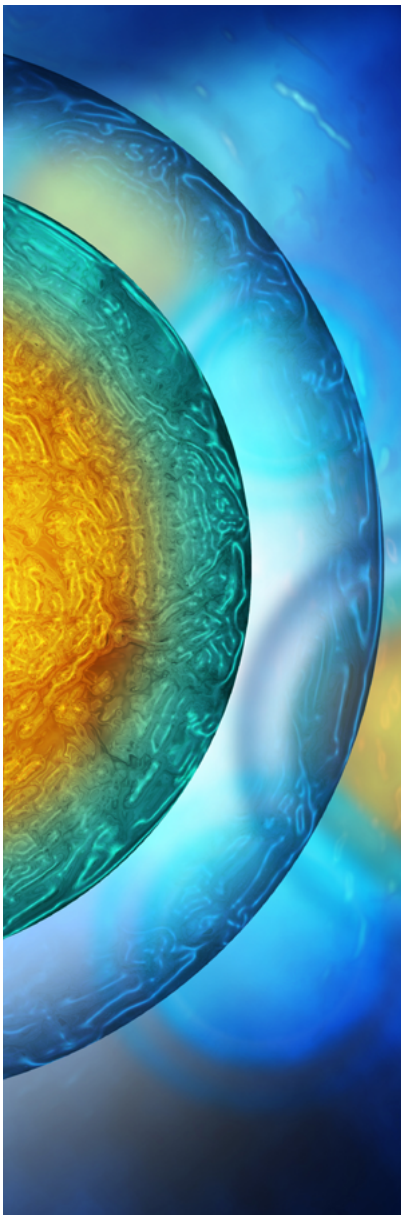
SEPTEMBER 20

SIMON EASTEAL
Research Professor at the John Curtin School of Medical Research, Director of Australia's National Centre for Indigenous Genomics (NCIG) and at the Australian National University
"Australia's National Centre for Indigenous Genomics: connecting Indigenous communities with genomic data to improve health and wellbeing"

NOVEMBER 23

KARMELA KRLEZA-JERIC,
Visiting Scientist, Mediterranean Institute for Life Sciences (Split, Croatia)
"IMPACT Observatory: tracking the evolution of evidence creation"

COMPLETED RESEARCH PROJECTS



Integrative Epigenomic Data Coordination Centre (EDCC) at McGill

January 2012 – December 2017

Canadian Institutes of Health Research (CIHR)

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.

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Innovative Chemogenomic Tools to Improve Outcomes in Acute Myeloid Leukemia

April 2013 – December 2017

Genome Canada

This project implemented 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 was to highlight the strengths and weaknesses of Canadian federal and provincial regulatory test approval models. To this end, we have undertaken a comparative analysis of US and EU models. Our second objective was 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).

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Framework for Decision-Making for Rare Diseases

April 2013 – March 2017

Canadian Institutes of Health Research (CIHR)

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 brought together a multidisciplinary team of experts in matters relating to treatment for rare diseases, and incorporated input from the public and key stakeholders to develop such a framework. It facilitated priority setting for orphan drug treatment decisions constrained by a limited budget that considered the relevant developmental, clinical, economic factors and ethical principles while being consistent with the values of society at large.

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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 2013 – December 2017

Fonds de Recherche du Québec- Société et Culture

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 proposed 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.

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Regenerative Cell Therapy Network (RCTN)

May 2014 – April 2017

Networks of Centres of Excellence (NCE)

The goal of the Regenerative Cell Therapy Network (RCTN) was 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 promoted 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 enabled 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 was enhanced.

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Treatment of Patients with Corneal Limbal Stem Cell Deficiencies using Epithelial Autografts

September 2016 – October 2017

Stem Cell Network (SCN)

This project completed our clinical trial and allowed 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 – are the first in Canada to offer CECA treatment for unilaterally blind or vision impaired patients suffering from LSCD.

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Faisabilité de traiter l'épidermolyse bulleuse par thérapie génique des cellules cutanées cultivées

April 2016 – March 2017

TheCell/Fonds de recheche du Quebec-Sante (FRQS)

L'épidermolyse bulleuse (EB) est une maladie génétique qui se manifeste par un manque d'adhésion entre le derme et l'épiderme de la peau. Elle entraîne des décollements de l'épiderme qui peuvent mener à des complications sévères, comme des cancers (e.g. carcinome), et à des complications sévères. Présentement, les traitements offerts permettent au mieux d'améliorer la qualité de vie des patients atteints, mais il n'existe aucun traitement curatif. L'épidermolyse bulleuse est caractérisée par des mutations dans un gène codant pour le collagène VII, présent à la jonction dermo-épidermique. L'objectif du projet est d'élaborer le meilleur traitement afin de corriger le gène défectueux par thérapie génique. Des des substituts cutanés (e.g. peaux reconstruites) seront produits à partir de cellules de patients atteints d'épidermolyse bulleuse cultivées in vitro et corrigées par thérapie génique. La greffe de ces tissus reconstruits à partir des cellules corrigées vise à offrir un traitement permanent aux patients atteints d'épidermolyse bulleuse.

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Demande d'autorisation à Santé Canada pour l'utilisation de cellules stromales humaines du muscle pour le traitement de dernier recours des non-unions de fractures

April 2016 – March 2017

TheCell/Fonds de recheche du Quebec-Sante (FRQS)

Sur environ 700 000 fractures/an au Canada, 5 à 10% ne guérissent pas. Des évidences expérimentales et cliniques indiquent que des cellules présentes dans le muscle squelettique contribuent à la guérison des fractures. Nous avons ainsi récemment identifié une population de cellules souches dans le muscle squelettique humain qui a la propriété de former de l'os dans des conditions expérimentales. Ce projet vise à exploiter la capacité de ces cellules à se différencier en cellules formant de l'os afin de les utiliser dans le cadre d'une thérapie cellulaire des fractures dont la guérison est plus complexe. Un traitement de dernier recours pour ces fractures aurait un impact économique mais surtout améliorerait la qualité de vie des patients aux prises avec cet important handicap.

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Genomics Technology Platform : Mcgill University and Genome Quebec Innovation Centre

April 2017- March 2021

Genome Canada

The McGill University and Génome Québec Innovation Centre (MUGQIC) focuses on genomics applied to populations and its impact on chronic diseases, aging, cancer and genomic responses to environment. The Centre reflects key challenges in harnessing next-generation sequencing power into innovations in biomedicine, including study design; tools to assess functional differences in human tissue and cells; and techniques to assess functional genomic variation in populations. MUGQIC supports some 900 academic and industry research teams from Canada and abroad each year, with revenues of $71.5 million over the past five years. MUGQIC has a successful track record of providing the Canadian scientific community with access to high-throughput genomic facilities and state-of-the-art methodologies. Its extensive networking with national and international genomics communities enhances its ability to adopt new methodologies and ensure their deployment in cutting-edge scientific programs. Over the coming five years, MUGQIC will extend its support to the scientific community through ongoing work on new technologies and methodologies. Among its unique features will be ethical, legal and social frameworks for research applications in human health; methods for population-wide interpretation of genomics data; and data-driven annotation of functional variation using in-house and public human population datasets. The Centre will also develop frameworks to use whole-genome sequencing as the primary tool for genetic analyses in humans and other species

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Treatment of Patients with Corneal Limbal Stem Cell Deficiencies using Epithelial Autografts

September 2016 – October 2017

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This project completed our clinical trial and allowed 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 – are the first in Canada to offer CECA treatment for unilaterally blind or vision impaired patients suffering from LSCD.

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CURRENT RESEARCH PROJECTS

Enhanced CARE for RARE Genetic Diseases in Canada

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Personalized Risk Stratification for the Prevention and Early Detection of Breast Cancer **(PERSPECTIVE)**

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

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GE3LS Network in Genomics and Personalized Health

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

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CellCAN: Canadian Cell, Tissue and Virus Manufacturing for Regenerative Medicine and Cell Therapy

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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

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The Cancer Genome Collaboratory

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

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Réseau en soins de santé personnalisés-Q-CROC

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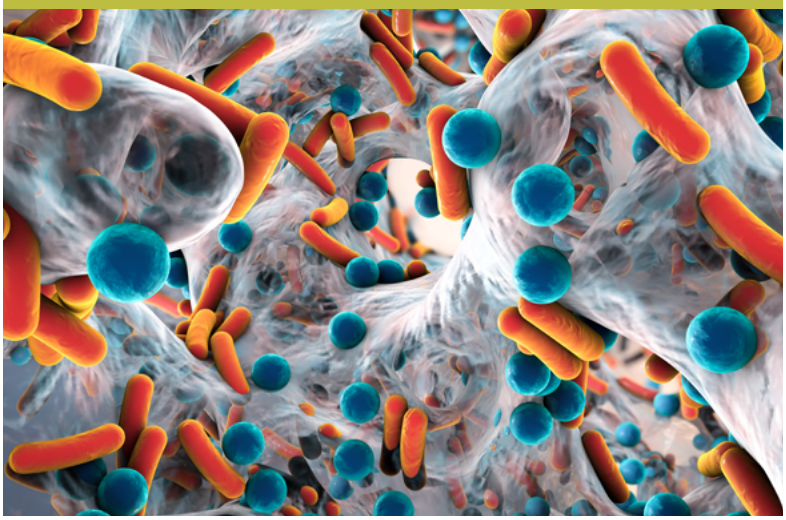

Enhanced CARE for RARE Genetic Diseases in Canada

April 2013 – March 2018

Genome Canada

CARE for RARE is a collaborative pan-Canadian project configured to improve the diagnosis and treatment of rare diseases. Powerful new DNA sequencing methods such as whole-genome (WGS) and whole-exome sequencing (WES) will be used to discover 60 new genes, each of which causes a rare disease. The identification of new genes provides useful biological information giving us insight into cellular pathways significant in human health. It is hoped that the research will lead to the implementation of WES as an effective and reliable diagnostic tool for clinical use.
However, in order to facilitate the integration of WES into the clinical setting, the GE3LS component of this study, which will be conducted at the Centre of Genomics and Policy, will include: 1) the drafting of clinical exome trial consent forms; 2) a qualitative analysis of the clinical utility of WES as a diagnostic tool for patients with rare diseases (from the patients' and clinicians' point of view); 3) the drafting of a national position statement and best practices outlining professional and ethical standards for the reporting of incidental findings found using WES; and 4) the development of clinical integration tools for use by clinics offering exome sequencing to patients with rare diseases.

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

April 2013 – March 2018

Fondation Cancer du sein du Québec

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 2018

Genome Canada/ Le Centre de recherche du CHU de Québec-Université Laval

The goal of this project is to develop an integrated information campaign 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 includes 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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ThéCell (Réseau de thérapie cellulaire et tissulaire) : enjeux socio-éthiques et juridiques des thérapies cellulaires et tissulaires

April 2009 – March 2018

Fonds de recherche du Québec - Santé (FRQS)

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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GE3LS Network in Genomics and Personalized Health

April 2016 – December 2018

Genome Canada

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 enables 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 addresses 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. 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 accelerates their common goal of transforming research results into practical applications adopted by health systems for the benefit of patients.

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

Réseau de médicine génétique appliquée (RMGA) Infrastructure

April 2006 – March 2018

Fonds de recherche du Québec - Santé (FRQS)

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.

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CellCAN: Canadian Cell, Tissue and Virus Manufacturing for Regenerative Medicine and Cell Therapy

August 2016 – March 2018

Networks of Centres of Excellence (NCE)

Collaboration and information sharing between researchers, regulators, funding agencies and industry will be essential to implement new treatments that will benefit patients, and a central hub of information will be crucial for better implementation and patient care.
The CellCAN Regenerative Medicine and Cell Therapy Network provides the physical, management and regulatory infrastructure needed to build patient awareness of regenerative medicine and cell therapy (RMCT), expedite regulatory approvals and promote RMCT treatments for diseases such as diabetes, cancer and heart disease by sharing and harmonizing operating procedures and clinical trial protocols. CellCAN's multidisciplinary effort involving scientists, physicians, patients, ethicists, economists, the private sector and other stakeholders increases efficiencies and reduces costs between Canada's cell manufacturing centres, while sharing procedures, patient samples, expertise and knowledge.

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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

September 2015 – August 2018

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

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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The Cancer Genome Collaboratory

April 2014 – March 2019

Natural Sciences and Engineering Research Council of Canada (NSERC)

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

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

April 2014 – March 2019

Networks of Centres of Excellence (NCE)

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 provides 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, it is analyzing the legal liability of health professionals undertaking such research.

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Réseau en soins de santé personnalisés-Q-CROC

April 2014 – March 2019

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

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

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

April 2016 – March 2019

Fondation du cancer du sein de Québec / Ministère de l'Économie, de la Science et de l'Innovation (MEIE) / CHU Laval / Fondation Cancer du Sein

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. 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.

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Genome Quebec Policy Briefs

May 2017 – April 2019

Genome Québec

For this project, the Centre of Genomics and Policy (CGP) has developed three Policy Briefs pertaining to emerging themes in genetics. More precisely, members of the CGP have authored Policy Briefs on Genetic Discrimination, Gene Editing, as well as Access and Sharing of Information with Genetic Researchers.

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

October 2015 – September 2019

Genome Québec/ Genome Canada

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.

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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

Canadian Institutes of Health Research (CIHR)

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 is 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 child participants once they become adults.

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> "The role of the CGP is to act as a collaborator-consultant, supporting the project with analysis, reflections and recommendations that pertain to the ethics and legality of consent"

Research Advancement through Cohort Cataloguing and Harmonization (ReACH)

April 2016 – March 2021

Canadian Institutes of Health Research (CIHR)

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.

> "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."

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Sino-Canada HeLTI:

A Multifaceted Community-Family- Mother-Child Intervention Study for the Prevention of Childhood Obesity (SCHeLTI)

April 2016 – March 2021

Canadian Institutes of Health Research (CIHR) / The National Natural Science Foundation of China (NSFC)

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.

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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 2018

Genome Canada

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.

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> "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."

Can DIG:
Canadian Distributed cyber-Infrastructure for Genomics

April 2016 – March 2020

Canadian Foundation for Innovation (CFI)

The Distributed Infrastructure for Genomics Data Sharing and Analysis project is divided into four activities. In Activity 1, they will develop a broad Canadian data sharing framework, using the APIs that we and others are developing under the auspices of the Global Alliance for Genomics and Health (GA4GH); Activity 2, they will continue the development of GenAP: a computational gateway for data analysis in life sciences that is configured to take advantage of Compute Canada infrastructure; Activity 3, they will build a data-sharing platform that will allow for the collection of standardized clinical data, dynamic definition of cohorts, and performance of genome analytics across datasets that are being stored on various Compute Canada nodes; and, to enable genome-guided clinical trials across Canada, in Activity 4 they will establish the Canadian Molecular Profiling in Cancer Trials (CAMPACT) Interchange. Together, the four Activities will utilize Compute Canada infrastructure to build a distributed and secure computational framework for the analysis of genomic datasets relevant to human diseases and beyond. The Centre of Genomics and Policy will also contribute to the implementation of the data sharing and privacy policy framework of the International Human Epigenome Consortium (IHEC) as well as the GA4GH.

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Multidimensional Epigenomics Mapping Centre (EMC) at McGill

August 2016 – March 2018

Canadian Institutes of Health Research (CIHR)

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

April 2016 – March 2024

Le Centre de recherche du CHU de Québec-Université Laval

In a framework of scientific collaboration, the Centre of Genomics and Policy (CGP) oversees and prepares 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.

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> "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"

RESEARCH AWARDS

CANADA RESEARCH CHAIR IN LAW AND MEDICINE

Prof. Bartha Maria Knoppers, PhD

Sequencing the human genome has provided the biomedical community with unprecedented opportunities for unlocking answers to some of the most complex human diseases.
Biomedical research is a collaborative, international endeavor and relies on the sharing of data to accelerate innovation and discovery. To share data in this way requires the harmonization of guidelines, policies and laws that span data protection, research ethics and health policy. The proposed Canada Research Chair in Law and Medicine seeks to enhance data sharing capacities among international researchers by activating, testing and most importantly implementing the human right of citizens' to benefit from science advances.

Chaires de recherche du Canada
Canada Research Chairs
Canada

RECHERCHE TRANSLATIONNELLE EN MÉDECINE PERSONNALISÉE, PERSPECTIVES ET ENJEUX POUR LE QUÉBEC

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.

Fonds de recherche Santé Québec

COURSES

HGEN-660 B
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 allows students to benefit from a close collaboration with experts at the crossroads of the ethico-legal, medical, and policy fields.

The Center of Genomics and Policy | and WYNG TRUST Visiting Scholar Program

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.

P3G

International Policy interoperability and data Access Clearinghouse (IPAC)

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 research.

THE IPAC PROVIDES TWO MAIN TYPES OF SERVICES:

ELSI INTEROPERABILITY

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.

DATA ACCESS COMPLIANCE OFFICE

The Data Access Compliance (DAC) office services to 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.

IN 2017

The P3G-IPAC has been involved in providing services to 9 international and Canadian projects. Among these, 4 were undertaken in collaboration with the CGP: Canadian Partnership for Tomorrow Project (see pg. 52), the Canadian Alliance for Healthy Hearts and Minds (see pg. 51), the International Cancer Genome Consortium (ICGC) (see pg. 52) and the International Cancer Genome Consortium for Medicine (ICGCmed) (see pg. 51).

CGP & P3G ▸ IPAC COLLABORATIONS

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 that aims to understand 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 is approximately 10,500. P^{3}G and the Centre of Genomics and Policy have worked with the research team, since the inception of the CAHMM, to review and finalize consent forms and develop a pan-Canadian policy for the management of severe structural abnormalities that will be used across Canadian sites.

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International Cancer Genome Consortium for Medicine (ICGCmed)

November 2015-March 2017

Following up on the success of the ICGC, the goal of ICGCmed (the second phase of ICGC) is to link genomic data to clinical and health information, including lifestyle, patient history, response to therapies and cancer diagnostic data. Because of this transition from ICGC and its move into the clinic, ICGCmed must adapt itself to meet the needs of the consortium in this new role. To this end, the P3G-IPAC has assisted ICGCmed with the adaptation of the ICGC "Policies and Procedures" to address the clinical needs of ICGCmed including, for instance, the following additional considerations: Cloud computing, Access to medical records, Access to specimens (e.g. tumors), Return of results and Incidental Findings (IFs), Patient confidentiality, Physician liability, Retrospective use of samples/data, Intellectual property issues, and, Pediatrics. Furthermore, P3G-IPAC has customized the Global Alliance for Genomes and Health (GA4GH) Policies on consent and privacy and security, according to the needs of the new "clinical" components of ICGCmed.

In addition to the preparation of topic-specific background documents, P3G-IPAC collaborated with the ICGCmed Ethics and Governance Committee (EGC) to develop the following policy documents: Core Bioethics Elements; Recommendations on the Return of Individual Research Results; Assessment Tool for Retrospective (Legacy) Data; and Consent Tools.

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Canadian Partnership for Tomorrow Project (CPTP)

April 2009 – March 2018

The Canadian Partnership for Tomorrow Project (CPTP) has enrolled 300,000 Canadians between the ages of 35 and 69 years, who have agreed 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. P3G also runs the Access Office (AO) of the CPTP, which reviews access requests from national and international researchers.

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

July 2009 – March 2018

The International Cancer Genome Consortium (ICGC) has coordinated 90 national cancer research projects that have the common aim of elucidating the genomic changes present in many forms of cancers contributing to the burden of disease in people throughout the world.
Housed at the CGP, the ICGC's Data Access Compliance Office (DACO) grants ICGC Controlled Data Access to international researchers in genomics, bioinformatics, and other related fields. A total of 335 applications, submitted by researchers in 31 countries, are currently approved for access. To date, DACO has processed over 2000 applications for ICGC Controlled Data Access (including resubmissions and renewals).

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HUMGEN DATABASE

http://www.humgen.org

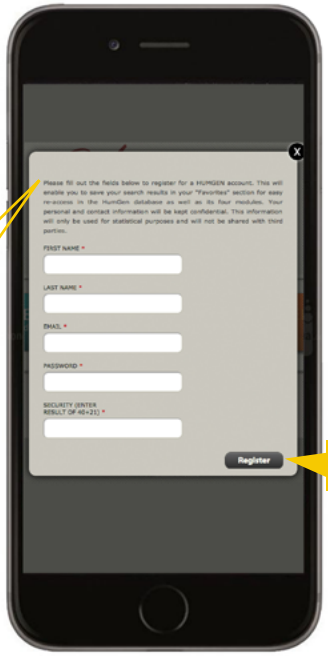
The optimized HumGen international database search engine promotes online access to widespread information on laws, policies, and guidelines in human genetic research. HumGen trivially searches through four modules making it easier for users to conduct research into ethical, legal, and social issues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

HUMGEN DATABASE

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.

Please fill out the fields below to register for a HUMGEN account. This will enable you to save your search results in your “Favorites” section for easy re-access in the HumGen database as well as its four modules. Your personal and contact information will be kept confidential. This information will only be used for statistical purposes and will not be shared with third parties.



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

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