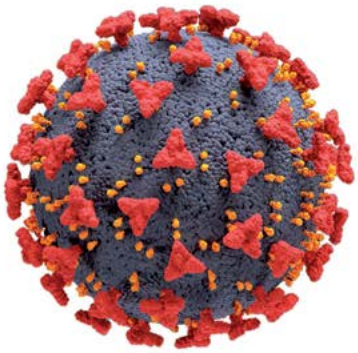
CENTRE OF GENOMICS AND POLICY

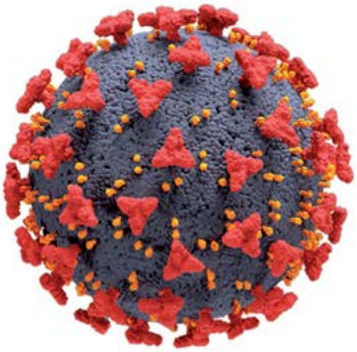
ANNUAL REPORT

CGP

2020

2020





CONTENT

MESSAGE FROM PROF. BARTHA M. KNOPPERS

The last line of my Message in the CGP 2019 Annual Report read as follows:

"May 2020 bring us the time, energy and funding to meet these challenges while anticipating new ones".

How portentous did this wish prove to be!

2020 has brought with it the most challenges of my 40 years as a Professor. I look wistfully at the faces of our excellent Academic Associates in our 2020 Report. I see the names of Research Assistants that I have not even met in person, hired during this past "COVID" year. We closed our offices to work from "home" on March 13th, 2020, perhaps to return in 2021.

The trials and tribulations of the global pandemic did however expand our research domains to include the ensuing international and national fallout. Hopefully, we contributed to addressing and solving some of the novel human rights and other ethical and legal issues including those surrounding COVID data sharing, viral and genomic sequencing, and equitable vaccine procurement while continuing to fulfill our other ongoing research obligations.

Productivity remains as high as ever but there is something to be said for human encounters in face to face meetings and international conferences (despite air travel). Online meetings chop up relationships into visible, talking squares all the while adding a veneer of artificial (and often painstaking) efficiency. Give me back real colleagues and real encounters in 2021 without the fear of viral risk, but the vibrancy of human exchange and the intellectual insights of the CGP environment and family!

Bartha Maria Knoppers
Director, Centre of Genomics and Policy (CGP)

PROF.

YANN JOLY'S MESSAGE

It is safe to say that 2020 will be a year that everyone will remember for a long time. Having to adapt to remote working, endless hours spent on videoconference, and missing the pleasure of in-person discussions with colleagues and students has been challenging. Nevertheless, I feel highly privileged to be able to continue my research in a positive environment like that provided by the CGP in these troubled times. My heartfelt thoughts go out to those most affected by the pandemic.

The capacity of the CGP to rise to the operational challenges set by COVID-19 is self-evident from the significant research contributions we have made on topical issues associated with sharing health data, genetic discrimination, privacy, gene editing, digital health and AI, as shown by the 36 articles published by CGP members in 2020. We were also able to secure funding for 16 new research projects, including five projects addressing COVID-19. Our excellent reputation has also contributed to our participation in different consulting roles in 11 COVID-19 related projects and task forces. These projects include CanCOGeN Host-Seq and Virus-Seq, genomic sequencing projects, The COVID-19 vaccine task force, and the Quebec COVID-19 Biobank.

Finally, the CGP also welcomed three new graduate students (Jacqueline Bradbury-Jost, Emily Doerksen, Cassandra Haley), one articling student (Gabriel Marrocco) and two interns (Julie-Alexia Dias, Kai-Lee Gibeault) this year. I look forward to 2021 with optimism and look forward to resuming in-person collaboration on innovative research projects, locally, nationally, and internationally.

Yann Joly

ABOUT US

Located within the McGill Genome Centre, the Centre of Genomics and Policy (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 several areas of genomics and policy that include: stem cell research and therapies, personalized medicine, prevention and treatment of cancer, data sharing in research, pediatrics, genetic counselling, digital health and AI, intellectual property and open science, epigenetics, intersex and diversity in health, gene editing, genetic discrimination and biobanking (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. Secondly, the CGP actively participates in the creation of international consortia with a view to promoting multidisciplinary policymaking. Finally, via its numerous workshops and lecture series, the CGP encourages knowledge transfer.

https://www.genomicsandpolicy.org/

CGP TEAM

PROFESSOR
KNOPPERS Bartha Maria - DIRECTOR

ASSOCIATE PROFESSOR
JOLY Yann - RESEARCH DIRECTOR

ASSISTANT PROFESSOR
ZAWATI Ma'n H.- EXECUTIVE DIRECTOR

ACADEMIC ASSOCIATES
BEAUVAIS Michael
BERNIER Alexander
COSQUER Marie
DALPÉ Gratien - COORDINATOR
DUPRAS Charles
GALLOIS Hortense
GRANADOS-MORENO Palmira
HAGAN Julie
KIRBY Emily
KLEIDERMAN Erika
LANG Michael
LÉVESQUE Emmanuelle
NGUENG FEZE Ida
NGUYEN Minh Thu
PATRINOS Dimitri
SAULNIER Katie
SONG Lingqiao
THOROGOOD Adrian

ASSOCIATE MEMBERS
BEREZA Eugene
GOLD Richard
KIMMELMAN Jonathan

SCIENTIFIC CONSULTANTS
AVARD Denise
LABERGE Claude

PhD STUDENTS
NOOHI Forough
SO Derek

MASTER'S STUDENTS
BRADBURY-JOST Jacqueline
CROCKER Kelsey
DOERKSEN Emily
HALEY Cassandra

INVITED SCHOLARS
ISSA Amalia

RESEARCH ASSISTANTS
ALARIE Samuel
BONILHA Ana
CHARRON Marilou
CROUSE Alanna
FARAJI Sina
GRAHAM Leah
HUA Fenling
KÉKESI-LAFRANCE Kristina
KNOPPERS Terese
KOAYES Myriam
LAGUIA Kristen
LI Katherine
LIU Hanshi
MARROCCO Gabriel
OLVERA Elena
SHEMIE Genevieve
XU Handi

INTERNS
DIAS Julie-Alexia
GIBEAULT Kai-Lee
YAO Karen

ADMINISTRATORS
HOZYAN Rose-Marie
THORSEN Nadine

CGP DIRECTOR

PROF. BARTHA MARIA KNOPPERS

Bartha Maria Knoppers, Ph.D. (Comparative Medical Law), is a Full Professor, Canada Research Chair in Law and Medicine and Director of the Centre of Genomics and Policy of the Faculty of Medicine at McGill University. She was the Chair of the Ethics and Governance Committee of the International Cancer Genome Consortium (2009-2017). She is currently Chair of the Ethics Advisory Panel of WADA (2015-), and was the Co-Chair of the Regulatory and Ethics Workstream of the Global Alliance for Genomics and Health (2013-2019). In 2015-2016, she was a member of the Drafting Group for the Recommendation of the OECD Council on Health Data Governance and gave the Galton Lecture in November 2017. She holds four Doctorates Honoris Causa and is a Fellow of the American Association for the Advancement of Science (AAAS), the Hastings Center (bioethics), the Canadian Academy Health Sciences (CAHS), and the Royal Society of Canada. She is also an Officer of the Order of Canada and of Quebec, and was awarded the 2019 Henry G. Friesen International Prize in Health Research, the Till and McCulloch Award for science policy (2020) and, was appointed to the International Commission on the Clinical Use of Human Germline Genome Editing.

RESEARCH DIRECTOR PROF. YANN JOLY

Yann Joly, Ph.D. (DCL), FCAHS, Ad.E. is the Research Director of the Centre of Genomics and Policy (CGP). He is an Associate Professor at the Faculty of Medicine and Health Sciences, Department of Human Genetics cross-appointed at the Bioethics Unit at McGill University. He was named advocatus emeritus by the Quebec Bar in 2012 and a Fellow of the Canadian Academy of Health Sciences in 2017.

Prof. Joly is a member of the Canadian Commission for UNESCO (CCU) Sectoral Commission for Natural, Social and Human Sciences. He is the current Chair of the Bioethics Workgroup of the International Human Epigenome Consortium (IHEC) and Co-Lead the Regulatory and Ethics Work Stream of the Global Alliance for Genomics and Health (GA4GH). He was Chair (2017-2019) of the Ethics and Governance Committee of the International Cancer Genome Consortium (ICGC). He is also a member of the Human Genome Organization (HUGO) Committee on Ethics, Law and Society (CELS) and a member of the SARS-CoV-2 Data Portal Management Committee of the VirusSeq, a COVID-19 task force in which he provides his expertise and leadership.

Prof. Joly's research interests lie at the interface of scientific knowledge, health law (biotechnology and other emerging health technologies) and bioethics. In 2018, he created a national Genetic Discrimination Observatory and, in 2020, established it as an international organization with experts and collaborators from over 20 countries (GDO, https://gdo.global/en). He has published his findings in over 150 peer-reviewed articles featured in top legal, ethical and scientific journals. He served as a legal advisor on multiple research ethics committees in the public and private sectors. Prof. Joly also sits on editorial committees and acts as a reviewer for a wide range of publications in his field. In 2012, he received the Quebec Bar Award of Merit (Innovation) for his work on the right to privacy in the biomedical field. In 2015-2019, he was a Chercheur boursier niveau junior 2 (Fonds de la recherche du Québec) and in 2017, he became a Fellow of the Canadian Academy of Heath Sciences (FCAHS).

EXECUTIVE DIRECTOR

PROF.
MA'N H. ZAWATI

Ma'n H. Zawati (LL.B., LL.M., Ph.D. (DCL)) is an Assistant Professor at McGill University's Faculty of Medicine and Health Sciences and the Executive Director of the Centre of Genomics and Policy in the Department of Human Genetics. He is also an Associate Member of McGill's Biomedical Ethics Unit and the Division of Experimental Medicine. His research concentrates on the legal, ethical and policy dimensions of health research and clinical care, with a special focus on biobanking, data sharing, professional liability, and the use of novel technologies (e.g. mhealth apps, WGS, WES) in both the clinical and research settings. His work is interdisciplinary, drawing together perspectives from law, ethics, bioinformatics, genomics, and policy. In 2020, he has contributed to the development of the ethical and policy tools for the BQC19 biobank, the HostSeq project and the Canadian Immunity Task Force.

He has appeared at 100+ international conferences, symposia, meetings, and has shared his expertise with universities, research ethics boards and law firms. Dr. Zawati has published 15 book chapters and 65+ peer-reviewed articles in leading publications. In 2015, he was awarded the Queen Elizabeth II Diamond Jubilee Scholarship (stay at Oxford University) and was named a Royal Society of Canada Delegate for the IAP Young Scientists of the Year international symposium. In 2014, the Young Bar Association of Montreal named him as one of its Lawyers of the Year.

ACADEMIC ASSOCIATES

GRATIEN DALPÉ

ACADEMIC ASSOCIATE & COORDINATOR

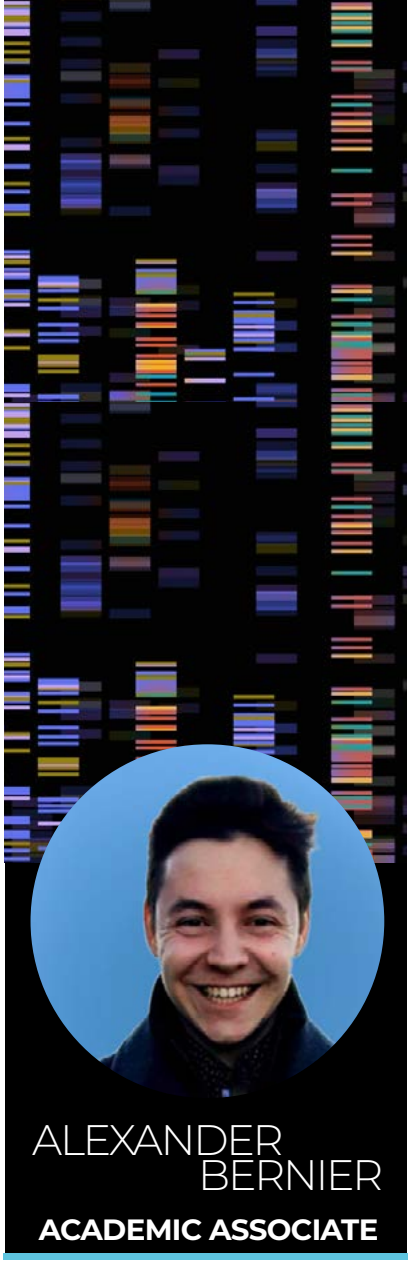
Gratien Dalpé completed his undergraduate and master studies (B.Sc/M.Sc) in biochemistry at Université de Sherbrooke. He holds a doctorate (Ph.D.) in molecular biology from Université de Montréal. He later worked as a post-doctoral fellow and research associate at the Samuel Lunenfeld Research Institute in Toronto. During his career, he uncovered new molecular signalling networks that regulate the nervous system's development and degeneration. He later obtained his LL.B. in civil law at Université de Montréal and joined the Centre of Genomics and Policy as an academic associate with interest in law and bioethics, specifically genomic medicine and genetic discrimination. He is also the Coordinator of the Centre and a regular guest lecturer in HGEN 400 and INDS 302 at Mcgill's Faculty of Medicine and Health Sciences.

MICHAEL BEAUVAIS

ACADEMIC ASSOCIATE

Michael Beauvais, BA (McGill), BA (Oxford), BCL/JD (McGill), MSc (UCL) is an academic associate at the Centre of Genomics and Policy. He obtained law degrees from Oxford University and McGill University. In a former life, he studied human geography and Italian literature at McGill University and urban planning at University College London. These experiences continue to inform his perspectives on law and ethics.

At the Centre, Michael specializes in the governance of genomic, neuro, and health-related data in Canada and Europe. He is particularly interested in science policy and its relation to international human rights law, in addition to comparative biomedical research regulation and its interface with contemporary big data research. Michael's interest in ethico-legal issues surrounding research with children and adolescents further present him with difficult practical issues with rich theoretical implications which he hopes to explore.



ALEXANDER BERNIER

ACADEMIC ASSOCIATE

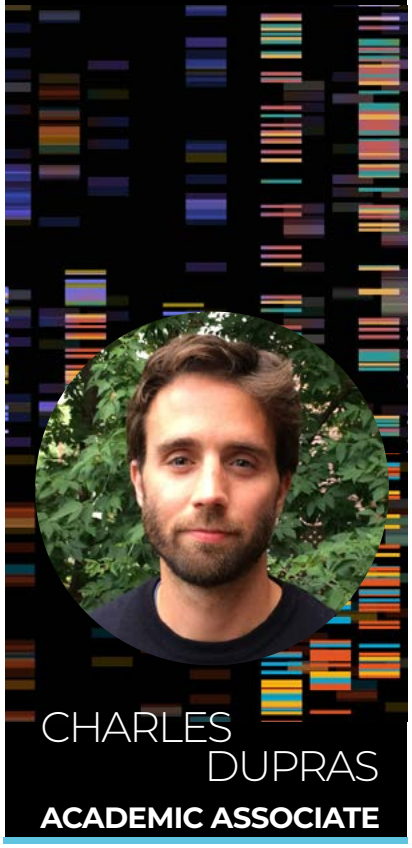
Alexander Bernier holds a BCL/JD degree from the Faculty of Law at McGill University. As an academic associate at the Centre of Genomics and Policy, his research is primarily concerned with medical ethics, research ethics, and international privacy law in the field of genomics. He previously served as director of Innocence McGill and has a strong interest in the use of forensics in criminal law.

MARIE COSQUER

ACADEMIC ASSOCIATE

Marie Cosquer (M.Sc) is an academic associate at the Centre of Genomics and Policy at McGill University. She obtained a master's degree in political science from Université de Montréal and holds degrees in geography and environmental projects management (B.Sc. M.Sc. Université Montpellier III, M.Sc. Université Paris VII). She is also the co-coordinator of the journal Possibles.

At the CGP, she contributes to different projects by doing qualitative research and works under the supervision of Professors Ma'n Zawati and Yann Joly. She is currently involved in research projects about personalized therapy for individuals with cystic fibrosis and, interrogating and implementing omics for precision medicine in acute myeloid leukemia.



CHARLES DUPRAS

ACADEMIC ASSOCIATE

Charles Dupras, B.Sc., M.Sc., Ph.D. was a postdoctoral fellow (2017-2020) and became an academic associate at the Center of Genomics and Policy. He completed a master's degree in molecular biology at INRS-Institut Armand-Frappier, then completed a doctoral degree in bioethics at Université de Montréal. He was awarded a three-year fellowship (2017-2020) by the Canadian Institutes of Health Research (CIHR) for pursuing research on the translation of emerging knowledge in epigenetics. In particular, Charles is interested by the ethical, legal and social implications of epigenetics. He examines the impact of epigenetics on nature vs nurture representations and questions of environmental and social justice. At the Centre, Charles explores Canadian laws and public policies related to 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.

HORTENSE GALLOIS

ACADEMIC ASSOCIATE

Hortense Gallois holds a Master of Law from the University of Lille 2 (France) and the Universidad de Murcia (Spain), specializing in new technology and health law. She obtained her master's degree in bioethics from Université de Montréal in 2019. As an academic associate at the CGP, her main interests are the ethical and legal implications of genetic and genomic research as well as the ethics of reproduction. Since 2018, she has been involved in Genome Canada's Pegasus 2 project which studies the ethical and social acceptability of non-invasive prenatal testing (FNITP) in Canada.

PALMIRA GRANADOS M.

ACADEMIC ASSOCIATE

Palmira Granados (Ph.D., LL.M.) is a Mexican lawyer and academic associate at the Centre of Genomics and Policy of McGill University. She specializes on the interface between intellectual property and biomedicine and information technologies, genetic discrimination, legal issues associated with open science/ open source in biomedicine and information technologies, bioethics, and on the regulation of software as medical device. She is a regular guest lecturer in different graduate classes at McGill University and the University of Southern California, San Diego. She is a member of the International Expert Group of the Genetic Discrimination Observatory and the Centre for Intellectual Property and Policy of McGill University.

Prior to working at the Centre of Genomics and Policy, she was a member of the International Expert Group of the Innovation Partnership and of the New Researchers Group of VALGEN. She has also been closely involved with the Free Software Foundation and Creative Commons Mexico.

JULIE HAGAN

ACADEMIC ASSOCIATE

Julie Hagan (B.Sc/M.Sc) is an academic associate at the Centre of Genomics and Policy. She obtained a master's degree in sociology from Université de Montréal and completed a doctoral internship at the University of São Paulo, Brazil. She is pursuing a Ph.D. in sociology at Laval University.

At the Centre, she contributes her experience in qualitative research methodologies to foster stakeholder engagement. She is currently involved in research about the social acceptability of omics approaches for the detection of Salmonella in fresh produces. She is also involved in projects examining how the changes brought about by the advances in genomics and the development of personalized medicine affects patients and health professionals as well as its effects on service delivery and policymaking.

EMILY KIRBY

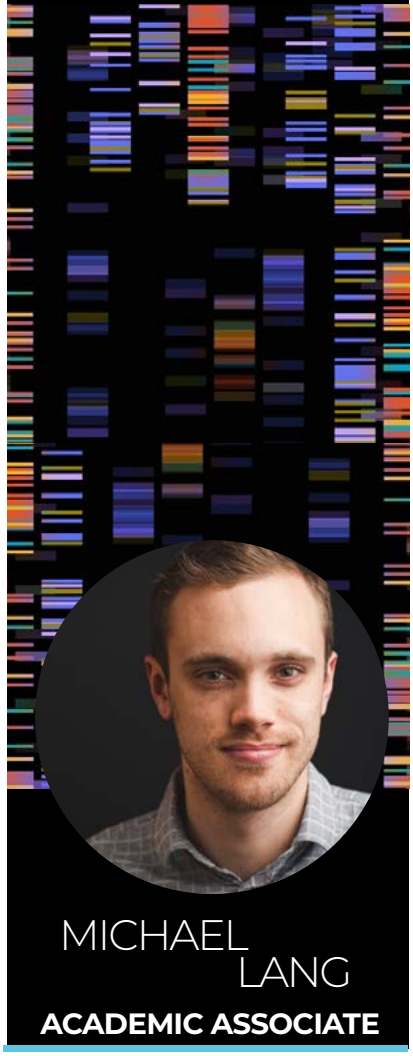
ACADEMIC ASSOCIATE

Emily Kirby is a lawyer and academic associate at the Centre of Genomics and Policy. She holds degrees in biology (B.Sc. McGill University), a master's in environmental project management (M. Env., Université de Sherbrooke), and a civil law degree (LL. B., Université de Montréal). She has been a member of the Québec Bar since 2011. Prior to joining the Centre, Emily was a project coordinator at the Public Population Project in Genomics and Society (P3G). She currently works on the development of ethical and legal documents and tools used to facilitate policy interoperability and data sharing in the context of data-intensive research (-omics, clinical data, etc.). Emily has been involved in examining ethical, legal and policy issues in a number of Canadian and international data sharing initiatives (e.g. MSSNG database, Care4Rare-SOLVE, Terry-Fox PROFYLE, International Cancer Genome Consortium (ICGC) for medicine, Human Cell Atlas, Global Alliance for Genomics and Health task forces, Transforming Autism Care Consortium's Q1K project, etc.). She is currently the academic coordinator of the Ethics Working Group of the Human Cell Atlas (HCA; https://www.humancellatlas.org/).

ERIKA KLEIDERMAN

ACADEMIC ASSOCIATE

Erika Kleiderman is a lawyer and an academic associate at the Centre of Genomics and Policy (CGP) at McGill University. She holds a civil law degree (LL.B.) from the Université de Montréal, as well as a B.Sc. in psychology from McGill University. Her research focuses on the ethical, legal, and social implications surrounding human genome editing, new assisted reproductive technologies, stem cell research, and cell and gene therapies, as well as access to data and genetic information (biobanking). Erika is also interested in the implications of gene therapy and enhancement in minors within a sporting context. She is actively engaged in the stem cell and regenerative medicine community through her involvement with various committees, networks and initiatives. Erika is also a member of the Quebec Bar, CIHR's Stem Cell Oversight Committee and the McGill University Health Centre Research Ethics Board.



MICHAEL LANG

ACADEMIC ASSOCIATE

Michael Lang is a member of the Law Society of Ontario and a graduate of McGill University's Faculty of Law (BCL/LLB, 2018) and of the University of Alberta (BA, 2014). During law school, he wrote an honour's paper on the history of the tort of wrongful life, was executive editor of the McGill Journal of Sustainable Development Law, and was co-convenor of a student-initiated seminar on fertility law. As an academic associate at the CGP, his research focuses on the ways that technology is changing healthcare, with a particular focus on mobile health applications, artificial intelligence, and professional responsibility. Michael is broadly interested in the ways that technology affect the relationship between physicians and their patients, how the law understands personhood, and how humans interact with the natural environment.

EMMANUELLE LEVESQUE

ACADEMIC ASSOCIATE

Emmanuelle Lévesque is a lawyer and a member of the Québec Bar. She holds a master of law (specializing in biotechnology, law and society) from the Université de Montréal and an LL.B. from Laval University. 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.

As an academic associate at the CGP, she specializes in questions concerning ethical and legal issues in health research, particularly in biomedical and genetic research. Over the past several years, she advised researchers about the ethical and legal issues raised by the deployment of their projects, especially on the development and the framework of biobanks. She works on projects conducted in Québec, in the rest of Canada and overseas. She has published several articles and held conferences on different ethical and legal issues raised by research.

IDA NGUENG FEZE

ACADEMIC ASSOCIATE

Ida Ngueng Feze is a lawyer and member of the New York Bar. She is also an academic associate at the Centre of Genomics and Policy. Her research projects at the Centre deal with the applications of novel biotechnologies in health and environmental contexts. In terms of health applications, her work focuses on data governance and the ethical, legal and social implications of the collection, access and uses of human and pathogen genomic data. She has served as a member of the research ethics board of the Montreal General Hospital. In the environmental context, she has worked on several Genome Canada large-scale projects including the Salmonella SystOMICS (food safety and pathogen) and the Applied Metagenomics of the Watershed (water quality). She is a guest lecturer at the Université de Montréal and Laval University teaching sessions on bioethics. Before joining the Centre, she worked at the UNFAO, the Environmental Law Institute, and a U.S.-based law firm.

MINH THU NGUYEN

ACADEMIC ASSOCIATE

Minh Thu Nguyen holds a Master of Laws (LL.M.) degree in health law and policy from the University of Toronto, a Civil Law (LL.B.) degree from the Université de Montréal, and a B.Sc. degree in physical therapy from McGill University. 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 and has been involved in several Canadian 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 and information forms for rare disease research projects such as FORGE and CARE for RARE (pan-Canadian) and PRISMES (Québec). As an academic associate at the CGP, 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.

DIMITRI PATRINOS

ACADEMIC ASSOCIATE

Dimitri Patrinos is a lawyer and an academic associate at the Centre of Genomics and Policy. He is a graduate of the civil law (LL.B.) and common law (J.D.) programs at Université de Montréal, Faculty of Law. He also holds a B.Sc. in biology from Concordia University. He was called to the Ontario Bar in 2020.

At the Centre, Dimitri conducts research on the issues associated with the legal recognition of genetic counsellors in Canada. He is also involved in a number of other projects related to data sharing, biobanking, and governance.

KATIE SAULNIER

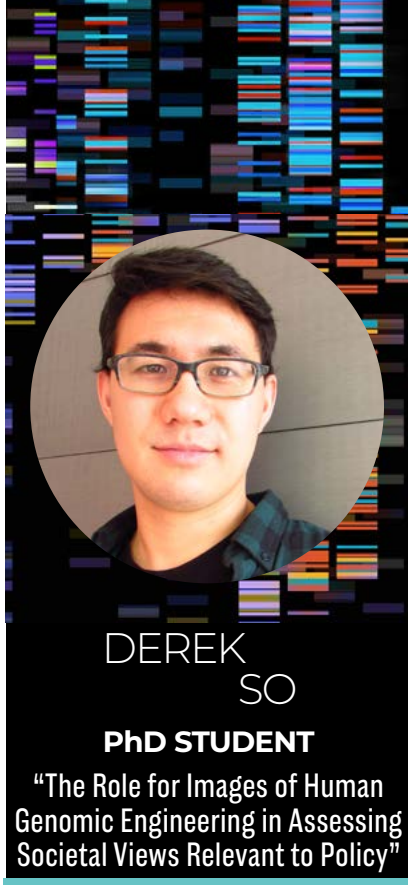
ACADEMIC ASSOCIATE

Katie Saulnier graduated from Mount Allison University in 2010 with a Bachelor of Arts (philosophy and English) focusing on ethics, and from the McGill Faculty of Law in May 2014 with a Bachelor of Civil Law (LL.B.) and a Bachelor of Common Law (B.C.L.). They were called to the Bar of the Law Society of Ontario in June 2016. They completed an M.A. in philosophy with a specialization in bioethics from McGill University (2020), focusing on using a disability theory lens to examine the ways in which discourse around epigenetic research is changing conceptions of normative values assigned to bodies. As an academic associate at the Centre, Katie is currently involved in research into the ethical, legal and social issues surrounding epigenetics and data sharing, as well as research on improving the quality of healthcare communication for intersex Canadians. Their 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 gender, neurodiversity and disability theory as they relate to the field of genomics.

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 master's degree of international business law at Université de Montréal and was awarded the "Dean's Award: Best Overall Academic Achievement." In 2016, she was been admitted to the Bar association of Wuhu, Anhui, China and worked as a legal consultant for Anran Law, Wuhu, China. She is also a member of Institutional Review Board of McGill's Faculty of Medicine and assistant to the Data Access Officer of the International Cancer Genome Consortium. As an academic associate at the Centre, Lingqiao is working with Prof. Yann Joly and Ida Ngueng Feze focusing on ethical, legal, social Issues (ELSI) of gene technology, such as intellectual property law of biotechnology, misusage of genetic information outside of therapeutic context, policy approaches to address genetic discrimination, global data sharing of biobanks, and regulatory framework of microbiological genetic tests.

Adrian Thorogood (B.A. & Sc., B.C.L. & LL.B., LL.M.) is a lawyer and academic associate at the Centre of Genomics and Policy. His legal research focuses on how genomic sequencing, cyberinfrastructure, open science practices, and patient-empowerment movements are disrupting biomedical research and health care. He is also the Regulatory and Ethics Manager of the Global Alliance for Genomics and Health, a public-private consortium that develops standards to enable responsible genomic data exchange. In this position, he leads the development of international policy frameworks addressing consent, privacy and security, and coordinated research oversight. He also works with the neuroscience community in Canada to promote open science practices. Adrian completed his LL.M. at the University of Toronto. His thesis proposed strategies to overcome incompatibilities between legal systems that hinder international health research. Adrian holds a joint common law / civil law degree from McGill University.

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.



DEREK SO

PhD STUDENT

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

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

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.

FOROUGH NOOHI

PhD STUDENT

"Promoting Responsible Governance of Mitochondrial Replacement Therapy in Canada"

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

Mitochondrial Replacement Therapy (MRT) is a new type of in vitro fertilization that aims to prevent the transmission of mitochondrial diseases by replacing the mitochondria of unfertilized oocytes or zygotes with normal mitochondria from a healthy donor. Since mitochondria have their own DNA distinct from nuclear DNA, MRT is often referred to as "three-parent IVF". Besides the UK, which became the first country to approve MRT in 2015, only a few countries have addressed this controversial technique through public policy. This PhD thesis aims to fill the important gaps in the MRT debate by using qualitative methods.

JACQUELINE BRADBURY-JOST

MASTER'S STUDENT

"Return of Material Incidental Findings to Participants in the Context of Research Conducted by Direct-to-Consumer Genetic Testing Companies"

Supervisor: Ma'n H. Zawati
CO-Supervisor: Yann Joly
Centre of Genomics and Policy,
McGill University

Jacqueline is a Master of Science student in the Department of Human Genetics at McGill University. She is also pursuing a Master's Specialization in Bioethics through McGill's Biomedical Ethics Unit. Prior to beginning her studies at McGill, Jacqueline completed undergraduate studies in humanities and biology with particular interests in philosophy, political science, and genetics. In her fourth year, she undertook directed studies projects in genetics, with a focus on anti-angiogenesis cancer therapy, as well as in philosophy, looking at moral agency in Spinoza's Ethics. She received a Bachelor of Humanities and Biology (Combined Honours) with High Distinction from Carleton University in 2019. Under the supervision of Prof. Ma'n Zawati and the co-supervision of Prof. Yann Joly, Jacqueline's research at the CGP focuses on the ethical and legal implications of novel health technologies and is funded by a CIHR Master's award.

KELSEY CROCKER

MASTER'S STUDENT

"Investigating the Perceptions of Genetically Edited Individuals by Healthcare Providers to Inform Future Medical Practice and Policy"

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

Kelsey is a Master of Science student in the Department of Human Genetics at McGill University and Génome Québec Innovation Centre under the supervision of Dr. Yann Joly. She obtained a Bachelor of Science (High Distinction), majoring in both Fundamental Genetics and its Applications and Ecology and Evolutionary Biology at the University of Toronto in 2019. During her bachelor's, Kelsey completed a University Research Apprentice Program (URAPs) at the National University of Singapore in summer 2018. This research was focused on the Androgen-dependent tissue factor gene (ADTRP) and its association with coronary heart disease through the exploration of variable tandem repeats. Kelsey's research at the Centre of Genomics and Policy focuses on the ethical implications of genetic discrimination.

EMILY DOERKSEN

MASTER'S STUDENT

"Public Perception and Biobank Ethics Governance During Pandemics"

Supervisor: Ma'n H. Zawati
Centre of Genomics and Policy,
McGill University

Emily is currently pursuing a Master of Science at the Department of Human Genetics and the Biomedical Ethics Unit at McGill University. She holds a Bachelor of Humanities with a combined Honours in Biology from Carleton University, a B.A. in Philosophy from KU Leuven (Belgium), and an M.A. in Philosophy from the University of Ottawa. Her undergraduate and graduate educations inform her interdisciplinary interests in public health and bioethical issues relating to human genetics and research ethics. At the CGP, Emily is working under the supervision of Prof. Ma'n Zawati, researching the landscape of pandemic ethics, informed consent laws, and biobanking networks/data collection.

CASSANDRA HAYLEY

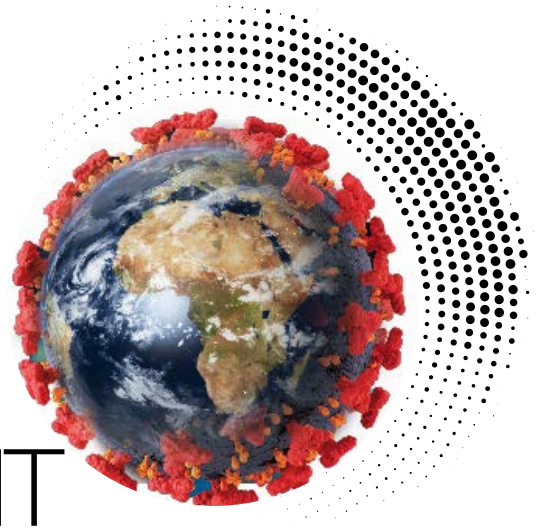
MASTER'S STUDENT

"Direct-to-consumer genetic tests: Is there a role for Canadian genetic counsellors?"

Supervisor: Ma'n H. Zawati
Centre of Genomics and Policy,
McGill University

Cassandra Haley is a Master of Science student from the Department of Experimental Medicine and the Biomedical Ethics Unit at McGill University under the supervision of Dr. Zawati. She holds a Bachelor of Science from the University of Western Ontario, where she pursued an honours specialization in genetics and a major from the School for Advanced Studies in the Arts and Humanities. Cassandra's undergraduate thesis was on the genotoxicity of microplastics, and through her humanities courses she worked closely with local Indigenous communities to research the Indigenous experience of WWI. Cassandra has also written extensively on the sociological and cultural history of music for an internship through the Faculty of Music. This interdisciplinary background motivated Cassandra to pursue genetics and bioethics at the graduate level at the CGP, where she will be researching how Canadian genetic counsellors can respond to the rise of direct-to-consumer genetic tests.

In 2020, the CGP took part in national and international efforts to respond to the current COVID-19 pandemic. The CGP has contributed its expertise in data governance, data sharing and privacy for the following collaborative COVID initiatives:



CGP INVOLVEMENT IN THE FIGHT AGAINST COVID-19

EXPERT ADVISORY GROUP ON THE PAN-CANADIAN HEALTH DATA STRATEGY
Bartha Knoppers: Member

NATIONAL COVID-19 VACCINE TASK FORCE
Bartha Knoppers: Member

CANADIAN COVID-19 HUMAN HOST GENOME SEQUENCING PROGRAM (CGEn)
Bartha Knoppers: Member, Steering Committee

CanCOGen
Bartha Knoppers: Member, Steering Committee (HostSeq)
Yann Joly: Chair, Data Sharing Committee
Yann Joly: Member, Management Committee (SARS-CoV-2 Data Portal, VirusSeq)
Ma'n Zawati: ETHICS AND POLICY PILLAR—HostSeq (CanCOGeN), research project funded by Genome Canada
Yann Joly: ELSI COMPONENT: VirusSeq—CanCOGen, research project funded by Genome Canada

PROACTIVE MITIGATION PROGRAMME, LUXEMBOURG
Bartha Knoppers: Member, Strategic Advisory Board

SOCIETY, TECHNOLOGY AND ETHICS IN A PANDEMIC (STEP)
Bartha Knoppers: Member, Expert Advisory Group (Report, April 30, 2020)

COVID-19 RESOURCES CANADA
Yann Joly: Member (Initial)

QUEBEC BIOBANK ON COVID-19
Yann Joly: Member, Initial Workgroup
Ma'n Zawati: Member, Steering Committee
Ma'n Zawati: Member, Task Force

ETHICAL LEGAL EXPERTISE – COVID-19 IMMUNITY TASK FORCE (CITF)
Ma'n Zawati: Research project funded by the Public Health Agency of Canada

COVID-19 CLOUD: DIGITAL TECHNOLOGY SUPERCLUSTER
Ma'n Zawati: Research project funded by the Government of Canada

MINISTERS EXPERT GROUP (COVID) (Canada)
Bartha Knoppers: Member

CGP COMPLETED RESEARCH PROJECTS

THE QUÉBEC NETWORK OF APPLIED GENETIC MEDICINE
APRIL 2006 – MARCH 2020

CE IN BIOMARKER-DRIVEN CLINICAL RESEARCH FOR PERSONALIZED MEDICINE IN CANCER (EXACTIS)
APRIL 2014 – MARCH 2020

A Syst-OMICS APPROACH TO ENSURING FOOD SAFETY AND REDUCING THE ECONOMIC BURDEN OF SALMONELLOSIS
OCTOBER 2015 – SEPT2020

PROGRAMME DE RECHERCHE ET D'INNOVATION SUR LES MALADIES RARES (PRISMES)
APRIL 2016 – MARCH 2020

BUILDING A GOVERNANCE TOOLKIT FOR CANADIAN HEALTHY INFANT LONGITUDINAL DEVELOPMENT (CHILD)
APRIL 2018 – MARCH 2020

EPIGENOME-WISE: ETHICAL, LEGAL AND SOCIETAL ISSUES OF NEW ASSAYS FOR DNA-METHYLATION IN CANCER DIAGNOSTICS AND SCREENING
JULY 2018 – APRIL 2020

PROTECTING PRIVACY IN THE POSTGENOMIC ERA: ENSURING RESPONSIBLE DATA GOVERNANCE BY DIRECT-TO-CONSUMER COMPANIES ENGAGING WITH EPIGENETICS, MICROBIOMICS AND INTEGRATIVE MULTI-OMICS
APRIL 2019 – MARCH 2020

THE IMPACTS OF THE LACK OF LEGAL RECOGNITION OF GENETIC COUNSELORS IN QUEBEC
APRIL 2019 – MARCH 2020

LE DÉVELOPPEMENT D'UNE THÉRAPIE GÉNIQUE EFFICACE ET SÉCURITAIRE POUR L'ÉPIDERMOLYSE BULLEUSE RECESSIVE DYSTROPHIQUE ET JONCTIONNELLE
APRIL 2019 – MARCH 2020

PROJECT ARCHI (PILOT STUDY OF "PRECINOMICS")
APRIL 2019 – JUNE 2020

THE QUÉBEC NETWORK OF APPLIED GENETIC MEDICINE

APRIL 2006 – MARCH 2020

Réseau de médecine génétique appliquée (RMGA) du Québec

Fonds de Recherche du Québec - Santé (FRQS)

The RMGA is a Québec network of multi- and trans-disciplinary researchers seeking to facilitate both applied research in medical genetics in Québec and the transfer of new knowledge useful to this population. More specifically, 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. For example, in 2016, the Centre of Genomics and Policy (CGP) consolidated a decade of RMGA policies into a prospective Statement of Principles addressing ten different issues raised by research involving humans: recruitment of research participants, informed consent, secondary use of data and/or biosamples, privacy and confidentiality, professionalism, conflicts of interest, discrimination and stigmatization, governance of biobank and databases, commercialization and return of results. The Québec Network of Applied Genetic Medicine has also been actively involved in the legal and social debate regarding the federal law on genetic discrimination. The RMGA had notably developed a Position Statement on Genetic Discrimination.

PRINCIPAL INVESTIGATORS
ROULEAU Guy
SINNETT Daniel

CO-INVESTIGATORS
BERNARD Geneviève
DUPRÉS Nicolas
FERRETTI Vincent
GRAVEL Simon
GIRARD Simon
JOLY Yann
KNOPPERS Bartha Maria
LABERGE Anne-Marie
ROUSSEAU François
RIOUX John
SIMARD Jacques
SHOUBRIDGE Eric
VÉZINA Hélène

PhD STUDENT
NOOHI Forough

CE IN BIOMARKER-DRIVEN CLINICAL RESEARCH FOR PERSONALIZED MEDICINE IN CANCER (EXACTIS)

APRIL 2014 – MARCH 2020

Networks of Centres of Excellence (NCE)
Canadian Institutes of Health Research (CIHR)
Natural Sciences and Engineering Research Council of Canada (NSERC)
Social Sciences and Humanities Research Council (SSHERC)

The objective of the project was to create and expand a biomedical ecosystem that could overcome the major rate-limiting steps involved in realizing and expanding biomarker-driven clinical research for personalized medicine in cancer. The CGP provided a review of the ethical and legal issues while ensuring that federal and provincial legal consent requirements were met (on re-use of samples, governance, confidentiality, data-sharing, e-consent, risks, etc.). Other considerations reviewed by the Centre concern public-private partnerships (PPPs). These considerations were assessed through a three-round Delphi survey involving a panel of 27 experts in the field of precision medicine – preferably, but not limited to, oncology – who have interest or experience with accessing or managing biobanks, including representatives from the public and private sectors. The survey covered expectations when initiating PPPs; preconditions for successful PPPs; benefits associated with PPPs in medical research; major barriers preventing organizations from engaging in PPPs and solutions to these barriers; factors hindering the functioning of PPPs and solutions for their optimal functioning; as well as the respective roles that the public and private sectors should play in an ideal public-private partnership.

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DROIT Arnaud
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OZA Amit
SAAD Fred

ACADEMIC ASSOCIATES
GRANADOS MORENO Palmira
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RESEARCH ASSISTANT
FARAJI Sina

A SYST-OMICS APPROACH TO ENSURING FOOD SAFETY AND REDUCING THE ECONOMIC BURDEN OF SALMONELLOSIS

OCTOBER 2015-SEPTEMBER 2020

Genome Canada
Genome Québec

Each year, there are an estimated 88,000 cases of foodborne illnesses related to the consumption of fresh produce contaminated with Salmonella. Using whole-genome sequencing, the research team developed new tools that: (1) allowed public health officials to better determine the source and treatment of Salmonella illnesses; (2) enabled stakeholders along the food supply chain to more rapidly identify and remove contaminated fresh produce from grocery stores and restaurants; and (3) controlled the presence of Salmonella on fresh produce. An anticipatory governance approach integrated considerations of the evidentiary requirements as well as the economic, legal, ethical, and regulatory implications of supporting such a paradigm shift. More precisely, the CGP team assessed the perspectives of key stakeholders regarding the development, adoption and implementation of the subtyping testing method and the biocontrol. This included integrating the perspectives of experts (Delphi survey), the general public (national public opinion survey) as well as in-depth interviews with consumer protection, industry and organic farming representatives, and a stakeholder workshop bringing together various experts in the field of agri-food, researchers, and public health representatives.

PRINCIPAL INVESTIGATORS
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NGUENG FEZE Ida
SAULNIER Katie

RESEARCH ASSISTANT
ALARIE Samuel

PROGRAMME DE RECHERCHE ET D'INNOVATION SUR LES MALADIES RARES (PRISMES)

APRIL 2016 – MARCH 2020

Le Centre de recherche du CHU de Québec-Université Laval

The aim of this project was to improve knowledge of the molecular dysfunctions associated with certain rare diseases. This project aimed to: 1) identify the genetic causes associated with certain rare diseases in children and young adults whose genetic cause had not yet been identified; and 2) obtain a better understanding of the molecular mechanisms involved in the development of these rare diseases. In addition, this project aimed to establish a biobank for future research at the national and international levels. In a framework of scientific collaboration, the CGP oversaw and prepared the ethical documents required for initial approval by the Research Ethics Committee of CHU of the Québec-Université de Laval. Subsequently, the CGP provided support on ethical and legal issues, including changes/modifications to ethical documents or preparation of documents arising from the evolution of the project and the initiation of new collaborators with groups of international research.

PRINCIPAL INVESTIGATOR
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SIMARD Jacques

ACADEMIC ASSOCIATES
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NGUYEN Minh Thu

BUILDING A GOVERNANCE TOOLKIT FOR CANADIAN HEALTHY INFANT LONGITUDINAL DEVELOPMENT (CHILD)

APRIL 2018 – MARCH 2020

AllerGen
National Centres Excellence (NCE)

The development and implementation of an ethically and legally robust governance structure for research biobanks and databases is a pre-requisite to building and maintaining the trust of funders, research participants, research ethics boards, and collaborators. A comprehensive governance framework and related policies not only provide immediate guidance for the managers, researchers, participants and other stakeholders involved in the project, but also fosters a continuous and uniform management of the resource for future prospective uses. The P3G2 project was tasked with developing a governance framework to ensure maintenance of the scientific utility, validity and usability of the datasets and biospecimens generated by the CHILD Study, for the future. Currently, datasets and samples collected as part of the CHILD study are heterogeneous and vary across different recruitment sites. The Governance Framework provides a common ethical and policy structure for the future use of these datasets and samples so that the voluntary participation of Canadians is respected.

The purpose of this Governance Framework is to provide a general overview of the core elements related to the management, operations and ethical governance of a health database and, where applicable, an associated biobank. Detailed policies and procedures also accompany this guidance.

PRINCIPAL INVESTIGATOR
KNOPPERS Bartha Maria

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KOAYES Myriam

EPIGENOME-WISE: ETHICAL, LEGAL AND SOCIETAL ISSUES OF NEW ASSAYS FOR DNA-METHYLATION IN CANCER DIAGNOSTICS AND SCREENING

JULY 2018 – APRIL 2020

Netherlands Organisation for Scientific Research (NWO)
Erasmus Medical Center

Epigenetics is the study of molecular mechanisms for the regulation of gene expression, such as DNA methylation, which switch genes off or on without altering the DNA sequence. The Building Blocks of Life project 'Cut out for the future!' is developing a novel assay (MeD-seq technology) for genome-wide DNA methylation profiling in colon and cervical cancer. This new technology will help to understand the role of DNA-methylation in the pathogenesis of cancer. It may ultimately improve the ability to predict disease progression and treatment outcome in colon and cervical cancer, and potentially other cancers. However, such advances may also give rise to pressing ethical, legal and societal issues regarding autonomy, informed consent with unsolicited findings, harms and benefits of screening tests, privacy, personal responsibility and solidarity.

Through close cooperation with the BBoL project, the CGP will identify and address ethical, legal and societal issues arising from early phase research and development of MeD-seq technology. Moreover, we will anticipate and explore issues that may arise in the future when epigenetic technologies become introduced into population screening. We will develop practical guidelines to help investigators, test developers and policy makers to consider in the phase of research & development and in anticipation of its potential implementation in population screening.

PRINCIPAL INVESTIGATOR
BOLT Ineke

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PROTECTING PRIVACY IN THE POSTGENOMIC ERA: ENSURING RESPONSIBLE DATA GOVERNANCE BY DIRECT-TO-CONSUMER COMPANIES ENGAGING WITH EPIGENETICS, MICROBIOMICS AND INTEGRATIVE MULTI-OMICS

APRIL 2019 – MARCH 2020

Office of the Privacy Commissioner of Canada

Over the past few years, epigenetic and microbiomic tests have been commercialized by private companies, some of which are currently being advertised and offered to the Canadian public online. The collection and use by private companies of such biological information raises serious legal and ethical privacy concerns. Specifically, the privacy implications raised by the increase in diversity of these new forms of biological data – and their integration with genomic datasets – have not been seriously addressed yet. This project will investigate the privacy issues emerging from the rapid scientific development and commercialization of what the researchers call "postgenomic biometrics."

PRINCIPAL INVESTIGATOR
JOLY Yann

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COLLABORATORS
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DEWAR Ken
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RESEARCH ASSISTANT
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THE IMPACTS OF THE LACK OF LEGAL RECOGNITION OF GENETIC COUNSELORS IN QUEBEC

APRIL 2019 – MARCH 2020

Réseau de médecine génétique appliquée du Québec (RMGA)

As genomic medicine is increasingly used in the clinic, demand for genetic counselling is growing. Genetic counselling, however, is not regulated in most Canadian provinces, including Québec. Understanding the potential impacts of this lack of regulation on the provision of health services, on the clinical uptake of genomic research findings, and on the risks incurred by the public is essential. The existence of frameworks regulating the practice of a medical profession is one of the options for safeguarding the protection of the public by reserving the acts and titles of specific health professionals. To determine how the activities of a genetic counsellor could be translated into legal duties, our project aimed to categorize the main tasks of genetic counsellors and the risks associated with these tasks in the context of Québec. To do this, we combined our legal expertise, the expertise of an Expert Advisory Committee composed of RMGA members and a broader stakeholder consultation (e.g., genetic counsellors, medical geneticists, and other medical specialists). Understanding the scope, limits and possible overlap of genetic counselling with acts currently reserved for other health professionals optimized the integration of genetic medicine applied to the practices and policies of the Québec health system.

PRINCIPAL INVESTIGATOR
ZAWATI Ma'n H.

ACADEMIC ASSOCIATES
HAGAN Julie
PATRINOS Dimitri

RESEARCH ASSISTANT
ALARIE Samuel

INTERN
DIAS Julie-Alexia

LE DÉVELOPPEMENT D'UNE THÉRAPIE GÉNIQUE EFFICACE ET SÉCURITAIRE POUR L'ÉPIDERMOLYSE BULLEUSE RECESSIVE DYSTROPHIQUE ET JONCTIONNELLE

APRIL 2019 – MARCH 2020

Fonds de recherche Santé Québec (FRQS)
ThéCell

Epidermolysis Bullosa (EB) is a genetic disease manifested by a lack of adhesion between the dermis and the epidermis. It causes detachment of the mucous membrane and epidermis, which can lead to serious complications such as ulcers, infections and cancer (carcinoma). Currently, the treatments offered are palliative, mainly with bandages to protect epithelial wounds. EB is characterised by mutations in different genes. The aim of the project was to develop an effective gene therapy treatment for two types of EB: dystrophic EB (D) and junction EB (J). Skin substitutes (reconstructed skin) were produced from EB patient cells, grown in vitro and corrected by gene therapy. The efficacy of this treatment was tested on reconstructed human skin in the laboratory. The CGP reviewed the ethical and legal issues associated with this project.

PRINCIPAL INVESTIGATORS
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ACADEMIC ASSOCIATE
KLEIDERMAN Erika

PROJECT ARCHI (PILOT STUDY OF "PRECINOMICS")

APRIL 2019 – JUNE 2020

Ministère de l'Économie et de l'Innovation (MEIE)

ARCHI is the pilot phase portion of a project aimed at setting up a prototype for a national platform (PRECINOMICS) to ensure responsible access to and exchange of genomic and clinical-administrative data for health research purposes, particularly in precision medicine. The project aimed to 1) integrate data from 20,000 participants enrolled in two separate research cohorts (the Montreal Heart Institute and the CanPATH); and 2) enrich these data with genomic data. The completion of ARCHI demonstrated the feasibility of integrating research, clinical-administrative / hospital and multi-omics data.

In this project, the role of the CGP was to develop policies governing the ethical and legal framework of the future PRECINOMICS platform in terms of data privacy and security, as well as data access and consent management. To do so, the CGP surveyed existing biobank consent forms and access policies to identify regulatory, ethical and governance-related issues and barriers. During the development of the governance framework, several elements of the future PRECINOMICS platform were yet to be finalized/confirmed. As such, the headings included in the draft governance framework are generic and represent the key information, requirements, and issues to be considered beyond the pilot phase to ensure responsible oversight and access to data (to be adapted).

PRINCIPAL INVESTIGATOR
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PATRINOS Dimitri

CURRENT CGP RESEARCH PROJECTS

ThéCell : RÉSEAU DE THÉRAPIE CELLULAIRE, TISSULAIRE ET GÉNIQUE DU QUÉBEC
APRIL 2009 – MARCH 2021

CANADIAN PARTNERSHIP FOR TOMORROW'S HEALTH (CanPath)
APRIL 2009 – MARCH 2022

RESEARCH ADVANCEMENT THROUGH COHORT CATALOGUING AND HARMONIZATION (ReACH)
APRIL 2016 – MARCH 2021

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
APRIL 2016 – MARCH 2021

Sino-Canada HeLTI: A MULTIFACETED COMMUNITY-FAMILY- MOTHER-CHILD INTERVENTION STUDY FOR THE PREVENTION OF CHILDHOOD OBESITY (SCHeLTI)
APRIL 2016 – MARCH 2021

THE GENDER SPECIFIC EFFECTS OF PRENATAL ADVERSITY ON THE DEVELOPMENT OF ANXIOUS AND DEPRESSIVE PSYCHOPATHOLOGY IN EARLY ADOLESCENCE
APRIL 2016 – MARCH 2021

CanDIG: CANADIAN DISTRIBUTED CYBER-INFRASTRUCTURE FOR GENOMICS
APRIL 2016 – MARCH 2021

CANADIAN GENOMICS PARTNERSHIP FOR RARE DISEASE (CGP4-RD): POLICY TOOLKIT
APRIL 2016 – MARCH 2021

MULTIDIMENSIONAL EPIGENOMICS MAPPING CENTRE (EMC) AT MCGILL
FEB 2017 – JAN 2022

HEALTHY LIFE TRAJECTORIES (HELTI): GOVERNANCE FRAMEWORK
JAN 2018 – MARCH 2022

REGULATION OF INTERNATIONAL DIRECT-TO-PARTICIPANT (DTP) GENOMIC RESEARCH
MARCH 2018 – JAN 2021

TOWARD EFFECTIVE HEALTH COMMUNICATION WITH INTERSEX CANADIANS: A STUDY OF ETHICAL AND LEGAL CHALLENGES

MARCH 2018 – MARCH 2022

QUEBEC 1000 FAMILIES (Q1K) PROJECT (TRANSFORMING AUTISM CARE CONSORTIUM)

APRIL 2018 – MARCH 2021

PRECISION ONCOLOGY FOR YOUNG PEOPLE (PROFYLE 2)

APRIL 2018 – MARCH 2021

INTERROGATING AND IMPLEMENTING OMICS FOR PRECISION MEDICINE IN ACUTE MYELOID LEUKEMIA

APRIL 2018 – MARCH 2022

GENCOUNSEL: OPTIMIZATION OF GENETIC COUNSELLING FOR CLINICAL IMPLEMENTATION OF GENOME-WIDE SEQUENCING

APRIL 2018 – MARCH 2022

PERSONALIZED RISK ASSESSMENT FOR PREVENTION AND EARLY DETECTION OF BREAST CANCER: INTEGRATION AND IMPLEMENTATION (PERSPECTIVE II)

APRIL 2018 – MARCH 2022

PERSONALIZED THERAPY FOR INDIVIDUALS WITH CYSTIC FIBROSIS

APRIL 2018 – APRIL 2022

CARE4RARE CANADA: HARNESSING MULTI-OMICS TO DELIVER INNOVATIVE DIAGNOSTIC CARE FOR RARE GENETIC DISEASES IN CANADA (C4R-SOLVE)

APRIL 2018 – MARCH 2022

MCGILL UNIVERSITY AND GÉNOME QUÉBEC INNOVATION CENTRE

APRIL 2018 – MARCH 2022

MSSNG DATABASE – DATA ACCESS COMPLIANCE OFFICE

JULY 2018 – JUNE 2021

GENOMICS, ISLAMIC ETHICS AND PUBLIC ENGAGEMENT (GIEPE): TOWARDS BRIDGING THE KNOWLEDGE AND COMMUNICATION GAPS

OCT 2018 – SEPT 2021

EPIGENOMICS SECURE DATA SHARING PLATFORM FOR INTEGRATIVE ANALYSES (EPISHARE)

OCT 2018 – SEPT 2021

EUCANSHARE: AN EU-CANADA JOINT INFRASTRUCTURE FOR NEXT-GENERATION MULTI-STUDY HEART RESEARCH

OCT 2018 – SEPT 2022

HUMAN CELL ATLAS

NOV 2018 – OCT 2021

CANADIAN OPEN NEUROSCIENCE PLATFORM (CONP) – ETHICS AND GOVERNANCE COMMITTEE; SCHOLARSHIP SUPERVISION

JAN 2019 – MAY 2021

CAN-SHARE CONNECT: SUPPORTING THE REGULATORY AND ETHICS WORK STREAM OF THE GLOBAL ALLIANCE FOR GENOMICS AND HEALTH (GA4GH)

JAN 2019 – DEC 2022

OBSERVATOIRE INTERNATIONAL SUR LES IMPACTS SOCIÉTAUX DE L'INTELLIGENCE ARTIFICIELLE ET DU NUMÉRIQUE

MARCH 2019 – APRIL 2023

LE CONSORTIUM QUÉBÉCOIS CONTRE LE CANCER POUR DE NOUVEAUX AGENTS THÉRAPEUTIQUES ET BIOMARQUEURS

APRIL 2019 – MARCH 2021

THE CANCER GENOME COLLABORATORY

APRIL 2019 – MARCH 2023

EUCANCAN: A FEDERATED NETWORK OF ALIGNED AND INTEROPERABLE INFRASTRUCTURES FOR THE HOMOGENEOUS ANALYSIS, MANAGEMENT AND SHARING OF GENOMIC ONCOLOGY DATA FOR PERSONALIZED MEDICINE

APRIL 2019 – MARCH 2023

CopaQ : INITIATIVE DE SCIENCE PARTICIPATIVE EN RECHERCHE SUR LES POPULATIONS

MAY 2019 – APRIL 2021

THE McGILL CLINICAL GENOMICS (McG) PROGRAM

OCT 2019 – DEC 2021

ETHICAL AND LEGAL FRAMEWORK FOR DIRECT-TO-PARTICIPANT (DTP) RECRUITMENT

JAN 2020 – JAN 2022

SELF-ASSEMBLY SKIN SUBSTITUTES (SASS) FOR THE TREATMENT OF ACUTE WOUNDS OF CANADIAN BURN PATIENTS

JAN 2020 – JAN 2022

CULTURED EPITHELIAL CORNEAL AUTOGRAFTS FOR THE TREATMENT OF CANADIANS WITH LIMBAL STEM CELL DEFICIENCY

JAN 2020 – JAN 2022

THE QGPRS STUDY:
QATAR GENOME POLYGENIC RISK SCORE, A PRECISION MEDICINE APPROACH TO PREVENT DIABETIC COMPLICATIONS IN THE AFFECTED QATARI INDIVIDUALS

JAN 2020 – JULY 2023

OPPORTUNITIES AND CHALLENGES OF USING EPIGENETIC TECHNOLOGIES IN DEFENCE AND SECURITY CONTEXTS

APRIL 2020 – SEPT 2021

VALIDATING, SPECIFYING & PRIORITIZING THE ETHICAL, LEGAL AND SOCIAL IMPLICATIONS OF IMPLEMENTING ARTIFICIAL INTELLIGENCE WITHIN ANTI-DOPING STRATEGIES: AN INTERNATIONAL DELPHI STUDY

APRIL 2020 – APRIL 2022

DOvEEgene

APRIL 2020 – MARCH 2024

OF BIOBANKING AND POLICY: EMERGING ETHICAL AND LEGAL CHALLENGES DURING THE COVID-19 PANDEMIC

MAY 2020 – APRIL 2021

CURRENT CGP RESEARCH PROJECTS

UN NANO-VACCIN CONTRE LES MALADIES CARDIOVASCULAIRES (AUDACE)
APRIL 2020 – APRIL 2022

ETHICAL LEGAL EXPERTISE – COVID-19 IMMUNITY TASK FORCE (CITF)
JULY 2020 – MARCH 2022

COVID-19 CLOUD
JULY 2020 – JUNE 2021

ETHICS AND POLICY PILLAR – HostSeq (CanCOGeN)
JUNE 2020 – MAY 2022

ELSI COMPONENT: VIRUSSEQ – CANCOGEN
MAY 2020 – MARCH 2022

INNOVE-ONCO – TECHNOLOGICAL AND ORGANIZATIONAL INNOVATIONS GO HAND IN HAND: A COLLABORATIVE MODEL TO RENDER ONCOGENETICS MORE FLEXIBLE, ACCESSIBLE AND EFFICIENT
SEPT 2020 – OCT 2022

TOWARDS AN EPIDERMOLYSIS BULLOSA CLINICAL TRIAL WITH TISSUE-ENGINEERED SKIN AFTER EX VIVO GENE THERAPY CORRECTION
SEPT 2020 – OCT 2022

DEVELOPPEMENT D'UN CADRE ETHIQUE ET LEGAL POUR LE DEPLOIEMENT DES ACTIVITES DU RQDM ET L'HARMONISATION DU CONSENTEMENT DES PATIENTS/ DEVELOPMENT OF AN ETHICAL AND LEGAL FRAMEWORK FOR THE DEPLOYMENT OF RQDM ACTIVITIES AND THE HARMONIZATION OF PATIENT CONSENT
NOV 2020 – NOV 2022

ThéCell : RÉSEAU DE THÉRAPIE CELLULAIRE, TISSULAIRE ET GÉNIQUE DU QUÉBEC

APRIL 2009 – MARCH 2021

Fonds de recherche du Québec - Santé (FRQS)

Created in 2009, the Québec Cell, Tissue and Gene Therapy Network (ThéCell) focuses on the development of novel cell, tissue and gene therapies to improve patient care in an innovative and sustainable manner. It brings together researchers with diverse expertise in the field of regenerative medicine within Québec to build a multi-disciplinary team. The Network aims to promote and structure translational research and advance knowledge, technological tools and treatments in regenerative medicine. Prof. Knoppers and CGP members support researchers in their reflections on ethical, legal and social issues (ELSI) raised by the transition from bench to bedside of emerging cell and gene therapies. This comprises two components: 1) assisting researchers in the development of research protocols (sample governance mechanisms, recruitment and participants' consent processes) and 2) providing support in the regulatory approval process for these clinical trials. The multidisciplinary aspect of the Network makes it possible to consider and integrate ELSI concerning the scientific reality of clinical trials in regenerative medicine.

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CANADIAN PARTNERSHIP FOR TOMORROW'S HEALTH (CanPath)

APRIL 2009 – MARCH 2022

Canadian Partnership Against Cancer (CPAC)

The Canadian Partnership for Tomorrow's Health (CanPath) 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, and BC Generations Project). Hosted at the Centre of Genomics and Policy, the ELSI Standing Committee built the ELSI infrastructure of the CanPath platform. The goals are to bring together ELSI experts and develop relevant policies, documents, and procedures that are needed either by CanPath 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, ranging from developing interoperable recruitment, access policies, and procedures to dealing with ethical issues surrounding consent, privacy, data sharing, and proposing governance structures for CanPath. P3G2 also ran the Access Office of CanPath until 2018, which reviewed access requests from national and international researchers.

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RESEARCH ADVANCEMENT THROUGH COHORT CATALOGUING AND HARMONIZATION (ReACH)

APRIL 2016 – MARCH 2021

Canadian Institutes of Health Research (CIHR)

Increasingly, 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). 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 the 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 provides 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 cohort data and biological samples. The CGP's role is to study the existing processes addressing sharing, access and data linkage and by performing a comprehensive analysis of the ethical and legal clauses included in the documents used by these cohorts (i.e. consent forms, data sharing policies, governance framework, etc.). The CGP will compare the different clauses and processes to identify similarities and divergences and has notably developed a Points-to-Consider document from an ethical and legal point of view, for access to research databases.

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.

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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

APRIL 2016 – MARCH 2021

Canadian Institutes of Health Research (CIHR)

The advanced 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. Precise knowledge of how risk factors interact to predict those at higher risk is lacking. For instance, gender differences in stress response are well documented in early emotional development, but not in later development. Genetic differences in susceptibility to prenatal events are also important. 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, the United Kingdom, the Netherlands and Singapore include and share measures of genes, maternal care, child psychopathology, and sensitive data with different consent forms, measures, access approaches, laws and regulations. The CGP acts 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, and 2) addressing issues of consent and the need to re-contact child participants once they become adults.

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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 large birth cohort studies, clinical trials and studies on the development of metabolic disorders, our transdisciplinary Chinese-Canadian team will conduct a multi-site and community-based randomized controlled trial. This trial will test the effect of a family-mother-child intervention package (incorporated into routine patient care) on childhood OWO rates in children aged one through six. The CGP is developing the 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 aim to facilitate policy interoperability and access authorizations as well as streamline the ethical and legal aspects of international collaborative research.

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THE GENDER SPECIFIC EFFECTS OF PRENATAL ADVERSITY ON THE DEVELOPMENT OF ANXIOUS AND DEPRESSIVE PSYCHOPATHOLOGY IN EARLY ADOLESCENCE

APRIL 2016 – MARCH 2021

Canadian Institutes of Health Research (CIHR)

The gender dimorphic effects of prenatal stress are well demonstrated. Girls may be more susceptible to the effects of fetal adversity on fearful temperament, emotional reactivity and internalizing problems. Little research has examined whether gender differences in the case of fetal adversity are maintained in the prediction of anxiety and depression in older children. A landmark study reports that maternal prenatal depression is associated with an increased risk of depressive symptoms in 18-year-old female offspring. It suggests the need to consider the interaction between gender and prenatal adversity and the role of genotype and postnatal environments. Accordingly, gender considerations will be approached as follows: 1) careful examination of gender-based age-specific trends in the development of anxious and depressive psychopathology from preschool through pre-adolescence; 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 ethical and legal guidelines for: 1) the safeguarding of pediatric genomic data; and 2) the consent for data use from children as they become adults.

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CanDIG: CANADIAN DISTRIBUTED CYBER-INFRASTRUCTURE FOR GENOMICS

APRIL 2016 – MARCH 2021

Canadian Foundation for Innovation (CFI)

The Distributed Infrastructure for Genomics Data Sharing and Analysis project is divided into four activities. In Activity 1, the CGP will develop a broad Canadian data sharing framework, using the APIs developed under the auspices of the Global Alliance for Genomics and Health (GA4GH). Activity 2 continues 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 builds a data-sharing platform to allow for the collection of standardized clinical data, dynamic cohorts, and the performance of genome analytics across datasets stored on various Compute Canada nodes, and to enable genome-guided clinical trials across Canada. Finally, Activity 4 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 CGP will also contribute to the implementation of the data sharing and privacy policy framework of the International Human Epigenome Consortium (IHEC) as well as that of the GA4GH.

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CANADIAN GENOMICS PARTNERSHIP FOR RARE DISEASE (CGP4-RD): POLICY TOOLKIT

APRIL 2016 – MARCH 2021

Genome Canada
Genome Québec

With rare diseases (RD), sufficient patient numbers are not available at any one site. Data needs to be centralized, integrated and broadly accessible to drive RD research for gene identification and understanding. Harmonized policies, an overarching governance framework and the sharing of data through a nation-wide data sharing resource would make a significant impact on research and treatment of RDs. The Canadian Genomics Partnership for Rare Diseases (CGP4-RD) Policy Toolkit aims to address disparities between current institutional, provincial and federal regulatory frameworks to foster sharing of research and health data. Building from a stakeholder engagement process, a set of broad, inclusive and actionable policy resources are being developed for implementation by Genome Canada funded Genomic Applications Partnerships Program (GAPP) projects. This policy toolkit also aims to enable pan-Canadian data sharing by projects funded by the Genome Canada GAPP initiative that would incorporate the data sharing principles and practices as well as the protection of patient interests particular to rare diseases. Though tailored to the rare disease clinical research community, the tools developed by the CGP4-RD Policy Toolkit can be adapted and used as models for common diseases as we move towards precision medicine.

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MULTIDIMENSIONAL EPIGENOMICS MAPPING CENTRE (EMC) AT MCGILL

FEBRUARY 2017—JANUARY 2022

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 which employs epigenome mapping to understand interactions between environment and genome in human blood cells, to interpret diseases impacting metabolism using tissue samples, and to study how epigenetic changes can alter function of the brain. The large-scale generation and sharing of human epigenome data present challenges to the process of informed consent which 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 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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HEALTHY LIFE TRAJECTORIES (HELTI): GOVERNANCE FRAMEWORK

JANUARY 2018 — MARCH 2022

Canadian Institutes of Health Research (CIHR)

The HeLTI program was developed by the Institute of Human Development (Child and Youth Health) under the Canadian Institutes of Health Research (CIHR). The program represents a partnership between CIHR, the South African Medical Research Council, India's Department of Biotechnology, the National Natural Science Foundation of China and the World Health Organization. HeLTI was developed to address the increasing burden of non-communicable diseases (including obesity, diabetes, cardiovascular disease and poor mental health) around the world. There are four separate but harmonized projects that are commencing in Soweto (South Africa), Mysore (India), Shanghai (China), and across Canada. All projects are focused towards developing evidence-based interventions that span from pre-conception across pregnancy and into the postnatal period with a goal improving maternal, infant and child health. The CGP is involved in the development of governance tools to foster international data sharing.

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REGULATION OF INTERNATIONAL DIRECT-TO-PARTICIPANT (DTP) GENOMIC RESEARCH

MARCH 2018 — JANUARY 2021

National Institutes of Health (NIH)

This study aims to understand and document the regulation of Direct-To-Participant (DTP) genomic research around the world. We developed and distributed a survey to law and policy experts in 31 countries in order to clarify the law, regulation, and policy governing this novel and emerging approach to research recruitment in the genomics context. Our team at the CGP played a central role in research design, participated in expert working groups to identify and prioritize the key issues for the standard questionnaire, identified and recruited potential expert participants, and analysed final research results. We played an active role in the formulation of conclusions and recommendations for the future governance of DTP genomic research. We also coordinated the preparation of a special issue of the Journal of Law, Medicine, and Ethics detailing our findings and presenting the team's recommendations. The special issue was published in 2020. We have further disseminated our findings in several international conference presentations.

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TOWARD EFFECTIVE HEALTH COMMUNICATION WITH INTERSEX CANADIANS: A STUDY OF ETHICAL AND LEGAL CHALLENGES

MARCH 2018 – MARCH 2022

Social Sciences and Humanities Research Council (SSHERC)

About 1.7% of the population falls under the umbrella of "intersex", with bodies that develop along a spectrum of sex differences. Intersex individuals face egregious human rights violations, discrimination, and stigmatization. In healthcare, this includes unnecessary surgical interventions, the withholding of accurate health information, and overemphasis of incidental health risks. At present, there is a lack of Canadian-specific guidance or explicit legal protections to guide healthcare providers in their professional relationship with intersex patients.

This project engages two communities of stakeholders: intersex individuals and healthcare professionals (HCPs). The core objectives are to generate qualitative evidence on the experiences of intersex individuals in the healthcare system and to use this evidence to develop improved standards of care. Following a comparative review of relevant laws and policies, we will conduct a series of semi-structured interviews with intersex adults and their HCPs. From these, the CGP will develop: 1) a guidance document for healthcare practitioners; 2) an issues paper on person-centered research with vulnerable populations; and 3) information sheets for intersex individuals navigating the Canadian healthcare system.

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QUEBEC 1000 FAMILIES (Q1K) PROJECT (TRANSFORMING AUTISM CARE CONSORTIUM)

APRIL 2018 –SEPTEMBER 2021

Fonds de Recherche du Québec - Santé (FRQS)

Launched in 2018, the Transforming Autism Care Consortium (TACC) network aims to bring together the autism research community in Québec, by improving access and availability of resources and integrating knowledge into practice. The Québec 1000 families project (the "Q1K project") is a TACC network's flagship project. It provides a platform (database, biobank and registry) to facilitate research by creating a large cohort of ASD family trios (proband participant, and first-degree relatives) in families where a child has been diagnosed with an autism spectrum disorder. The CGP has developed a governance framework (which includes relevant policies on privacy, data access, return of research findings, etc.), template consent forms/assent forms and support to research ethics board submission for the Q1K project and is providing ongoing support with the management of emerging ethical questions pertaining to the implementation of the Q1K project and the TACC network.

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PRECISION ONCOLOGY FOR YOUNG PEOPLE (PROFYLE 2)

APRIL 2018 – MARCH 2021

Terry Fox Research Institute

The PRecision Oncology For Young peopLE (PROFYLE) program aims to transform the treatment of cancer in children, adolescents, and young adults by using next-generation molecular tools and cancer model systems to identify disease and patient-specific biomarkers. The project emphasizes real-time molecular profiling to personalize cancer treatment and improve outcomes. The CGP studies questions surrounding access to genetic data by parents and the use of mobile health applications when streamlining recruitment processes. Our team proposes policy recommendations for improving access to molecular profiling and associated treatment applications. The team will further identify ethical and legal issues raised by the development of mobile health technologies that facilitate patient recruitment and that promote equitable access to molecular profiling. This research will lead to the development of a points to consider document to guide PROFYLE's work toward developing a mobile application.

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INTERROGATING AND IMPLEMENTING OMICS FOR PRECISION MEDICINE IN ACUTE MYELOID LEUKEMIA

APRIL 2018 – MARCH 2022

Genome Canada
Genome Québec

Acute myeloid leukemia (AML) is a leading cause of cancer-related death in young adults and a highly lethal disease in older adults. The Leucegene project aims to contribute to the more effective targeting of AML treatment according to genomics risk profiles, especially in the case of patients in intermediate risk categories for whom no reliable curative treatment measures exist. Alongside its genetics research objectives, the Leucegene project team will also assemble a ground-breaking prognostic and therapeutic web portal that will make the project's findings widely available to researchers, clinicians, and patients. The CGP undertook an extensive review of policy instruments adopted for similar functions as well as significant engagement with patients, caregivers, and healthcare providers. Notably, in-depth interviews were conducted with healthcare providers to assess their expectations for using a web portal for accessing and sharing information about AML research, which, in turn, informed the development of the portal. These efforts will also contribute to the drafting of internal policy guidance for managing the Leucegene portal. At the same time, the CGP will draw on international policy and case law to produce a Good Practices document for informing the development of prognostic and therapeutic web portals in other healthcare contexts.

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GENCOUNSEL: OPTIMIZATION OF GENETIC COUNSELLING FOR CLINICAL IMPLEMENTATION OF GENOME-WIDE SEQUENCING

APRIL 2018 – MARCH 2022

Genome Canada
Genome British Columbia
Genome Québec

Genome-wide sequencing (GWS; whole genome or exome sequencing) is a powerful new tool that analyzes a person's entire genetic make-up. However, the information garnered from this type of testing can be overwhelming and may be misinterpreted by non-experts. Genetic counsellors are health professionals that aid patients and families in making informed decisions for this type of testing. However, due to the small number of genetic counsellors in Canada and lack of legal recognition, access to their services is extremely limited. As access to GWS improves and cost decreases, the use of this technology will increase along with the need for genetic counselling. As a result, further exploration of the possible legal recognition of genetic counsellors and key related strategies is necessary.

The CGP oversees policy development for the future legal recognition of genetic counsellors in Canada. Specifically, the CGP will: 1) research models of legal recognition available to genetic counsellors; 2) categorize the main tasks performed by genetic counsellors and assess how they translate into legal duties; and 3) convene a pan-Canadian working group comprised of key stakeholders to discuss the feasibility of and potential pathways toward legal recognition.

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PERSONALIZED RISK ASSESSMENT FOR PREVENTION AND EARLY DETECTION OF BREAST CANCER: INTEGRATION AND IMPLEMENTATION (PERSPECTIVE II)

APRIL 2018 – MARCH 2022

Genome Canada
Genome Québec

This project aims to provide evidence that can significantly expand the benefits of current age- based population breast cancer screening programs by supporting the transition to a risk-based approach. A population-based cohort is assembled to evaluate the acceptability and feasibility of using a new comprehensive risk prediction web tool and a genomic profiling test. The CGP will provide health authorities with acceptable policies that address emergent socio-ethical and legal issues of the implementation of a personalized risk-based screening approach in Canada. To achieve this, the CGP will examine five issues via a legal and sociological transdisciplinary analysis: 1) extension of the roles of health professionals; 2) integration of phone and videoconferencing technologies to provide timely clinical and informational support; 3) management of privacy when using risk calculation algorithms such as BOADICEA with electronic health records; 4) compliance with federal and provincial regulatory requirements and technology transfer options; and 5) information of women on the risks of genetic discrimination and existing protections to mitigate them. The CGP will also support the research team in regard to the ethics approvals required and specific ethical issues associated to the establishment of the research cohort.

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PERSONALIZED THERAPY FOR INDIVIDUALS WITH CYSTIC FIBROSIS

APRIL 2018 – APRIL 2022

Genome Canada
Ontario Genomics

Cystic fibrosis (CF) is the most common fatal genetic disease, affecting 4,000 Canadians and 80,000 people throughout the world. The debilitating disease causes difficulties in breathing, lung infections, and digestive disorders and those affected die at a median age of 35 in Canada. Treatments can ease symptoms, but there is currently no cure. Newer drugs can address the underlying genetic defect that causes CF, but only some patients respond positively to them. Given the side effects and the high cost of these drugs, there is a pressing need for robust predictors of who will respond to what treatment. Dr. Felix Ratjen (Hospital for Sick Children) and his team are developing predictive tools to help clinicians determine the right medicine for the right patient. The team will examine how genetic factors can help predict individual treatment responses and examine if drug testing on tissue samples can be used to inform the potential clinical response to drugs by each patient. The team will work with industry partners, patient organizations and the Ontario Ministry of Health to integrate these strategies into patient care. The result of the team's work will be a shift toward individualized treatment for CF, assistance for clinicians in making treatment decisions, guidance for policymakers on reimbursement and better health outcomes for patients.

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CARE4RARE CANADA: HARNESSING MULTI-OMICS TO DELIVER INNOVATIVE DIAGNOSTIC CARE FOR RARE GENETIC DISEASES IN CANADA (C4R-SOLVE)

APRIL 2018 – MARCH 2022

Genome Canada
Genome Alberta
Genome British Columbia
Ontario Genomics

To understand unsolved rare diseases (RDs), C4R-SOLVE explores new sequencing technologies and seeks to improve data sharing world-wide, enabling the discovery of new causes of RDs. The goal of C4R-SOLVE, aligned with Canada's national RD strategy, is to fully understand the molecular pathogenesis of unsolved RDs and facilitate timely access to clinical genome-wide sequencing. As part of its activities, C4R-SOLVE will develop a pan-Canadian RD repository (Genomics4RD) to optimize data sharing and analysis. P3G2 developed a governance framework to oversee the Genomics4RD database.

This framework outlines the policies with respect to the creation, management, and use of the Genomics4RD repository. It includes, amongst others, provisions on the identification of eligible participants, core consent requirements (prospective/retrospective), terms of the collection and integration of data from different sources (e.g., genomic data, clinical data, cost data, patient-contributed data, etc.), re-contact options and, where relevant, mechanisms for the return of results. Furthermore, an assessment of legacy (retrospective) datasets to be shared with Genomics4RD and PhenomeCentral was undertaken.

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MCGILL UNIVERSITY AND GÉNOME QUÉBEC INNOVATION CENTRE

APRIL 2018 – MARCH 2022

Genome Canada
Genome Québec

The McGill University and Génome Québec Innovation Centre is a world class research facility for genomics and proteomics. Founded in 2002, the Centre has developed a world-renowned expertise in complex genetic disorders such as cardiac disease, asthma and Type 2 diabetes, and has become a resource and a networking site for various research initiatives in human health, forestry, infectious diseases, agriculture and environment.

Ambitious projects in recent years are a testimony of the ability of Génome Québec to provide data of exceptional quality in the pursuit of various genomics studies. The Innovation Centre provides complete DNA and RNA analysis services, from a few samples to several tens of thousands per week. Large-scale genomics and proteomics services at the Innovation Centre are articulated around sequencing (including massively parallel sequencing), genotyping, functional genomics and extraction supported by a solid infrastructure, tools (Nanuq), unique expertise in bioinformatics and nucleic acid extraction. The Innovation Centre also hosts the Canadian Centre for Computational Genomics (C3G) which offers bioinformatics services. All services work in parallel to provide comprehensive, reliable services to the Québec, Canadian and international scientific community. Located on the campus of McGill University in the heart of Montreal, the Innovation Centre acts as a vast resource of knowledge and technology to the academic and industrial sectors. The CGP provides ongoing ethical and policy consultation on this project.

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MSSNG DATABASE – DATA ACCESS COMPLIANCE OFFICE

JULY 2018 – JUNE 2021

Autism Speaks Inc.

Autism Speaks launched the MSSNG project with the overall goal to store and analyze the world's largest collection of genomes of people with autism and their families. With the goal of sequencing the DNA of 10,000 families affected by autism, MSSNG will help answer the many questions we still have about the disorder. Thanks to the Google Cloud, this vast sea of information is accessible for free to researchers. Scientists from around the world will be able to study trillions of data points in one single database. Already, MSSNG has led to new discoveries about autism and its associated health conditions.

As part of the MSSNG Database project, the CGP is offering Data Access Compliance Office (DACO) services to the MSSNG project. From January 1st to December 31st 2020, the DACO processed 28 applications (including renewals).

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GENOMICS, ISLAMIC ETHICS AND PUBLIC ENGAGEMENT (GIEPE): TOWARDS BRIDGING THE KNOWLEDGE AND COMMUNICATION GAPS

OCTOBER 2018–SEPTEMBER 2021

Qatar National Research Fund

Genomic medicine and personalized healthcare are becoming increasingly prevalent in the Gulf region, raising difficult ethical and policy questions for the public and regulators alike. As healthcare systems increasingly emphasize these emerging fields, the public will be exposed both to the science of genomic medicine and to associated issues in Islamic ethics. There has been little scholarly or public debate on the implications of genetics on Islamic ethics. This project attempts to address these gaps by developing an understanding of public engagement for the development of policies and regulations in the genomics and personalized medicine contexts that is both religiously and culturally sensitive. The team at the CGP has performed a comparative analysis of international genomics norms that will serve as a grounding to inform genomics and personalized medicine policy development in the Gulf region. The project aims to present concrete proposals for addressing key ethical issues in the field of genomics, including privacy, consent, the return of results, sensitive data management, communication of incidental findings, and data sharing.

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EPIGENOMICS SECURE DATA SHARING PLATFORM FOR INTEGRATIVE ANALYSES (EPISHARE)

OCTOBER 2018–SEPTEMBER 2021

Genome Canada
Genome Québec

Advances in next-generation epigenetic sequencing have led to a vast increase in available human epigenetic data, including transcriptomic data (via RNA-seq) and chromatin data (via ChIP-seq). These epigenetic datasets have led to the development of expression-wide association studies (EWAS) and chromatin-wide association studies (CWAS). This may lead to improved biomedical applications by providing mechanistic explanations and key insights into the interpretation of genome-wide association studies (GWAS). However, obtaining raw data stored at multiple controlled access repositories can be a very challenging task, because access needs to be controlled to protect the research participants' right to privacy.

We need mechanisms to make the process of analyzing epigenomic data more flexible, while addressing the ethical and privacy aspects of data sharing. The Global Alliance for Genomics and Health (GA4GH) has developed tools and standards to address these issues for genomic data. Such tools are now needed for epigenomic data. The EpiShare framework will provide a user-friendly web resource for scientists to access and visualize large epigenomics datasets, alongside privacy and confidentiality assessment tools to ensure that the methods by which data will be stored, accessed and analyzed meet requirements set by international laws and standards.

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EUCANSHARE: AN EU-CANADA JOINT INFRASTRUCTURE FOR NEXT-GENERATION MULTI-STUDY HEART RESEARCH

OCTOBER 2018—SEPTEMBER 2022

Canadian Institutes for Health Research (CIHR)
Fonds de Recherche du Québec - Santé (FRQS)

H2020 euCanSHare aims to build the first one-stop-shop platform for multi-cohort cardiac data integration and exploitation, integrating computational tools and data models to a unified metadata catalogue. This consortium intends to leverage data from Canadian and European cohorts, including the Canadian Alliance for Healthy Hearts and Minds (CAHHM) and the European BiomarCare project.

In collaboration with Dr. Borry (KU Leuven), the CGP coordinates the ELSI research activities regarding the legal and ethical implications of implementing blockchain technology and associated smart contracts in a Canadian-European data sharing context. The CGP has contributed to this initiative by translating research ethics consent and data governance documentation into standard-form profiles that can be parsed using automated means. The CGP is also producing policy documentation that addresses considerations relative to data governance and blockchain technologies.

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HUMAN CELL ATLAS

NOVEMBER 2018—OCTOBER 2021

The Chan Zuckerberg Initiative

The Human Cell Atlas (HCA) is a global biomedical research collaboration to create a reference map of all human cells – an international, public resource for better understanding human health and disease. The HCA's success relies on the expertise of researchers across several countries, undertaking work in different research domains and settings.

The CGP hosts the HCA ethics policy platform and assists the HCA in the ongoing coordination of its Ethics Working Group (EWG), the development of an ethics and data governance framework, template consent forms, relevant tools (retrospective consent filter, ethics submission guidance), template agreements (material/data transfer agreement templates, data submission agreement template, data use agreement template) and a helpdesk to support the HCA community. The CGP is also in the process of producing specialized guidance relating to holistic international data governance and to pediatric populations and other vulnerable groups.

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CANADIAN OPEN NEUROSCIENCE PLATFORM (CONP) — ETHICS AND GOVERNANCE COMMITTEE; SCHOLARSHIP SUPERVISION

JANUARY 2019 — MAY 2021

Brain Cancer Foundation
Canadian Brain Research Fund

The Canadian Open Neuroscience Platform (CONP) aimed to bring together many of the country's leading scientists in basic, translational, and clinical neuroscience to form an interactive network of collaborations in brain research, interdisciplinary student training, international partnerships, clinical translation and open publishing. The platform provided a unified interface to the research community, so as to propel Canadian neuroscience research into a new era of open neuroscience research with: the sharing of both data and methods; the creation of large-scale databases; the development of standards for sharing; the facilitation of advanced analytic strategies; the open dissemination to the global community of both neuroscience data and methods, and the establishment of training programs for the next generation of computational neuroscience researchers. CONP aimed to remove the technical barriers to practicing Open Science and improve the accessibility and reusability of neuroscience research to accelerate the pace of discovery.

The CGP hosted the Ethics and Governance Committee for the CONP to ensure neuroscience data are shared in a respectful and responsible manner. The Committee is Chaired by Prof. Knoppers and managed by Michael Beauvais. The Committee has generated an Ethics and Data Governance Framework, as well as Publication and Commercialization Policies to promote responsible open neuroscience and a Portal privacy policy to ensure the responsible use of portal users' data by CONP. The Committee's Open-Science consent clauses and retrospective filter are soon to be completed, with authentication policies and other novel outputs in the pipeline.

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CAN-SHARE CONNECT: SUPPORTING THE REGULATORY AND ETHICS WORK STREAM OF THE GLOBAL ALLIANCE FOR GENOMICS AND HEALTH (GA4GH)

JANUARY 2019—DECEMBER 2022

Canadian Institutes of Health Research (CIHR)
Genome Québec

The Global Alliance for Genomics and Health (GA4GH) is an international consortium that frames policy and establishes standards for the international exchange of genomic and health related data. Data sharing between institutions, sectors and countries is essential for accelerating research, ensuring databases are ethnically diverse, and improving health care. To guide effective and responsible data sharing, the GA4GH formed a foundational Regulatory and Ethics Work Stream (REWS). "CanSHARE Connect" will support the continued Canadian leadership and coordination of the REWS by the CGP.

A central responsibility of the REWS is to develop a forward-looking policy toolkit addressing ethical and legal issues consistent with the Framework for the Responsible Sharing Genomic and Health-Related Data that was developed in 2017. This tool-kit addresses consent, privacy & security, accountability, and coordinated ethics review of international collaborative research. T. The goal is to promote harmonization of policies and protections across countries and settings, to improve certainty and foster the trust that data sharing protects the rights and interests of participants, researchers, and society. Some recent outputs have been familial consent clauses and a revision to the ethics review recognition policy. Policy subjects expected to be completed in 2021 include return of results, participant engagement, and procedural standards for data access committees. The REWS also supports the implementation of the toolkit by 24 real-world genomic data sharing "Driver Projects."

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OBSERVATOIRE INTERNATIONAL SUR LES IMPACTS SOCIÉTAUX DE L'INTELLIGENCE ARTIFICIELLE ET DU NUMÉRIQUE

MARCH 2019—APRIL 2023

Fonds de recherche Santé Québec (FRQS)

In partnership with numerous universities and colleges, and with the support of 88 research centres, non-governmental organizations, businesses, government players and various groups in Québec, Canada and abroad, Université Laval proposes to set up the International Observatory on the Societal Impacts of Artificial Intelligence and Digital Technologies (OBVIA). The ambition of this innovative institution is to distinguish itself internationally through the quality of its research, its ability to federate various types of expertise and its ability to foster collaboration among all parties concerned by the challenges posed by the development of artificial intelligence (AI) and digital technology. OBVIA is based on four different but interdependent functions. It will conduct intersectoral and interdisciplinary research and creative activities on several priority themes. Members from the CGP will be involved in the "Éthique, gouvernance, démocratie et responsabilité sociale des organisations" Pillar within OBVIA.

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LE CONSORTIUM QUÉBÉCOIS CONTRE LE CANCER POUR DE NOUVEAUX AGENTS THÉRAPEUTIQUES ET BIOMARQUEURS

APRIL 2019—MARCH 2021

Oncopole

The goal of this project is to create a dynamic, leading North American centre for oncology research and innovation. Formed by the Goodman Cancer Research Centre, the Jewish General Hospital, the Centre hospitalier de l'Université de Montréal (CHUM), the Maisonneuve-Rosemont Hospital, the Institute for Research in Immunology and Cancer (IRIC) and the Research Institute of the McGill University Health Centre (RI-MUHC), the consortium's mission to double enrollment in oncology clinical trials and to create a dynamic biobank of samples collected during clinical trials of new drugs will have a major impact on the advancement of science for the benefit of patients. The team at the CGP will assist in the development of project governance tools and will advise the consortium on its legal and ethical obligations. In doing so, the Centre will draw on its extensive expertise in the biobanking field. The team will likewise draw on its background in the adoption of mobile health technologies for facilitating largescale genomic oncology research.

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THE CANCER GENOME COLLABORATORY

APRIL 2019—MARCH 2023

Canadian Foundation for Innovation (CFI)

The Cancer Genome Collaboratory (CGC) is a unique Canadian cloud compute facility that holds the world's most comprehensive public collection of cancer genomes and associated clinical information. The proposed work will extend the CGC's data holdings, improve accessibility to the data, add a series of high-quality vetted pipelines for standardized cancer genomic analysis, and implement services that apply new cutting-edge algorithms for the interpretation of cancer genomes. The CGP is drafting a code of practice for the international sharing of cancer genomic data. The CGP has also performed research concerning data identifiability standards, data protection law, and international data transfers with a particular emphasis on data transfers between Canada and the European Union.

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EUCANCAN: A FEDERATED NETWORK OF ALIGNED AND INTEROPERABLE INFRASTRUCTURES FOR THE HOMOGENEOUS ANALYSIS, MANAGEMENT AND SHARING OF GENOMIC ONCOLOGY DATA FOR PERSONALIZED MEDICINE

APRIL 2019—MARCH 2023

Canadian Institutes for Health Research (CIHR)
Fonds de Recherche du Québec - Santé (FRQS)

EUCanCan aims to federate existing European and Canadian infrastructures to analyze and manage genomic oncology data. The CGP is co-leading the development of guidance and ethico-legal tools regarding international sharing of clinical and research oncology data. The aims include: 1) to perform a legal, policy, and normative interoperability analysis to develop guidance aimed at Canadian oncology projects when sharing personal health data with European countries and within Canada; 2) to analyze the requirements Canadian projects will have to satisfy pursuant to the EU General Data Protection Regulation when receiving personal health data from European partners; 3) to deliver a Report these first two topics; 4) develop overarching guidance for the project on the use and sharing of clinical cancer-related genomic and other health related data; and 5) describe generalized compliance tools to be used by future international collaborations, whether they are studying cancer or other diseases. Thus far, the CGP has compiled guidance and research related to the pan-Canadian and Canada-EU sharing of data. The CGP intends to produce further research and guidance relating to the use of centralised platforms to store health data across Canada and the European Union.

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COPAQ : INITIATIVE DE SCIENCE PARTICIPATIVE EN RECHERCHE SUR LES POPULATIONS

MAY 2019 — APRIL 2021

Fonds de la recherche en santé du Québec (FRSQ)

In recent years, genetic testing available to consumers online through private companies, also known as direct-to-consumer (DTC) genetic testing, has increased significantly. A growing number of individuals now have access to information about their genome, which represents a person's complete set of genes. With this information, people are able to discover information about their ancestors, genealogical links with other people and, in some cases, genetic risk factors.

DTC genetic testing has enabled the assembly of large cohorts, which represent a group of people that can provide valuable information for scientific research. However, this information remains mostly under the control of private companies, limiting opportunities for research.

The objective of CopaQ is to develop a platform for the collection, sharing, and simplified interpretation of population research results. This platform will collect genetic, genealogic and basic demographic information from individuals who have already performed a genetic test with a private company (e.g. 23andMe, Ancestry, etc.) in order to securely share this information with members of the research community that agree to protect its confidential nature. The CGP is developing the consent form for this project and also advises on ethical and legal issues.

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THE McGILL CLINICAL GENOMICS (McG) PROGRAM

OCTOBER2019-DECEMBER2021

Jewish General Hospital Foundation

The McGill Clinical Genomics program (McG) aims to implement hospital-based genomic medicine building on robust research to improve clinical care. McG seeks to improve disease diagnosis and risk-stratification, the efficiency of test ordering and prediction of drug responses that will deliver benefits to person-centered patient care and value to the wider healthcare system and across the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal/Center West Montreal. As part of this project, members of the Centre of Genomics and Policy will lead the Ethics and Governance Pillar and develop a set of ethics policies and templates to ensure that the Project will be able to recruit participants as well as use and share their data and samples for research purposes in an ethical and efficient manner, which complies with international best practice. Special focus will be put on COVID-19 related recruitment in light of the pandemic.

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ETHICAL AND LEGAL FRAMEWORK FOR DIRECT-TO-PARTICIPANT (DTP) RECRUITMENT

JANUARY 2020– JANUARY 2022

Canadian Institutes of Health Research (CIHR)
Natural Sciences and Engineering
Research Council of Canada (NSERC)
The Social Sciences and Humanities
Research Council (SSHRC)
Networks of Centres of Excellence (NCE)
Stem Cell Network (SCN)

This study examines the ethical and legal issues regarding the use of internet-based Direct-to-Participant (DTP) recruitment and provides guidance for its practice in stem cell research. The main objective of this project is to fill the ethical and policy gap by: 1) examining the ethical/legal issues of international DTP recruitment (for adult and minor participants) and 2) yielding concrete, practical ethical guidance and tools for Canadian researchers and REBs. In collaboration with the Program for Individualized Cystic Fibrosis Therapy (CFIT) at SickKids, the CGP will first build a case study to examine the feasibility and utility of international DTP recruitment, while producing practical, context specific governance framework and recruitment tools. Knowledge and pragmatic experience gained from the CFIT case study, along with consultations with national stakeholders (REB representatives, researchers, and policy makers), will contribute to the development of Canadian Best Practice Guidelines for DTP recruitment. As innovative and fundamental resources for Canadian REBs and researchers, the guidelines and practical tools will directly address an immediate need for clear policy and guidance for international DTP recruitment in stem cell research. They will also set the standards for Canada and internationally, consolidating Canada's position as a leader in policy development.

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SELF-ASSEMBLY SKIN SUBSTITUTES (SASS) FOR THE TREATMENT OF ACUTE WOUNDS OF CANADIAN BURN PATIENTS

JANUARY 2020– JANUARY 2022

Canadian Institutes of Health Research (CIHR)
Natural Sciences and Engineering
Research Council of Canada (NSERC)
The Social Sciences and Humanities
Research Council (SSHRC)
Networks of Centres of Excellence (NCE)
Stem Cell Network (SCN)

Treatment for burn wounds is based on skin autografts, but when the surface that needs to be covered is more than 50 percent of one's total body surface area, autografts becomes strategic. With tissue engineering methods developed in Dr. Moulin's lab (Université Laval) , autologous Self-Assembly Skin Substitutes (SASS) can be produced from only a small skin biopsy and could permanently cover all the patient wounds. This early phase clinical trial has now been accepted by Health Canada and few patients have been treated in Québec. This project will allow expanding the trial to burn units in other Canadian provinces. The aim of this trial is to evaluate this novel therapeutic approach, treating 17 patients to help skin regeneration. Dr. Moulin plans to recruit at least seven patients during the next two years and evaluate graft take and post-grafting scarring over a two-to-three-year period. Her aim is to treat most Canadian patients that have been burns over more than 50 percent of their body. SASS treatment should have economic and social benefits, as our preliminary results have demonstrated that treatment decreases morbidity caused by standard treatments and increases quality of life for patients. At the end of the clinical trial and acceptance by Health Canada, Dr. Moulin's lab will be the first in Canada to routinely treat patients with autologous reconstructed skin.
Our interdisciplinary team is composed of four internationally known researchers in regenerative medicine from two universities and of plastic surgeons working in major Canadian burn unit sites. The CGP (CGP) will assist in preparing the necessary requirements for research ethics approval (including preparing standardized recruitment procedures and protocols, consent forms and information pamphlets). This will require coordination of REB approval. The CGP will also be involved preparing documentation for the pre-CTA meetings and for regulatory approval with Health Canada.

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CULTURED EPITHELIAL CORNEAL AUTOGRAFTS FOR THE TREATMENT OF CANADIANS WITH LIMBAL STEM CELL DEFICIENCY

JANUARY 2020– JANUARY 2022

Canadian Institutes of Health Research (CIHR)
Natural Sciences and Engineering
Research Council of Canada (NSERC)
The Social Sciences and Humanities
Research Council (SSHRC)
Networks of Centres of Excellence (NCE)
Stem Cell Network (SCN)

The aim of this project is to demonstrate through a clinical trial that autologous epithelium tissue, engineered from corneal limbal stem cells, offers an efficient strategy to treat Canadian patients with visual deficits due to limbal stem cell deficiency. As one of the leading organ reconstruction laboratories in the world, LOEX, CHU de Québec-Université Laval, will be the first to launch a multicentre trial using a human fibroblast feeder layer (instead of a murine feeder layer) to expand and preserve human stem cells in vitro, thus possibly improving vision for many Canadians. The CGP provides consultation on the socio-ethical and legal issues and assists in developing the necessary documentation for approvals from Health Canada and research ethics boards.

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THE QGPRS STUDY: QATAR GENOME POLYGENIC RISK SCORE, A PRECISION MEDICINE APPROACH TO PREVENT DIABETIC COMPLICATIONS IN THE AFFECTED QATARI INDIVIDUALS

JANUARY 2020–JULY 2023

Qatar National Research Fund
Sidra Medicine

This project aims at creating a knowledge-based platform and electronic medical record (EMR) that will integrate clinical and genomic information into clinically actionable reports for clinicians. Such platform will be flexible and adaptable to different biomarkers independently of their "omics" origin. The CGP will work to develop privacy and confidentiality policies to facilitate this integration of genomic and clinical data. Ultimately, this work will culminate in best-practice documents that will be shared with the Qatar team for local and territorial use.

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OPPORTUNITIES AND CHALLENGES OF USING EPIGENETIC TECHNOLOGIES IN DEFENCE AND SECURITY CONTEXTS

APRIL 2020–SEPTEMBER 2021

Department of National Defense (Canada)
Mobilizing Insights in Defence
and Security (MINDS) program

Epigenetics refers to heritable or non-heritable changes to the DNA structure and gene activity that can occur in response to exposure to various environmental or social factors. This project aims to identify opportunities and challenges in using epigenetic technologies in the context of defense and security, with a focus on four applications: 1) exposure to nuclear, chemical or biological weapons; 2) epigenetic age (e.g., proving child soldiers' age through DNA methylation analysis); 3) mental health monitoring (e.g., PTSD); and 4) enhancement of bodily functions (memory, cognition, muscle strength) through epigenome editing.

The CGP has carried out trailblazing research on the opportunities and technical, ethical and legal challenges associated with epigenetics. In this project, the CGP will undertake extensive documentary research (funded research, military directives and orders, laws and government policies) that would yield a peer-reviewed article on epigenetics' anticipated uses. This research will complement a one-day workshop with US and Canada experts on epigenetics, DARPA researchers in epigenetics and DND/CAF staff. The workshop's outcomes will be translated into a policy brief and briefings for interested DND/CAF officials, highlighting paths to effectively implementing epigenetic technologies in defense and security contexts.

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VALIDATING, SPECIFYING & PRIORITIZING THE ETHICAL, LEGAL AND SOCIAL IMPLICATIONS OF IMPLEMENTING ARTIFICIAL INTELLIGENCE WITHIN ANTI-DOPING STRATEGIES: AN INTERNATIONAL DELPHI STUDY

APRIL 2020– APRIL 2022

Fonds de recherche du Québec (FRQ)
Ministère de l'Économie et de l'Innovation (MEI)
World Anti-Doping Agency (WADA)

This study aims to explore the potential ethical, legal and social implications (ELSI) associated with the use of artificial intelligence (AI) within WADA's anti-doping strategies. This will be accomplished using a three-round, consensus-building online survey method (Delphi study) whereby the perspectives of experts and stakeholders with varied expertise and experiences will converge to inform a forward-looking approach for the ethical application, regulation and design of AI within a sport anti-doping context. These include (but are not limited to): anti-doping organization administrators; anti-doping laboratory administrators; bioinformatics experts with knowledge about AI; ELSI scholars (e.g., ethicists, social scientists, legal scholars) working on AI and/or anti-doping; and advocates of elite athletes' rights and interests.

Ultimately, this will assist in better informing and facilitating the translation of the relevant ELSI into normative guidance (i.e., ethical principles and legal norms), as well as shape regulatory and governance approaches in the applications of AI within anti-doping strategies. This will foster coherence and provide overarching ethical guidance to effectively navigate and address the issues and challenges identified.

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DOvEEgene

APRIL 2020– MARCH 2024

Genome Canada
Genome Québec

This project aims to develop and implement a plan that raises awareness in Healthcare professionals, key opinion leaders, the Canadian public and Funding Agencies about the DOvEEgene screening test that will be made available to the public, initially in the context of a trial and following successful validation as a clinical test. Our milestone is an effective DOvEEgene Awareness Campaign developed on evidence-based strategies. Methods/Tools will be developed after analysing the literature on barriers and promoters that are relevant to implementation of a screening test and taking into account contextual factors, such as the healthcare system itself, providers, and patient groups, as well as economic impact. We will use a variety of television, newspaper, magazines, radio, features & interviews, our website, and social media. We will send an information letter to gynecologists and general practitioners to inform them about the trial using lists obtained from the College Des Médecins. This will be repeated every six months. We will invest in Continuing Medical Education of Healthcare Professionals (general physicians, gynecologists, nurses) and in lectures and events aimed at middle-age and mature women, who will be the target population.

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OF BIOBANKING AND POLICY: EMERGING ETHICAL AND LEGAL CHALLENGES DURING THE COVID-19 PANDEMIC

MAY 2020– MARCH 2022

Social Sciences and Humanities Research Council of Canada (SSHRC)
MI4 Emergency COVID-19 Research Funding (ECRF)

The COVID-19 pandemic has demonstrated the on-going need for scientific cooperation and response at a global level. Recent research has already brought several vaccines to market, as well as possible therapeutics to combat the disease. COVID-19 specific biobanks and data repositories have been positioned at the forefront of these biomedical developments, providing researchers tools to study the novel virus at unprecedented speeds. Still, important ethical, legal, and social tensions arise between the need for rapid collection and the clinical realities faced on the ground by professionals responsible for both patient care and recruitment into research.

The goal of this project is to provide policy evidence – as well as ethical and legal guidance – to inform newly created COVID-19 research infrastructures. The CGP plans to conduct a comparative analysis of existing COVID-19 international biobanking policies and launch a national survey on the lived experiences of health professionals involved in participant recruitment during the pandemic. In co-ordination with the Biobanque Québecoise de la COVID-19 and researchers in the UK, Italy, Australia, South Africa, and Hong-Kong, the CGP will ensure this work can provide objective evidence for policy development.

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UN NANO-VACCIN CONTRE LES MALADIES CARDIOVASCULAIRES (AUDACE)

APRIL 2020– APRIL 2022

Fonds de recherche du Québec (FRQ)

This project aims to create a platform to revolutionize the treatment of heart disease. The project will establish a scientific basis for a nano-vaccine intended to reduce the need for medication that prevents cardiovascular events. It will simultaneously assess the ethical and legal complications raised by the development of such technology. The team at the CGP is engaged in studying the ethical and legal implications of shifting from personalized therapy (medication) to universal therapy (vaccine). Among other things, the team will determine whether the predicted transition will affect the legal responsibilities of health professionals. We focus in particular on the obligations of health professionals engaged in the care of minors and asymptomatic populations.

PRINCIPAL INVESTIGATOR
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CO-INVESTIGATORS
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PICARD Frédéric
POIRIER Paul
ZAWATI Ma'n H.

ETHICAL LEGAL EXPERTISE – COVID-19 IMMUNITY TASK FORCE (CITF)

JULY 2020–MARCH 2022

The Government of Canada
Public Health Agency of Canada (PHAC)
Canadian Institutes for Health Research (CIHR)

The COVID-19 Immunity Task Force (CITF) is collecting blood samples and survey data for the purposes of assembling a national repository of data relating to seroprevalence and immunization, as well as vaccine surveillance. The CITF is coordinating numerous local and multi-centre seroprevalence studies, and is collaborating with Canadian Blood Services, Héma-Québec, and the National Microbiology Laboratory, among other partners, to collect and interpret data in a harmonized manner.

The CGP is responsible for creating ethico-legal deliverables for the CITF and for guiding the data governance initiatives thereof.

To this end, the CGP has produced a data governance framework, template informed consent materials, and retrospective consent guidance for legacy datasets and samples. Further, the CGP has been actively involved in the CITF's efforts to ensure the normative interoperability of its cohorts, through direct engagement with study coordinators and CITF leadership.

PRINCIPAL INVESTIGATORS
BUCKERIDGE David
EVANS Timothy

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ACADEMIC ASSOCIATE
BERNIER Alexander

COVID-19 CLOUD

JULY 2020–JUNE 2021

Digital Technology Supercluster – Government of Canada

As COVID-19 continues to spread globally, there is an urgent need to understand the DNA footprint of this rapidly evolving virus. Led by DNAstack, the COVID Cloud Project harnesses Canada's genomic research capabilities to rapidly sequence, share and analyze the genomic profile of COVID-19 and the people who have contracted it in Canada and around the world. This information will help inform the development of public health policies, diagnostics, therapies and vaccines. The team at the CGP will map relevant provincial, federal, and international data privacy laws and research ethics regulations and will work to determine how their application is affected in emergency situations. We will further work to design a streamlined access model based on the international GA4GH research passport standard, allowing credentialed researchers to access data and search networks for specific purposes, including COVID-19 research.

PRINCIPAL INVESTIGATOR
FIUME Marc

CO-INVESTIGATOR
ZAWATI Ma'n H.

ETHICS AND POLICY PILLAR–HostSeq (CanCOGeN)

JUNE 2020– MAY 2022

Genome Canada

In response to the ongoing COVID-19 pandemic, CGen has received federal funding to sequence the genomes of thousands of Canadians, in order to better understand the variable clinical response to COVID-19, and share resulting genomic and sequencing data through the HostSeq databank. In doing so, HostSeq will leverage existing biobanking and sample collection efforts, as well as invite interested researchers to launch their own site-specific recruitment protocols to contribute to this Canadian COVID-19 resource. The CGP developed a governance framework for the HostSeq databank, which identifies ethical, operational and oversight mechanisms governing the databank. Additionally, the CGP has prepared a list of core consent elements to assist investigators in sites across Canada in collaborating in this effort and submitting their local projects to their research ethics committees or for determining the adequacy of already-existing projects to contribute to this effort. The CGP team will also perform a pre-assessment of existing informed consent forms of contributing collections in order to assess their compatibility with the HostSeq core consent elements (or identify items that may impede use, such as data storage limitations or international sharing limitations) and will provide ongoing policy consultation to the HostSeq databank.

PRINCIPAL INVESTIGATOR
ZAWATI Ma'n H.

ACADEMIC ASSOCIATES
KIRBY Emily
PATRINOS Dimitri

ELSI COMPONENT: VIRUSSEQ—CANCOGEN

MAY 2020– MARCH 2022

Genome Canada

The Canadian COVID-19 Genomics Network (CanCOGeN) was launched to coordinate and upscale the existing genomics-based research efforts to study the SARS-CoV-2 virus and COVID-19. The CanCOGeN project is organized into components focusing on human-disease component (HostSeq) and virus (VirusSeq) to address topics unique to each.

CanCOGeN-VirusSeq has multiple goals such as tracking viral transmission and exploring a multitude of pressing topics, such as the variability across patient outcomes, with each better informing both research and Public Health.

Currently, Prof. Yann Joly serves as the chair of both the CanCOGeN-VirusSeq Ethics and Governance Committee and the CanCOGeN Data-Sharing Committee, while also acting as an active member the VirusSeq Implementation Committee. Lingqiao Song and Hanshi Liu are also members of the CGP (CGP) who actively contribute to the various ethical and legal topics in the project. Overall, as a part of CanCOGeN-VirusSeq, the CGP team addresses essential ethical and legal issues derived from the CanCOGeN project.

PRINCIPAL INVESTIGATOR
JOLY Yann

ACADEMIC ASSOCIATES
GRANADOS-MORENO Palmira
SONG Lingqiao

RESEARCH ASSISTANT
LIU Hanshi

INNOVE-ONCO – TECHNOLOGICAL AND ORGANIZATIONAL INNOVATIONS GO HAND IN HAND: A COLLABORATIVE MODEL TO RENDER ONCOGENETICS MORE FLEXIBLE, ACCESSIBLE AND EFFICIENT

SEPTEMBER 2020– OCTOBER 2022

Fonds de recherche Santé Québec (FRQS)

The CHU de Québec-Université Laval has developed a "collaborative oncogenetic model" (COM) aimed at improving access to genetic counseling services and minimizing delays for genetic tests for patients. The Oncopole project seeks to understand the context in which the COM was developed and implemented, and to document the lessons that can be drawn from it to optimize the delivery of local and regional oncogenetics services in Quebec.

CGP missions:
- Review of the literature on legal, regulatory and ethical issues related to the extension of the role of non-genetic health professionals and the establishment of a register of patients benefiting from genetic counseling and testing for cancer hereditary breast and ovary.
- Comparative law analysis to identify the main legal variations and promote better coordination of the legal texts of the different national systems.

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TOWARDS AN EPIDERMOLYSIS BULLOSA CLINICAL TRIAL WITH TISSUE-ENGINEERED SKIN AFTER EX VIVO GENE THERAPY CORRECTION

SEPTEMBER 2020-FEBRUARY 2022

Canadian Institutes of Health Research (CIHR)
Natural Sciences and Engineering Research Council of Canada (NSERC)
The Social Sciences and Humanities Research Council (SSHRC)
Université Laval
Networks of Centres of Excellence (NCE)
Stem Cell Network (SCN)

The aim of this project is to demonstrate through a clinical trial that autologous tissue-engineered skin substitute, produced with fibroblasts and epithelial stem cells previously corrected ex vivo by gene therapy, offers an efficient strategy to treat Canadian patients suffering from dystrophic epidermolysis bullosa (DEB). As one of the leading organ reconstruction laboratories in the world, LOEX, CHU de Québec-Université Laval will be the first to launch a clinical trial using a bilayered human skin substitute (instead of a single cell type) in which the adhesion of epidermis to the dermis is functional in vitro before grafting on patients, thus possibly providing a curative treatment for the recurring wounds of many Canadians. The CGP (CGP) will assists in preparing the necessary requirements for research ethics approval (including preparing standardized recruitment procedures and protocols, consent forms and information pamphlets). The CGP will also be involved preparing documentation for the pre-CTA meetings and for the regulatory approval with Health Canada.

PRINCIPAL INVESTIGATORS
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GERMAIN Lucie
KNOPPERS Bartha Maria
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ACADEMIC ASSOCIATE
NGUYEN Minh Thu

DEVELOPPEMENT D'UN CADRE ETHIQUE ET LEGAL POUR LE DEPLOIEMENT DES ACTIVITES DU RQDM ET L'HARMONISATION DU CONSENTEMENT DES PATIENTS/ DEVELOPMENT OF AN ETHICAL AND LEGAL FRAMEWORK FOR THE DEPLOYMENT OF RQDM ACTIVITIES AND THE HARMONIZATION OF PATIENT CONSENT

NOVEMBER 2020-NOVEMBER 2022

Ministère de la Santé et des Services sociaux (MSSS)
Revue Québécoise de didactique des mathématiques (RQDM)

The Réseau québecois de diagnostic moléculaire (RQDM) is an initiative that aims to meet the current and future needs of the health and social services network in the field of molecular diagnosis and personalized medicine, particularly in the areas of rare disease diagnosis and cancer. It also aims to repatriate analyses performed in private national and international laboratories into the Québec public health and social services network. The CGP works on the development of an ethical and legal framework for the implementation of RQDM's activities and to harmonize consent for patients that are prescribed a molecular analysis in genetics or oncology. Accordingly, the CGP is developing template consent forms that address the following elements: compliance with ethical standards, management of incidental findings, storage and sharing of sequencing data and clinical information, storage of samples for future clinical use, and access to samples and data resulting from clinical analyses for research purposes.

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COURSES 2020

HGEN 660B

GENETICS, ETHICS AND LAW

Instructor: Prof. Yann Joly, Ph.D. (DCL)

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 clinical genetics. The classes are 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 counselling, personalized medicine, privacy and confidentiality, population genetics, regenerative medicine, commercialization and intellectual property, genetic discrimination, and genetic analysis of social and behavioural traits. Students are asked to reflect on the complex relationships between science, law, and ethics through class lectures, case studies, and discussions on a series of selected readings. Each member of the class participates and contributes to the learning. Such a collaborative learning experience is reflected in how the course is structured and the student's work is evaluated.

COURSES 2020

HGEN 674

RESEARCH INTERNSHIP IN GENOMICS AND POLICY

Instructor: Prof. Ma'n H. Zawati, Ph.D. (DCL)

The Research Internship in Genomics and Policy course aims to provide 1 to 2 graduate students in the Human Genetics program with an opportunity to research the ethical-legal and policy issues in human genetics. More specifically, graduate students are 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 the international comparative analysis of normative policy and legal instruments. As an internship, these objectives are achieved through active research under the supervision of a mentor working in the student's interest area. Specific research areas at the Centre of Genomics and Policy include but are not limited to: stem cell research and therapies, personalized medicine, prevention and treatment of cancer, data sharing in research, pediatrics, genetic counselling, digital health and AI, intellectual property and open science, epigenetics, intersex and diversity in health, gene editing, genetic discrimination and biobanking (population genetics). 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 ethical-legal, medical, and policy fields.

CGP ARTICLING & INTERN STUDENTS

The CGP proposes internships for students through different courses (e.g., HGEN 396, HGEN 674, McGill Legal Clinic Course) and articling positions for law graduates.

GABRIEL MARROCCO
ARTICLING STUDENT

"Articling at the CGP was a very formative experience. It offered me an opportunity to engage with timely ethical, legal, and social issues and to be involved in concrete projects where those issues needed to be resolved. I had the chance to interact with stakeholders from a diversity of backgrounds including lawyers, health professionals, industry leaders, philosophers, bioethicists. Not only did this broaden my perspective on those issues, but it also led me down my actual career path as a health professional. And most of all, the CGP is a wonderful workplace where hallway small talk can lead you to write a new paper, where curiosity is fostered and where no doors are closed (except during conference calls)."

"My placement at the Centre of Genomics and Policy has allowed me to dive deeper into the topic of genetic discrimination and gain a better understanding of its breadth and implications. I had the opportunity of being involved with the Genetic Discrimination Observatory, which taught me a lot about the different legal and policy responses to genetic discrimination around the world. Overall, it has been an eye-opening and enriching experience and I feel extremely fortunate to have been able to contribute to the CGP's meaningful work."

KAI-LEE GIBEAULT
MCGill LEGAL CLINIC COURSE

JULIE-ALEXIA DIAS
HGEN 674

"As an intern at the CGP I had the chance to work under the supervision of Prof. Ma'n Zawati and Julie Hagan on the regulation of genetic counselling and lack thereof and its implications in Quebec. This was an eye-opening internship where I got to interact first-hand with genetic counsellors and geneticists in order to understand their perspectives and opinions on this absence of regulation. I also learned how to design and run a qualitative analysis based on the interviews I conducted. Being part of the CGP, I got to collaborate with extremely talented people and combine my interests in health policy, ethics in genetics and human biology."

Genetic discrimination involves treating differently and negatively or unfairly profiling individuals or a group relative to the rest of the population based on actual or presumed genomic and other predictive data.

GENETIC DISCRIMINATION OBSERVATORY

WWW.GDO.GLOBAL

The Genetic Discrimination Observatory (GDO) is a network of international experts and collaborators from over 20 jurisdictions dedicated to researching and preventing genetic discrimination.

THE OBJECTIVES OF THE GDO ARE TO:

Document the issue of genetic discrimination in a scientific and evidence-based manner.

To use this information to assess existing normative models work best and develop new ones.

Engage the public, policymakers and other stakeholders in a collective debate about genetic discrimination.

THE OBSERVATORY'S ACHIEVEMENTS 2020

MAY 2020

THE INTERNATIONAL GENETIC DISCRIMINATION OBSERVATORY

was launched in May 2020 with a Nature Genetics publication. Since this publication, the GDO website has been visited over 31700 times by more than 5800 distinct visitors.

WWW.GDO.GLOBAL

NEW MEMBERS

From Colombia, Ukraine, and Kazakhstan, with expertise in genomics, public health, economics and law, joined the GDO's international expert panel.

JUNE 2020

ANNUAL RETREAT

The GDO held its first Annual Retreat on June 8 and 10, 2021.

2020

G4GH GLOBAL ALLIANCE FOR GENOMICS AND HEALTH (GA4GH)

The GDO's output are now integrated under the Global Alliance for Genomics and Health (GA4GH) Regulatory & Ethics Toolkit.

WWW.GA4GH.ORG

OCTOBER 2020

CIHR PROJECT GRANT

All members of the international expert panel and collaborators joined for the submission of a CIHR Project Grant co-led by Profs Yann Joly (Mcgill University) and Yvonne Bombard (University of Toronto).

NOVEMBER 2020

THE 'SHARE YOUR STORY' WEBPAGE

was re-designed to include an optional self-questionnaire that will help the research team assess participants' experience of genetic discrimination.

WYNG FOUNDATION

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 support the CGP/WYNG Trust Visiting Scholars Program.

VISITING SCHOLAR PROGRAM

DECEMBER 2020

University of Hong Kong

HOSTED 2 DAY WEBINAR

December 7-8, 2020,

Health and Artificial Intelligence: Law, Ethics and Society, was hosted by Dr. Calvin Ho and Dr. Philip Beh from the Centre for Medical Ethics. The webinar brought together experts from various stakeholders for an interdisciplinary discussion on AI's application and impact in healthcare.

The CGP would like to thank
The WYNG Foundation for its support of this research and event.

TEAM PUBLICATIONS

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-https://atomstalk.com/blogs/genome-editing-technologies-a-new-path-to-genetic-engineering/

CGP INTERNATIONAL COLLABORATIONS

WE ARE DEEPLY GRATEFUL TO ALL WHO SUPPORT OUR WORK!