



CGP ANNUAL REPORT 2022

Centre of Genomics and Policy
Centre de génomique et politiques



McGill

Faculty of
Medicine and
Health Sciences

MULTIDISCIPLINARY
PERSPECTIVE
PERSONALIZED
MEDICINE

POLICY
CONFIDENTIALITY

ETHICS

LAW

PAEDIATRICS

BIOBANKS

GOVERNANCE

REGENERATIVE
MEDICINE

LEGISLATION

GENETIC DISCRIMINATION

STEM CELLS

DNA

GENOMICS

GENE EDITING

EPIGENOMICS



RARE DISEASES

HUMAN RIGHTS



CANCER

INTELLECTUAL PROPERTY

ARTIFICIAL INTELLIGENCE

KNOWLEDGE
TRANSFER



DATA
SHARING

DATA PRIVACY

DIGITAL HEALTH

ACCESS

CONSENT

ACCESS



BIOETHICS



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A MESSAGE FROM THE DIRECTOR



*I look at clouds from both sides now
From up and down, and still somehow
It's cloud illusions I recall
I really don't know clouds at all*

- Joni Mitchell, From Both Sides Now, 1967

The cloudy interstices of 2022 with COVID mandates waxing and waning, created hope for some degree of clarity concerning the end (?) of the pandemic and a return to imaginative and innovative thinking beyond masks and vaccines. We gradually moved from the virtual meetings of assistants and associates to some in-person office work and meetings for the first time, to cautious maneuvering in the hallways and to the determination of safe distancing - the slow return to the “new normal” of the CGP team.

On a more positive note, our ongoing involvement in COVID research and participation in national and international committees was instructive. Indeed, we were introduced to the socio-ethical and legal issues of health data sharing based on public health priorities, to say nothing of the challenge of interpreting the present and future translation of the concept of “the public good” and the “public interest” in our role both as citizens and as researchers.

In 2022, international data sharing and the ideal of open science were however challenged by the cautious, conservative (clouded?) interpretations of the General Data Protection Regulation whose extra-territorial effect was felt by research consortia even outside of Europe. Within Canada, the interpretation of the principle of proportionality as applied to the risk of re-identifiability of individuals often suffered a similar protectionist fate with the ensuing privacy chill slowing down the transfer of health data so necessary to understanding the COVID pandemic.

Irrespective, our 2022 Annual Report speaks for itself (*res ipsa loquitur*). Productivity was not affected. It is wonderful however to return to a more in-person team, a living (not virtual) foundation for the exchange of ideas and research in real time and space – a different kind of sharing – clear not cloudy.

Bartha Maria Knoppers

PROFESSOR



A MESSAGE FROM THE RESEARCH DIRECTOR

Dear Readers,

2022 has been an eventful year at the CGP, transitioning towards a post pandemic Canadian society and work environment with all the challenges and opportunities this implies. I am delighted to announce that the Centre is now a foundational pillar of the new Victor Phillip Dahdaleh Institute for Genomic Medicine at McGill University. This welcome change will allow us to increase our already well-developed collaborations with scientific peers from the Genome Centre and the McGill Research Centre on Complex Traits. The new Institute will also allow us to both further the research culture that has flourished at McGill in genomic medicine and strategically position the CGP to apply for new funding opportunities in this promising scientific domain.

The last year has also been one of renewal for our research team with some of our long-time collaborators deciding to move on to new horizons. Hence, we have recruited new students and researchers to complete our ranks resulting in a vibrant work environment particularly propitious to the circulation of new ideas and projects. I would like to send my warmest welcome to all of them and, to thank those that have left for their invaluable contribution to our success.

On the scientific front, we have continued consolidating our leadership in our traditional domains of expertise such as genomics, epigenomics, cancer, regenerative medicine and biobanking while expanding on our funding successes on cutting edge topics of AI and data sharing. We have also diversified our research to investigate the ethics and policy aspects of new topics such as chatbot, psychotropic drugs in palliative care and gender affirming care.

If 2022 is an indication of things to come, the new year should bring plenty of scientific opportunities and success to our dynamic research team!

Yann Joly
PROFESSOR

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.

Learn more at www.genomicsandpolicy.org/





INTRODUCING THE
CGP TEAM

PROFESSOR

KNOPPERS Bartha Maria
DIRECTOR

PROFESSOR

JOLY Yann
RESEARCH DIRECTOR

ASSISTANT PROFESSOR

ZAWATI Ma'n H.
EXECUTIVE DIRECTOR

ACADEMIC ASSOCIATES

BERNIER Alexander
BIRKO Stanislav
COSQUER Marie
DALPÉ Gratien - COORDINATOR
GALLOIS Hortense
GRANADOS-MORENO Palmira
KÉKESI-LAFRANCE Kristina
KIRBY Emily
KNOPPERS Terese
LANG Michael
MONTEFERRANTE Erica
NGUYEN Minh Thu
PALMOUR Nicole
PATRINOS Dimitri
SONG Lingqiao

RESEARCH ASSISTANTS

BALTZAN Isabel
CHARRON Marilou
CHEUNG Katherine
DAUGE Aurélie
EXIUS Rutherford
HUERNE Katherine
JAMALI Narges
KAISER Beatrice
LAGUIA Kristen
MCDUGALL Robyn
MEHTA Preshka
OLVERA Elena

SCHOLARLY CONTRIBUTORS

ASSOCIATE MEMBERS

BEREZA Eugene
GOLD Richard
KIMMELMAN Jonathan

SCIENTIFIC CONSULTANTS

AVARD Denise
LABERGE Claude

INTERNS

FERNANDO Amy
KELLER Natalie
YAN Dylan

ADMINISTRATIVE ASSISTANTS

CHANG Mei-Chen
GAMBOA Kathryn
HOZYAN Rose Marie
THORSEN Nadine

INVITED SCHOLARS

MAHOMED Safia
MOLNÁR-GABOR Fruzsina
STOFFEL Bertrand

PHD STUDENTS

SO Derek
KLEIDERMAN Erika

MASTER'S STUDENTS

BONILHA Ana
BRADBURY-JOST Jacqueline
DOERKSEN Emily
HALEY Cassandra
LIU Hanshi

CGP DIRECTORS

BARTHA MARIA KNOPPERS DIRECTOR & PROFESSOR



Bartha Maria Knoppers, PhD (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 and Health Sciences at McGill University. She was the Chair of the Ethics and Governance Committee of the International Cancer Genome Consortium (2009-2017). She was the Chair of the Ethics Advisory Panel of WADA (2015-2020), and 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 an Officer of the Order of Canada and of Quebec and was appointed to the International Commission on the Clinical Use of Human Germline Genome Editing (2020). She was awarded the 2019 Henry G. Friesen International Prize in Health Research, the Till and McCulloch Award for science policy (2020) and the Canadian Bioethics Society lifetime Achievement Award (2021).

YANN JOLY RESEARCH DIRECTOR & PROFESSOR



Yann Joly, Ph.D. (DCL), FCAHS, Ad.E. is the Research Director of the Centre of Genomics and Policy (CGP). He is a Full 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 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 (GELS).

Prof. Joly's research interests lie at the interface of the fields of scientific knowledge, health law (biotechnology and other emerging health technologies) and bioethics. He created the first international genetic discrimination observatory (GDO: <https://gdo.global/en/gdo-description>) in 2018. He has published his findings in over 198 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 field of biomedicine.

MA'N H. ZAWATI EXECUTIVE DIRECTOR & ASSISTANT PROFESSOR



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 the Biomedical Ethics Unit and the Division of Experimental Medicine at McGill University. 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. He's also a frequent presenter on a variety of the most critical and topical issues in healthcare and the biosciences. He has appeared at 180 international conferences, symposia, meetings, and has shared his expertise with universities, research ethics boards and law firms. Prof. Zawati has published 20 book chapters and 80 peer reviewed articles in leading publications such as Nature Reviews Genetics, the Canadian Medical Association Journal, and the Journal of Law and the Biosciences. 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 2021, Prof. Zawati received a J1 FRQS Career Award.

ACADEMIC ASSOCIATES

ALEXANDER BERNIER ACADEMIC ASSOCIATE

Alexander Bernier is a Montreal-based lawyer and an Academic Associate at McGill University's Centre of Genomics and Policy. In this role, he coordinates the implementation of data governance tools for multiple biomedical research consortia, including the Human Cell Atlas, the European-Canadian Cancer Network (EUCANCan), and the Pediatric Cancer Consortium. He acts as the Ethics Officer for the Canadian Open Neuroscience Platform (CONP) and the Chair of the COVID-19 Immunity Task Force (CITF) Data Access Committee. In addition to participating in the governance of real-world biomedical data, Alexander is pursuing a doctorate at the University of Toronto Faculty of Law. His doctoral research uses law and economics methodologies to understand how organisations respond to legal rules that govern their use of data.



STANISLAV BIRKO ACADEMIC ASSOCIATE

Stanislav Birko completed their undergraduate studies (B.Sc.) in mathematics and philosophy at McGill University. After a few years as research assistant at the Centre of Genomics and Policy, they got a master's (M.A.) in bioethics from the University of Montreal, and are now a doctoral candidate in the same programme under the supervision of Prof. Vardit Ravitsky and Dre. Anne-Marie Laberge. Stanislav joins the CGP under the supervision of Prof. Ma'n Zawati as an Academic Associate with an interest primarily in feminist bioethics, child bioethics, disability studies, genetics, stem cell clinical trials, reproductive ethics, questions of race in health research, the limits of the 'human', and public engagement on health science and technology. Their doctoral thesis approaches ethical questions surrounding selective reproductive technologies within the context of modernist eugenic projects, conceiving of health, illness, and disability relationally through onto-ethico-epistemologies that queer and crip taken-for-granted dualisms such as nature/culture, human/nonhuman, organism/environment, medical/nonmedical, abled/disabled, consent/coercion. Stanislav is section editor at the Canadian Journal of Bioethics and coordinator of the International Association of Bioethics.



MARIE COSQUER ACADEMIC ASSOCIATE

Marie Cosquer (M.Sc) is an Academic Associate at the Centre of Genomics and Policy (CGP) 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 qualitative research projects and works under the supervision of Profs. 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.



GRATIEN DALPÉ ACADEMIC ASSOCIATE & CGP COORDINATOR

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





HORTENSE GALLOIS

ACADEMIC ASSOCIATE

Hortense holds a Master of Laws from the University of Lille 2 (France) and the Universidad de Murcia (Spain), specialising in new technology and health law. She obtained her Master's degree in Bioethics from the Université de Montréal in 2019. 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 the implementation of non-invasive prenatal testing (FNITP) in Canada. She leads the research of the CGP's project on anti-doping and AI funded by the World Anti-Doping Agency (WADA).



PALMIRA GRANADOS-MORENO

ACADEMIC ASSOCIATE

Palmira Granados (LL.M., Ph.D. (D.C.L.)) is a Mexican lawyer and Academic Associate at the Centre of Genomics and Policy of McGill University specialized in intellectual property and life sciences and bioethics. She recently obtained her PhD (Doctor of Civil Law) from the Faculty of Law at McGill University under the supervision of Professor Richard Gold.

Her work focuses on the ethical and legal aspects of research and development involving biomedicine and genomics, as well as the legal and implementation issues around open science. She has published and presented her work in international fora on the interface between intellectual property and biomedicine and information technologies, commercialization, genetic discrimination and immigration, legal issues associated with open science and open source in biomedicine and information technologies, and bioethics, to name a few. She is also a guest lecturer in the graduate class of Genetics and Bioethics at McGill University and in the graduate class of Global Health Ethics at the University of Southern California, San Diego. She is currently a member of the International Expert Group of the Genetic Discrimination Observatory and the Centre for Intellectual Property and Policy of McGill University.



KRISTINA KÉKESI-LAFRANCE

ACADEMIC ASSOCIATE

Kristina is a lawyer who completed her LLM in Bioethics at the McGill Faculty of Law in 2022. While in her undergraduate studies at Sherbrooke University Law Faculty, Kristina also studied abroad for a semester at the Law Faculty of Université Libre de Bruxelles. After successfully passing her bar exams, Kristina was called to the Quebec Bar in July 2018. She practiced as a lawyer in an international firm for over a year before joining the CGP.

As an Academic Associate, Kristina is interested in how law and ethics interact in the field of genomics. She is involved in different projects in both clinical and research ethics projects as well as others focused on international privacy laws and biobanking. Kristina is also a coordinator and policy developer for the Regulatory and Ethics Work Stream of the Global Alliance for Genomics and Health (GA4GH) and an Affiliate Graduate member of the Research Group on Health and Law at McGill.

EMILY KIRBY

ACADEMIC ASSOCIATE

Emily is a lawyer and Academic Associate at the Centre of Genomics and Policy (CGP), McGill University. 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 CGP, 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 and the International Cancer Genome Consortium (ICGC). Academic Coordinator of the Ethics Working Group of the Human Cell Atlas, she is also active in the Global Alliance for Genomics and Health task forces, and the Transforming Autism Care Consortium's Q1K project, etc.).



TERESE KNOPPERS

ACADEMIC ASSOCIATE

Terese holds a Bachelor of Arts in Sociology from McGill University and a Master of Arts in Counselling Psychology from Simon Fraser University. She has a background in qualitative methods and equity, diversity, and inclusion (EDI) research. She is particularly interested in research that helps improve healthcare access and provision.

At the CGP, Terese coordinates the qualitative components of a variety of projects. She is presently involved in research on the legal regulation of cancer risk prediction models, improvement of healthcare communication practices with intersex people, precision medicine in acute myeloid leukemia, impacts of the lack of legal recognition of genetic counsellors in Quebec, and practices of direct-to-consumer epigenetic companies.



MICHAEL LANG

ACADEMIC ASSOCIATE

Michael 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 honours 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.

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 affects the relationship between physicians and their patients, how the law understands personhood, and how humans interact with the natural environment.



ERICA MONTEFERRANTE

ACADEMIC ASSOCIATE

Erica is an Academic Associate of the Centre of Genomics and Policy at McGill University, and holds degrees from Université de Montréal (MA, Bioethics) and McGill University (BA, Western Religions). Her graduate research explored the concept of moral distress, as it relates to decision-making. Erica's other areas of focus include moral deliberation, research ethics, artificial intelligence, and the ethical, legal, and policy implications of health research and health governance.

She contributes to the CGP team on projects involving (1) responsible biobanking policies and (2) health policy guidelines for smartphone applications.





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 (Quebec). Her work focuses on the socio-ethical and legal aspects of paediatric genetic research, rare disease research, cell/tissue therapy and regenerative medicine. She also has an interest in reproductive health law, particularly issues surrounding emerging reproductive technologies, such as prenatal diagnosis and pre-implantation genetic diagnosis.



NICOLE PALMOUR

ACADEMIC ASSOCIATE

Nicole Palmour, an Academic Associate at the Centre of Genomics and Policy at McGill University, has a background in biology, psychology (BA), forensic psychology (MA), and human genetics with a bioethics specialization (PhD). She sits on the McGill University Faculty of Medicine Research Ethics Board and the Research Data Management Working Group. Her research interests are situated at the interface of the fields of bioethics, genetics and epigenetics, data sharing, scientific knowledge construction, neurodiversity, and health policy development. Presently, she is working on governance framework development, gender and diversity in epigenetics, intersex and healthcare communication, and AI in anti-doping HEC and teaching.



DIMITRI PATRINOS

ACADEMIC ASSOCIATE

Dimitri is a lawyer and an Academic Associate at the Centre of Genomics and Policy (CGP) at McGill University. He is currently pursuing his Master of Laws (LL.M.) degree at McGill University's Faculty of Law and is a graduate fellow of the McGill Research Group on Health and Law. 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 and is a jurist member of the McGill University Health Centre (MUHC) Research Ethics Board.

At the CGP, Dimitri's research focuses on the legal recognition of genetic counsellors in Canada, paediatrics, and data governance.



LINGQIAO SONG

ACADEMIC ASSOCIATE

Ms. 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 degree of international business law at University of Montreal and was awarded "Dean's Award: Best Overall Academic Achievement". In 2016, she was admitted as a Chinese Lawyer and working as a legal consultant for Anran Law firm in China.

At the Centre of Genomics and Policy, Lingqiao is focusing on the Ethical, Legal, Social Issues (ELSI) of gene technology, such as intellectual property law of biotechnology, misuse of genetic information outside of therapeutic context, policy approaches to address genetic discrimination, global data sharing of biobank and regulatory framework of microbiological genetic test.

ACADEMIC SCHOLARS

FRUZZINA MOLNÁR-GABOR INVITED SCHOLAR

Fruzsina is Professor of International Medical and Health Law as well as Data Protection Law at the University of Heidelberg. She received her doctorate in law from the University of Heidelberg and was research group leader at the Heidelberg Academy of Sciences and Humanities. Molnár-Gábor is co-editor of the monthly GDPR briefs published by the International Health Data Sharing Forum of the Global Alliance for Genomics and Health.

She is on a number of international expert committees and scientific advisory boards such as the EU's 1+ Million Genomes Initiative in the working group on ethical, legal and social issues. She is a member of the European Group on Ethics in Science and New Technologies and a member of the Young Academy of the Berlin-Brandenburg Academy of Sciences and Humanities and the National Academy of Sciences Leopoldina. She was awarded the Heinz Maier-Leibnitz Prize (2020). She visited the CGP from July until the first week of August 2022 and continues to co-lead the GDPR forum for GA4GH.



SAFIA MAHOMED INVITED SCHOLAR

Safia is a Professor at UNISA's School of Law and an honorary Associate Professor at the Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand, South Africa. Her research interests cluster around questions regarding health law and bioethics. Safia is an attorney with a Ph.D. from the University of the Witwatersrand (2018). One outcome of Safia's Ph.D. thesis (A Material Transfer Agreement Template) was presented to the National Department of Health and with minor revisions, gazetted for national use.

Safia is a current member and former Chair of UNISA's Biotechnology and Medical Law Flagship. She is also a member of various national and international committees. In 2018, Safia was awarded UNISA's Principal's prize for excellence in research. She is a current fellow of the National Department of Higher Education's Future Professor's Programme (Cohort 1) and holder of UNISA's Vision Keepers Grant. Safia is the editor of the South African Journal on Human Rights and has published and presented her research both nationally and internationally.



BERTRAND STOFFEL INVITED SCHOLAR

As a legal policy scholar, Bertrand studies the legal and socio-ethical dimensions of human enhancement, as well as the regulation of drugs in society. At the intersection of law, criminal justice, and health policy, his research focuses, among other things, on rule breakers' decision-making process and regulatory strategies to complement deterrence-based interventions.

Bertrand completed a Postdoctoral Fellowship at McGill's Institute for Health and Social Policy, holds a Doctorate of Law from the University of Zurich, Switzerland (2017), and is a member of the Bar of Zurich (2016). He is an editor for the Canadian Journal of Bioethics.



PH.D. STUDENTS

DEREK SO PH.D. STUDENT

Derek received his B.Sc from McGill in 2012, majoring in Biology and minoring in English Literature. He then joined the CGP as a Master's student under the supervision of Profs. Yann Joly and Rob Sladek, returning for his PhD in Human Genetics in 2015. Derek's thesis examines the ethical discourse around germline gene editing and the conceptual frameworks we use when imagining nonexistent people—particularly the idea of the “modular” human, in which different unitary characteristics are recombined like building blocks. His project is funded by a CIHR Doctoral Award.

ERIKA KLEIDERMAN PH.D. STUDENT

Erika Kleiderman is a Ph.D. Candidate working on her thesis titled “Unpacking the notion of ‘serious’ condition: Towards an operational and adaptive framework”. She works under the supervision of Profs. Bartha Maria Knoppers and Vardit Ravitsky.

The concept of ‘serious’ condition is a key element in the ethical and policy analyses of genomic technologies. It is used to define and delimit the scope of ethically appropriate and/or legally permissible research and clinical applications such as pre-implantation genetic testing (PGT) of embryos, prenatal testing, and human somatic/germline genome editing. Yet, it remains vague and poorly defined, rendering the application of ‘serious’ challenging and decision-making subjective and arbitrary. The objective of this thesis is to consider, challenge, and unpack the notion of ‘serious’ condition, so as to move towards greater definitional clarity and utility in clinical and policy decision-making, particularly within the context of new genomic and reproductive technologies. The future bioethics debate surrounding the concept of ‘serious’ requires a comprehensive and nuanced analysis, both in terms of its ethical implications and its use in the formulation of policy. The thesis aims to embark on such an analysis, and propose a framework that would help prioritize and qualify the notion of ‘serious’ as a function of various factors, including medical, social and individual ones.

MASTER'S STUDENTS

ANA BONILHA MASTER'S STUDENT

Ana Eliza is currently pursuing a Master of Science in Human Genetics and Bioethics, under the supervision of Prof. Ma'n Zawati. She also holds a bachelor's degree in Biomedical Sciences from McGill University. Her research focuses on ethical issues surrounding newborn screening, genetic counselling, and global health policy development. In addition to her thesis project, Ana is involved in various projects at the Centre of Genomics and Policy, including GenCOUNSEL, LeuceGene, and in different data sharing initiatives such as the International Cancer Genome Consortium (ICGC).

JACQUELINE BRADBURY-JOST MASTER'S STUDENT

Jacqueline is a Master of Science student in the Department of Human Genetics at McGill University under the supervision of Prof. Ma'n Zawati. She has also completed 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.

Jacqueline's research at the Centre of Genomics and Policy focuses on the ethical and legal implications of novel health technologies and is funded by a CIHR Master's award.

EMILY DOERKSEN MASTER'S STUDENT

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 HALEY MASTER'S STUDENT

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 Prof. 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, where she researches how Canadian genetic counsellors can respond to the rise of direct-to-consumer genetic tests.



HANSHI LIU MASTER'S STUDENT

Hanshi, under the supervision of Prof. Yann Joly, is pursuing a Master's degree in Human Genetics with a concentration in Bioethics. He is interested in new legal and ethical challenges raised by the development of recent medical and scientific advances in the field of Health. His master's thesis is a comprehensive review and analysis of ethical challenges and considerations surrounding the use of population descriptors such as race, ethnicity, and ancestry in genetics research. Particularly, he is interested in how to reconcile the tensions between the benefits of genetic research participation and their potential harms for both individuals and communities.

At the CGP, his primary research focuses on data sharing in the omic sciences, and the privacy and ethical issues associated with it. Hanshi has been involved in numerous projects at the Centre, from the Canadian COVID Genomics Consortium (CanCOGeN), D-PATH, the International Human Pangenetic Consortium, various Data Access Committees, and the Secure Data for Health initiative.



RESEARCH ASSISTANTS



ISABEL BALTZAN RESEARCH ASSISTANT

Isabel is a BCL/JD student at the McGill Faculty of Law and holds a BSc in Pharmacology from McGill. She joins the CGP as a Research Assistant and is interested in ethical, legal, and policy issues relating to access to care, the well-being of vulnerable groups, and considerations surrounding innovations in genomics and health.



MARILOU CHARRON RESEARCH ASSISTANT

Marilou first joined the CGP for an internship as a part of her B.Sc. in Biology at McGill under the supervision of Prof. Yann Joly. She was then hired as a Research Assistant to pursue the research projects she had started as an intern. Her research focuses on improving communication between healthcare practitioners and the intersex community in Canada and interrogating the ethical, legal and social implications of the implementation of Artificial Intelligence in the World Anti-Doping Agency's (WADA) anti-doping measures. She recently completed a Master's degree in Bioethics at Université de Montreal.



KATHERINE CHEUNG RESEARCH ASSISTANT

Katherine has completed a degree in International Development at McGill University, with a minor in Health Geography and Physiology. She is currently a Master's student in Bioethics at New York University. Her interests include bioethics and genetic discrimination. Since May 2021, she has been a Research Assistant at the Centre of Genomics and Policy at McGill University, working under the supervision of Profs. Ma'n Zawati and Yann Joly, and is a member of the GDO Secretariat.



AURÉLIE DAUGE RESEARCH ASSISTANT

Aurélie Dauge holds a Bachelor of Laws from the Law School of Aix en Provence in France and is currently pursuing a second Bachelor of Laws at the University of Montreal. While she completed her undergraduate studies, Aurélie also studied abroad for a year at the University of Exeter Law School.

She is interested in the interaction of law and bioethics in the context of human genetics, genetic discrimination, health law, comparative law and equality rights.

At the CGP, Aurélie is a Research Assistant under the supervision of Prof. Yann Joly. She works on the D-path project and the responsible use of Polygenic Risk Scores in medicine.

RUTHERFORD EXIUS

RESEARCH ASSISTANT

Rutherford is a law student at the University of Montreal and holds a Bachelor of Science in Pharmacology and a Master's in Experimental Medicine from McGill University with a focus on allergy to antibiotics in children. He is interested in data privacy, health law, research ethics, and pediatrics. At the CGP, Rutherford assists Prof. Ma'n H. Zawati.



KATHERINE HUERNE

RESEARCH ASSISTANT

Katherine Huerne (B.Sc., B.A.) has completed a M.Sc. at McGill University, studying experimental medicine, clinical translation and bioethics. She received a B.A. at McGill in Philosophy with First-Class Honours and a B.Sc. in Biochemistry on the Dean's Multidisciplinary Undergraduate Research List. She has received several awards for her research in biochemistry, such as the Canderel Rising Star Award. Her philosophy thesis (in the philosophy of science) focused on epistemological, metaphysical and ethical issues of novel molecular technologies and its relation to emerging scientific paradigms in the field of life science. Katherine's Master's thesis looks at demographic equity in clinical trial design in the stem cell and regenerative medicine field. She examines a blend of epistemic and ethical issues in science, taking a feminist or social approach of analysis. At the CGP, she works under the supervision of Prof. Yann Joly.



NARGES JAMALI

RESEARCH ASSISTANT

Narges holds a Bachelor of Science in Life Sciences, with a Specialization in Biomedical Sciences and Epidemiology, from Queen's University. She is currently a student at McGill University's Faculty of Law and has research interests in equitable access to healthcare, bioethics, and intellectual property and privacy in Life Sciences. At the CGP, Narges works as a Research Assistant under the supervision of Prof. Yann Joly.



BEATRICE KAISER

RESEARCH ASSISTANT

Beatrice is currently a student at McGill University's Faculty of Law. She holds a Master's in Biotechnology from McGill University and a Bachelor of Science in Biochemistry from Queen's University. At the CGP, Beatrice works as a Research Assistant under the supervision of Prof. Yann Joly on the Global Alliance for Genomics and Health (GA4GH) and other projects. Beatrice's interests include examining legal, ethical and policy issues in the context of human genomics.





KRISTEN LAGUIA

RESEARCH ASSISTANT

Kristen Laguia worked at the CGP from 2015-2022, assisting Drs. Bartha Knoppers, Yann Joly and Ma'n Zawati with their CVs and online platforms. She also worked on several creative projects, including the CGP annual report and cystic fibrosis animations. Kristen holds a B.A. in English and Creative Writing from Concordia University.



ROBYN MCDOUGALL

RESEARCH ASSISTANT

Robyn holds a Bachelor of Science in Exercise and Health Physiology from the University of Calgary. She is currently a law student at McGill with interests in data privacy, AI regulation in the medical field, and equitable access to healthcare. At the CGP, Robyn assists Prof. Bartha Maria Knoppers in examining ethical, legal, and policy issues in human genomics and stem cell research.



PREKSHA MEHTA

RESEARCH ASSISTANT

Preksha is currently completing her third year of the combined B.C.L/ J.D program at McGill University, where she will obtain her double degree in 2023. In completing her undergraduate degree with a double major in Sociology and French at the University of Toronto, she developed a keen interest in establishing a bilingual practice with a focus on advocacy and litigation. Preksha is also interested in business and health law, interests she developed while serving on the executive board of McGill Journal of Law and Health. In her free time, she contributes to McGill's Faculty of Law student newspaper, the Quid Novi, and the Contours Journal. Preksha joins the CGP as a Research Assistant working under the supervision of Prof. Ma'n Zawati.



ELENA OLVERA

RESEARCH ASSISTANT

Elena Olvera holds a Bachelor of Arts (BA) from the Autonomous University of Querétaro in Mexico, and has a diploma from Concordia University in Communications. Furthermore, she has a background in multidisciplinary studies from her past and on-going time as a student at the Université du Québec à Montréal. She has been working as a graphic designer in Montreal since 2008, and at McGill University's Centre of Genomics and Policy since 2012, where she develops graphics and layouts for scientific posters and presentations.

ADMINISTRATIVE ASSISTANTS

MEI-CHEN CHANG ADMINISTRATIVE ASSISTANT

Mei-Chen Chang holds a bachelor degree in Social Science from the Ritsumeikan Asia-Pacific University in Japan and is currently pursuing a Professional Development Certificate in Project Management at McGill University. At the Centre, she works with Professor Yann Joly.



KATHRYN GAMBOA ADMINISTRATIVE ASSISTANT

Kathryn Gamboa completed a B.A. in Philosophy and English at McGill University. She works as an Administrative Assistant at the Centre of Genomics and Policy (CGP) under the supervision of Prof. Ma'n Zawati. Outside of the CGP, Kathryn is a Digital Literacy Facilitator at Atwater Library.



ROSE-MARIE HOZYN ADMINISTRATIVE ASSISTANT

Rose-Marie Hozyan is HR Administrator and Executive Assistant to Prof. Bartha Maria Knoppers at the Centre of Genomics and Policy (2006 – present). In 2006, she joined Prof. Knoppers and her team at the Centre de recherche en droit public, Université de Montréal as a Coordinator. In 2009, she came over to McGill with Prof. Knoppers and her team to assist in her new Centre of Genomics and Policy. Now as an Administrator in the fast growing Centre, Rose-Marie is responsible for the coordination of the work of Prof. Knoppers, human resources, and human relations.

She is a graduate of Legal Secretarial Program at O'Sullivan College, where she taught the evening legal secretarial course from 1995-1997. From 1982 – 2006, she was a Legal Assistant in the fields of litigation, matrimonial, corporate and commercial law at Baron Abrams and Stein & Stein. From 1987 - 2006 she worked for Alex K. Paterson at Borden Ladner Gervais LLP where she assisted him in an administrative capacity in his malpractice cases, and in his work on Boards such as the MUHC Foundation, Chair of McGill and Chancellor of Bishops.



NADINE THORSEN ADMINISTRATIVE ASSISTANT

A native of Alberta, Nadine Thorsen has been working as a financial administrator at the Centre of Genomics and Policy since 2012. She eagerly supports the CGP team in travel reimbursement, fund management, financial reporting and compliance.



COMPLETED PROJECTS ✓

APR 2016
MAR 2022

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

APR 2016
JUN 2022

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

MAR 2018
JAN 2022

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

APR 2018
MAR 2022

MCGILL UNIVERSITY AND GÉNOME INNOVATION CENTRE

OCT 2018
SEP 2022

EPIGENOMICS SECURE DATA SHARING PLATFORM FOR INTEGRATIVE ANALYSES (EPISHARE)

JAN 2019
DEC 2022

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

APR 2019
DEC 2022

THE CANCER GENOME COLLABORATORY

SEP 2019
OCT 2022

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

OCT 2019
AUG 2022

THE MCGILL CLINICAL GENOMICS (MCG) PROGRAM

APR 2020
MAR 2022

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

MAY 2020
APR 2022

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

MAY 2020
JUN 2022

ELSI COMPONENT: VIRUSSEQ—CANCOGEN

SEP 2020
OCT 2022

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

NOV 2020
DEC 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

APR 2021
MAR 2022

REGENERATIVE MEDICINE CHARTER UPDATE PROJECT

CGP COMPLETED PROJECTS

APR 2016

MAR 2022

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

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 acted 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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CO-INVESTIGATORS
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GUZDER Jaswant
KIRMAYER Laurence J.
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MEANEY Michael J.P.

ROUSSEAU Cecile
STEINER Meir
SZATMARI Peter
TIEMERIER Henning

ACADEMIC ASSOCIATE
PATRINOS Dimitri

APR 2016

JUN 2022

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

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 was 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.

PRINCIPAL INVESTIGATOR
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MINDE Klaus
ROUSSEAU Cecile

SASSI Roberto Britto
ST-ANDRÉ Martin
STEINER Meir
SZATMARI Peter
TIEMEIER Henning

ACADEMIC ASSOCIATE
PATRINOS Dimitri

MAR 2018

JAN 2022

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

National Institutes of Health (NIH)

This study aimed 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.

PRINCIPAL INVESTIGATORS

KNOPPERS Bartha Maria
ROTHSTEIN Mark

CO-INVESTIGATORS

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BESKOW Laura M.
BROTHERS Kyle B.
HAMMACK Catherine
JOLY Yann
SALZMAN Andrea
ZAWATI Ma'n H.

ACADEMIC ASSOCIATES

LANG Michael
PATRINOS Dimitri

APR 2018

MAR 2022

MCGILL UNIVERSITY AND GÉNOME INNOVATION CENTRE

Genome Canada
Genome Québec

The McGill University and G nome Qu bec 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 G nome Qu bec 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 Qu bec, 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 provided ongoing ethical and policy consultation on this project.

PRINCIPAL INVESTIGATOR
LATHROP Mark

CO-INVESTIGATOR
JOLY Yann

ACADEMIC ASSOCIATE
GRANADOS-MORENO
Palmira

OCT 2018**SEP 2022****EPIGENOMICS SECURE
DATA SHARING PLATFORM
FOR INTEGRATIVE
ANALYSES (EPISHARE)**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. Mechanisms are needed 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 provides 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.

**PRINCIPAL
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FLICEK Paul
OUELLETTE Francis
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GRANADOS-MORENO
Palmira**CO-PRINCIPAL
INVESTIGATOR**
LATHROP Mark**RESEARCH ASSISTANT**
LIU Hanshi**JAN 2019****DEC 2022****CAN-SHARE CONNECT:
SUPPORTING THE
REGULATORY AND ETHICS
WORK STREAM OF THE
GLOBAL ALLIANCE FOR
GENOMICS AND HEALTH
(GA4GH)**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" supported the continued Canadian leadership and coordination of the REWS by the CGP. A central responsibility of the REWS was 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 2014. This toolkit addresses consent, privacy & security, accountability, and coordinated ethics review of international collaborative research. The goal was 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 pediatric and familial consent clauses as well as a revision to the ethics review recognition policy. Policy subjects completed in 2021 include return of results, participant engagement, and procedural standards for data access committees. The Consent Task Force published additional templates of sampled consent language for clinical genomics. The REWS also supported the implementation of the toolkit via 24 real-world genomic data sharing "Driver Projects."

**PRINCIPAL
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DOVE Edward
FRIEDMAN Jan
GREEN Robert
MURTAGH Madeleine
SUVER Christine
WALLACE Susan**ACADEMIC
ASSOCIATES**
BEAUVAIS Michael
KÉKESI-LAFRANCE
Kristina
KIRBY Emily
KLEIDERMAN Erika
NGUYEN Minh Thu

APR 2019

DEC 2022

THE CANCER GENOME COLLABORATORY

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 extended the CGC's data holdings, improved accessibility to the data, and added a series of high-quality vetted pipelines for standardized cancer genomic analysis. It implemented services that apply new cutting-edge algorithms for the interpretation of cancer genomes. The CGP drafted a code of practice for the international sharing of cancer genomic data. The CGP 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.

PRINCIPAL INVESTIGATOR
STEIN Lincoln

CO-INVESTIGATORS
BADER Gary
BOURQUE Guillaume
FERRETTI Vincent
KNOPPERS Bartha Maria
SHAH Sohrab
SIMPSON Jared

ACADEMIC ASSOCIATE
BERNIER Alexander

SEP 2019

OCT 2022

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

Oncopole

The goal of this project was 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 was to double enrollment in oncology clinical trials and to create a dynamic biobank of samples collected during clinical trials of new drugs to have a major impact on the advancement of science for the benefit of patients. The team at the CGP assisted in the development of project governance tools and advising the consortium on its legal and ethical obligations. In doing so, the Centre drew on its extensive expertise in the biobanking field. Likewise, the team drew on its background research in the adoption of mobile health technologies for facilitating largescale genomic oncology research.

PRINCIPAL INVESTIGATOR
PARK Morag

CO-INVESTIGATORS
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ZAWATI Ma'n H.

ACADEMIC ASSOCIATE
PATRINOS Dimitri

OCT 2019

AUG 2022

THE MCGILL CLINICAL GENOMICS (MCG) PROGRAM

Jewish General Hospital Foundation

The McGill Clinical Genomics program (McG) aimed to implement hospital-based genomic medicine building on robust research to improve clinical care. McG sought to improve disease diagnosis and risk-stratification, the efficiency of test ordering and prediction of drug responses that delivers 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 led the Ethics and Governance Pillar and developed a set of ethics policies and templates to ensure that the Project recruitment participants as well as use and sharing of data and samples for research purposes was done in an ethical and efficient manner, which complies with international best practice. Special focus was put on COVID-19 related recruitment in light of the pandemic.

PRINCIPAL INVESTIGATORS
MOOSER Vincent
RICHARDS Brent

CO-INVESTIGATORS
JOLY Yann
ZAWATI Ma'n H.

ACADEMIC ASSOCIATE
SONG Lingquiao

APR 2020**MAR 2022****OPPORTUNITIES AND CHALLENGES OF USING EPIGENETIC TECHNOLOGIES IN DEFENCE AND SECURITY CONTEXTS**

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 in response to exposure to various environmental or social factors. This project aimed to identify opportunities and challenges in using epigenetic technologies in the context of defence 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 carried out trailblazing research on the opportunities and technical, ethical and legal challenges associated with epigenetics. The CGP organized a workshop with interdisciplinary experts on epigenetics from different regions worldwide (law, bioethics, sociology, philosophy and science). The workshop's outcomes translated into a policy briefing for interested DND/CAF officials, highlighting opportunities and challenges to effectively implementing epigenetic technologies in defence and security contexts.

PRINCIPAL INVESTIGATOR
JOLY Yann

ACADEMIC ASSOCIATES
DALPÉ Gratien
KNOPPERS Terese

MASTER'S STUDENT
CROCKER Kelsey

RESEARCH ASSISTANTS
XU Handi
CHEUNG Katherine

MAY 2020**APR 2022****OF BIOBANKING AND POLICY: EMERGING ETHICAL AND LEGAL CHALLENGES DURING THE COVID-19 PANDEMIC**

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 was to provide policy evidence – as well as ethical and legal guidance – to inform newly created COVID-19 research infrastructures. The CGP conducted a comparative analysis of existing COVID-19 international biobanking policies and launched a national survey on the lived experiences of health professionals involved in participant recruitment during the pandemic. In co-ordination with the Biobanque Québécoise de la COVID-19 and researchers in the UK, Italy, Australia, South Africa, and Hong-Kong, the CGP provided objective evidence for policy development.

PRINCIPAL INVESTIGATOR
ZAWATI Ma'n H.

ACADEMIC ASSOCIATES
DUPRAS Charles
MONTEFERRANTE Erica

MAY 2020**JUN 2022****ELSI COMPONENT: VIRUSSEQ—CANCOPEN**

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 was organized into components focusing on human-disease component (HostSeq) and virus (VirusSeq) to address topics unique to each. CanCOGeN-VirusSeq had 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. Prof. Yann Joly served 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 of the VirusSeq Implementation Committee. Overall, as a part of CanCOGeN-VirusSeq, the CGP team addressed essential ethical and legal issues derived from the CanCOGeN project.

PRINCIPAL INVESTIGATOR
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RESEARCH ASSISTANTS
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FARAJI Sina
LIU Hanshi

SEP 2020

OCT 2022

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

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. The CGP reviewed 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 hereditary breast and ovarian cancers. Comparative law analysis was undertaken to identify the main legal variations and promote better coordination of the legal texts of the different national systems.

**PRINCIPAL
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LABERGE Maude

POMEY Marie-Pascale

SIMARD Jacques

NOV 2020

DEC 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**

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

The Réseau québécois 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 worked 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 has developed 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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APR 2021

MAR 2022

**REGENERATIVE MEDICINE
CHARTER UPDATE PROJECT**

Stem Cell Network (SCN)

Advances in regenerative medicine challenge both traditional legal classifications and professional ethics norms. The development of a Regenerative Medicine Charter by the CGP, founded on both international human rights and recent policy guidance, seeks to frame the future conduct of research in regenerative medicine. To do so, we examined the current international ethical and legal landscape concerning cellular genomics, bioengineering, human genome editing, and stem cell research in order to propose key pillars for the Regenerative Medicine Charter. In particular, we posit that the respect of the human right to science, to health, and to non-discrimination as well as the principles of quality/safety, integrity/accessibility, and transparency/accountability could guide the ethical future of regenerative medicine. Hopefully, the Charter will bring together and inspire the diverse communities of policymakers, scientists, clinicians, as well as patients and their families as they face the challenges of regenerative medicine.

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ONGOING PROJECTS

APR 2009

MAR 2023

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

APR 2016

MAR 2024

SINO-CANADA HeLTI: A MULTIFACETED COMMUNITY-FAMILY-MOTHERCHILD INTERVENTION STUDY FOR THE PREVENTION OF CHILDHOOD OBESITY (SHeLTI)

FEB 2017

JAN 2025

MULTIDIMENSIONAL EPIGENOMICS MAPPING CENTRE (EMC) AT MCGILL

MAR 2018

MAR 2024

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

APR 2018

MAR 2023

PRECISION ONCOLOGY FOR YOUNG PEOPLE (PROFYLE 2)

APR 2018

MAR 2024

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

APR 2018

MAR 2024

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

APR 2018

MAR 2024

PERSONALIZED THERAPY FOR INDIVIDUALS WITH CYSTIC FIBROSIS

APR 2018 MAR 2024	CARE4RARE CANADA: HARNESSING MULTI-OMICS TO DELIVER INNOVATIVE DIAGNOSTIC CARE FOR RARE GENETIC DISEASES IN CANADA (C4R-SOLVE)
APR 2018 MAR 2024	INTERROGATING AND IMPLEMENTING OMICS FOR PRECISION MEDICINE IN ACUTE MYELOID LEUKEMIA
JUL 2018 JUN 2024	GENCOUNSEL: OPTIMIZATION OF GENETIC COUNSELLING FOR CLINICAL IMPLEMENTATION OF GENOME-WIDE SEQUENCING
JUL 2018 DEC 2025	MSSNG DATABASE – DATA ACCESS COMPLIANCE OFFICE
OCT 2018 SEP 2025	EUCANSHARE: AN EU-CANADA JOINT INFRASTRUCTURE FOR NEXT-GENERATION MULTI-STUDY HEART RESEARCH
NOV 2018 OCT 2023	HUMAN CELL ATLAS
MAR 2019 APR 2023	OBSERVATOIRE INTERNATIONAL SUR LES IMPACTS SOCIÉTAUX DE L'INTELLIGENCE ARTIFICIELLE ET DU NUMÉRIQUE
APR 2019 MAR 2023	CANADIAN PARTNERSHIP FOR TOMORROW'S HEALTH (CANPATH)
APR 2019 MAR 2024	ALL FOR ONE TOOLKIT (CGP4-RD)
APR 2019 SEP 2025	EUCANCAN: A FEDERATED NETWORK OF ALIGNED AND INTEROPERABLE INFRASTRUCTURES FOR THE HOMOGENEOUS ANALYSIS, MANAGEMENT AND SHARING OF GENOMIC ONCOLOGY DATA FOR PERSONALIZED MEDICINE
JAN 2020 JAN 2023	ETHICAL AND LEGAL FRAMEWORK FOR DIRECT-TO-PARTICIPANT (DTP) RECRUITMENT
JAN 2020 JAN 2023	SELF-ASSEMBLY SKIN SUBSTITUTES (SASS) FOR THE TREATMENT OF ACUTE WOUNDS OF CANADIAN BURN PATIENTS
JAN 2020 JAN 2023	CULTURED EPITHELIAL CORNEAL AUTOGRAFTS FOR THE TREATMENT OF CANADIANS WITH LIMBAL STEM CELL DEFICIENCY

JAN 2020 JUL 2023	THE QGPRS STUDY: QATAR GENOME POLYGENIC RISK SCORE, A PRECISION MEDICINE APPROACH TO PREVENT DIABETIC COMPLICATIONS IN THE AFFECTED QATARI INDIVIDUALS
MAR 2020 FEB 2023	AUTISM SHARING INITIATIVE
APR 2020 MAR 2023	DELETING OVARIAN AND ENDOMETRIAL CANCER USING GENOMICS (DOvEEgene)
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APR 2020 JUN 2023	VALIDATING, SPECIFYING & PRIORITIZING THE ETHICAL, LEGAL AND SOCIAL IMPLICATIONS OF IMPLEMENTING ARTIFICIAL INTELLIGENCE WITHIN ANTIDOPING STRATEGIES: AN INTERNATIONAL DELPHI STUDY
JUN 2020 MAR 2023	ETHICS AND POLICY PILLAR-HostSeQ (CanCOGeN)
JUL 2020 MAR 2024	ETHICAL LEGAL EXPERTISE – COVID-19 IMMUNITY TASK FORCE (CITF)
SEP 2020 JAN 2023	TOWARDS AN EPIDERMOLYSIS BULLOSA CLINICAL TRIAL WITH TISSUE-ENGINEERED SKIN AFTER EX VIVO GENE THERAPY CORRECTION
NOV 2020 MAR 2026	SECUREDATA4HEALTH
JAN 2021 DEC 2023	SMARTPHONE CROWDSOURCED MEDICAL DATA FOR BIOMEDICAL RESEARCH: ADDRESSING THE ETHICAL, LEGAL AND HEALTH POLICY CONCERNS
JAN 2021 JUN 2024	THE QUEBEC SMARTCARE CONSORTIUM
JAN 2021 DEC 2024	ARTIFICIAL INTELLIGENCE AND DIGITAL HEALTH
APR 2021 MAR 2024	PARADIGM SHIFT IN THE CONDUCT OF CLINICAL TRIALS
APR 2021 MAR 2025	CANDIG: DISTRIBUTED INFRASTRUCTURE FOR GENOMICS DATA SHARING AND ANALYSIS – INFRASTRUCTURE OPERATING FUND (IOF)

JUL 2021 JUL 2024	GA4GH GENOMIC DATA SHARING TOOLS AGAINST COVID-19 FUNDING OPPORTUNITY
JUL 2021 JUL 2025	CANADA FOUNDATION FOR INNOVATION (CFI)'S INNOVATION FUND: "A CGMP FACILITY FOR PERSONALIZED TISSUE ENGINEERING"
JAN 2022 DEC 2023	THE CANADIAN OPEN NEUROSCIENCE PLATFORM (CONP)
MAR 2022 APR 2023	FEDERATED DATA ACCESS COMMITTEES FOR HARMONISED PAN-CANADIAN CANCER DATA STEWARDSHIP (CANFED)
MAR 2022 MAR 2024	THE 2022 GENETIC DISCRIMINATION OBSERVATORY SCIENTIFIC CONFERENCE
APR 2022 MAR 2023	PSILOCYBIN TO RELIEVE EXISTENTIAL DISTRESS AT THE END OF LIFE/ LA PSILOCYBINE POUR SOULAGER LA DÉTRESSE EXISTENTIELLE EN FIN DE VIE
APR 2022 SEP 2023	ALL FOR ONE HEALTH DATA ECOSYSTEM (HDE)
APR 2022 JAN 2025	ENGINEERED HEMATOPOIETIC STEM CELLS (EHSCS) AS VEHICLES FOR NEXT GENERATION THERAPIES
APR 2022 JAN 2025	TISSUE ENGINEERING TO TREAT CANADIAN BURN PATIENTS: THE SELF-ASSEMBLED SKIN SUBSTITUTES (SASS)
JUN 2022 JUN 2025	EXPLAINING THE RIGHT TO EXPLANATION: DATA PROTECTION LEGISLATION AND CLINICAL AUTOMATED DECISION-MAKING
JUL 2022 JUN 2025	RESPONSIBLE PATHWAYS FOR PEDIATRIC CELL THERAPIES
AUG 2022 JUL 2024	CANADIAN PEDIATRIC CANCER CONSORTIUM (CPCC)
JAN 2023 MAR 2024	AUTHENTIC LIVES AND THE RIGHT TO GENDER AFFIRMING CARE FOR YOUTH: ACTORS, VALUES, AND LEGISLATIVE APPROACHES IN THE US AND CANADA

CGP ONGOING PROJECTS

APR 2009

MAR 2023

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

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 aimed 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 the 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 made it possible to consider and integrate ELSI concerning the scientific reality of clinical trials in regenerative medicine.

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APR 2016

MAR 2024

SINO-CANADA HeLTI: A MULTIFACETED COMMUNITY-FAMILY-MOTHERCHILD INTERVENTION STUDY FOR THE PREVENTION OF CHILDHOOD OBESITY (SHeLTI)

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 is conducting a multi-site and community-based randomized controlled trial. This trial tests 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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FEB 2017**JAN 2025****MULTIDIMENSIONAL
EPIGENOMICS MAPPING
CENTRE (EMC) AT MCGILL**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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MAR 2018**MAR 2024****TOWARD EFFECTIVE HEALTH
COMMUNICATION WITH
INTERSEX CANADIANS: A
STUDY OF ETHICAL AND
LEGAL CHALLENGES**Social Sciences and Humanities
Research Council (SSHRC)

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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YOUNG PEOPLE (PROFYLE 2)**

Terry Fox Research Institute

The PRecision Oncology For Young peopLE (PROFYLE) program aims to transform cancer treatment 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 emphasized real-time molecular profiling to personalize cancer treatment and improve outcomes. The CGP studied questions surrounding access to genetic data by parents and the use of mobile health applications when streamlining recruitment processes. Our team proposed policy recommendations for improving access to molecular profiling and associated treatment applications. The team further identified ethical and legal issues raised by the development of mobile health technologies that facilitate patient recruitment and that promote equitable access to molecular profiling.

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APR 2018

MAR 2024

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

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 the 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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APR 2018

MAR 2024

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

Genome Canada
Genome Québec

This project aims to provide evidence that can significantly expand the benefits of the current age-based population breast cancer screening programs by supporting the transition to a risk-based approach. A population-based cohort is being assembled to evaluate the acceptability and feasibility of using a new comprehensive risk prediction web tool and a genomic profiling test. The CGP is providing health authorities with acceptable policies that address emergent socio-ethical and legal issues of implementing a personalized risk-based screening approach in Canada. To achieve this, the CGP examines 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 to women on the risks of genetic discrimination and existing protections to mitigate them. The CGP also supports the research team regarding the ethics approvals required and specific ethical issues associated with the establishment of the research cohort.

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APR 2018

MAR 2024

PERSONALIZED THERAPY FOR INDIVIDUALS WITH CYSTIC FIBROSIS

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 is examining 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 CGP team works with industry partners, patient organizations and the Ontario Ministry of Health to integrate these strategies into accessible 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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APR 2018

MAR 2024

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

Genome Canada
Genome Alberta
Genome British Columbia
Ontario Genomics Institute (OGI)

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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APR 2018**MAR 2024****INTERROGATING AND IMPLEMENTING OMICS FOR PRECISION MEDICINE IN ACUTE MYELOID LEUKEMIA**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 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. The Center will also organize several focus groups with patients to better understand their expectations in terms of online services to access health information and help the leucegene webportal to be more user-friendly.

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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. Yet, 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 is: 1) researching models of legal recognition available to genetic counsellors; 2) categorizing the main tasks performed by genetic counsellors and assessing how they translate into legal duties; and finally, 3) convening a pan-Canadian working group comprised of key stakeholders to discuss the feasibility of and potential pathways toward legal recognition.

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Autism Speaks Inc.

MSSNG and Autism Genetic Resource Exchange (AGRE) are the world's largest databases of genomic information collected from individuals with autism spectrum disorder (ASD) and their families. MSSNG in particular advances the goal of sequencing 10,000 families affected by ASD to answer significant remaining questions about autism, its causes, and effects. Scientists from around the world may access trillions of data points in a single database. The CGP hosts the Data Access Committee for MSSNG and AGRE, adjudicating access on the part of external researchers to these valuable resources. CGP manages the review of data access applications and grants access to qualified researchers. In 2022, the Data Access Committee approved 6 new applications.

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OCT 2018**SEP 2025**

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

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

The euCanShare platform is a data discovery tool that brings together summary statistics, metadata, and other information from 27 cardiovascular health studies and cohort studies across Canada and the European Union. Participating cohort studies include the Canadian Alliance for Healthy Hearts and Minds (CAHHM), and the European Biomarker Care project. The Centre of Genomics and Policy leads the ethical-legal work-package of euCanShare, including the development of ethical-legal metadata describing the data governance conditions and data stewardship conditions applicable to each participating study. This enables researchers to find, and obtain access to, data that is useful for their anticipated research purposes, considering both the scientific features and the governance conditions of the data. The euCanShare project is launching a follow-up effort to enable downstream access to data from multiple retrospective studies and cohorts through a single centralized Data Access Portal.

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NOV 2018**OCT 2023**

HUMAN CELL ATLAS

The Chan Zuckerberg Initiative
The Klarman Family Foundation
The Leona M. and Harry B.
Helmsley Charitable Trust

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 led the development of its ethics tools, including an ethics and data governance framework, template consent forms for adult and pediatric populations, relevant tools (retrospective consent filter, ethics submission guidance), template agreements (material/data transfer agreement templates, data submission agreement template, data use agreement template). The CGP further coordinated the HCA Ethics Working Group (EWG), and hosts an ethics helpdesk to support the HCA community. The CGP supported the governance activities of the HCA's Data Coordination Platform (DCP), including the implementation of its Data Access Compliance Office (DACO) and Data Access Committee (DAC).

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MAR 2019**APR 2023**

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

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 proposed to set up the International Observatory on the Societal Impacts of Artificial Intelligence and Digital Technologies (OBVIA). The ambition of this innovative institution was 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 was based on four different but interdependent functions. It conducted intersectoral and interdisciplinary research and creative activities on several priority themes. Members from the CGP were involved in the "Éthique, gouvernance, démocratie et responsabilité sociale des organisations" pillar within OBVIA.

**PRINCIPAL
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APR 2019

MAR 2023

CANADIAN PARTNERSHIP FOR TOMORROW'S HEALTH (CANPATH)

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 seven participating cohorts (Atlantic PATH, CARTaGENE, Ontario Health Study, Healthy Future Sask, Manitoba Tomorrow Project, Alberta's Tomorrow Project, and the BC Generations Project). The project's Ethical, Legal, and Social Issues (ELSI) Committee was hosted at the CGP and was responsible for developing ELSI infrastructure for the CanPath platform. Its goals were to bring together ELSI experts and develop relevant policies, documents, and procedures 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's mandate was 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.

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APR 2019

MAR 2024

ALL FOR ONE TOOLKIT (CGP4-RD)

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 Partnership 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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APR 2019

SEP 2025

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

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

The European-Canadian Cancer Network (EUCANCan) is a pilot project to develop and test a federated platform for the privacy-preserving, scalable analysis of clinical data across multiple healthcare organisations in Canada and the European Union. The Centre of Genomics and Policy drafted a number of legal analyses assessing the data protection implications of proposed technical implementations thereof, and of federated data analysis more generally. 1) Federated data analysis is a recent technological innovation that will help multiple clinical partners to pool and to analyze their data at scale without encountering the technical challenges and governance barriers of traditional efforts to centralize data for future use. 2) The policy proposals here articulated will be instrumental in formulating data governance and legal compliance strategies for future precision health initiatives.

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JAN 2020

JAN 2023

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

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 built 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, along with consultations with national stakeholders (REB representatives, researchers, and policy makers), has contributed 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 directly address an immediate need for clear policy and guidance for international DTP recruitment in stem cell research. They also set the standards for Canada and internationally, consolidating Canada's position as a leader in policy development. This project won the Best ELSI Poster Prize at the 2021 Stem Cell Network (SCN) Till & McCulloch meeting.

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JAN 2020

JAN 2023

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

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 become 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 was accepted by Health Canada and a few patients have been treated in Québec. This project served as a model by expanding the trial to burn units in other Canadian provinces. The aim of this trial was to evaluate this novel therapeutic approach, treating 17 patients to help skin regeneration. Dr. Moulin recruited patients to evaluate graft take and post-grafting scarring over a two-to-three-year period. Her aim was to treat most Canadian patients that have burns over more than 50 percent of their body. SASS treatment should have economic and social benefits, preliminary results having 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 was the first in Canada to routinely treat patients with autologous reconstructed skin.

Our interdisciplinary team was 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) assisted in preparing the necessary requirements for research ethics approval (including prepping standardized recruitment procedures and protocols, consent forms and information pamphlets). Coordination of REB approval was also undertaken. The CGP was involved in preparing documentation for the pre-CTA meetings and for regulatory approval with Health Canada.

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JAN 2020**JAN 2023****CULTURED EPITHELIAL CORNEAL AUTOGRAFTS FOR THE TREATMENT OF CANADIANS WITH LIMBAL STEM CELL DEFICIENCY**

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 project has demonstrated via 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, was 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 provided consultation on the socio-ethical and legal issues and assisted in developing the necessary documentation for approvals from Health Canada and research ethics boards.

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JAN 2020**JUL 2023****THE QGPRS STUDY: QATAR GENOME POLYGENIC RISK SCORE, A PRECISION MEDICINE APPROACH TO PREVENT DIABETIC COMPLICATIONS IN THE AFFECTED QATARI INDIVIDUALS**

Qatar National Research Fund
Sidra Medicine

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

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MAR 2020**FEB 2023****AUTISM SHARING INITIATIVE**

DNA Stack

The cost of biomedical data generation has decreased exponentially, due to technologies like genome sequencing and biometric tracking devices, with a corresponding increase in the volume and diversity of data. By 2025, there will be more genomic data generated than content uploaded to YouTube. Due to the size, complexity and sensitivity of biomedical data, traditional practices for searching and analyzing large co-located datasets do not work. New technologies must be developed to connect and derive insights in a federated model from networks of heterogeneous datasets translating to clinical and pharmaceutical applications in precision health.

Autism spectrum disorders (ASD) are a set of complex conditions characterized by difficulties in social interactions and communication, as well as repetitive behaviours, which collectively affect ~1% of the population. Today, there are no approved drugs designed to treat the core features of ASD. Those affected are treated with medicines designed for other conditions. There is great promise in resolving the complex causes of ASD (and many other disorders) by sharing large volumes of biomedical data from diverse geographic populations.

In 2019, DNASTack, Autism Speaks, and AIMS-2-Trials co-founded the Autism Sharing Initiative (ASI), with the goal of uniting the world's most ambitious efforts in autism to create the first federated, global sharing network to accelerate discoveries and development of precision therapeutics.

This project accelerated the mission of ASI by (1) building general-purpose technology to connect biomedical data into knowledge-sharing networks, (2) expanding the network to include new high-value data resources, (3) developing a platform to engage individuals with autism and their families, (4) building applications advancing precision diagnostics and therapies in autism, and (5) creating policies for responsible data sharing in the network.

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APR 2020

MAR 2023

DELETING OVARIAN AND ENDOMETRIAL CANCER USING GENOMICS (DOVEEGENE)

Genome Canada
Genome Québec

This project aimed to develop and implement a plan that raised 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 was an effective DOvEEgene Awareness Campaign developed on evidence-based strategies. Methods/Tools were 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 used a variety of television, newspaper, magazines, radio, features & interviews, our website, and social media. We sent an information letter to gynecologists and general practitioners to inform them about the trial using lists obtained from the College Des Médecins. This was repeated every six months. We invested in Continuing Medical Education of Healthcare Professionals (general physicians, gynecologists, nurses) and in lectures and events aimed at middle-age and mature women, who were the target population.

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APR 2020

APR 2024

UN NANO-VACCIN CONTRE LES MALADIES CARDIOVASCULAIRES (AUDACE)

Fonds de recherche du Québec (FRQ)

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

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APR 2020**JUN 2023**

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

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 was accomplished using a three-round, consensus-building online survey method (Delphi study) whereby the perspectives of experts and stakeholders with varied expertise and experiences converged to inform a forward-looking approach for the ethical application, regulation and design of AI within a sport anti-doping context. These included (but were 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 assisted 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 fosters coherence and provides overarching ethical guidance to effectively navigate and address the issues and challenges identified.

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MAY 2020**JUN 2022**

ELSI COMPONENT: VIRUSSEQ—CANCOGEN

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 was organized into components focusing on human-disease component (HostSeq) and virus (VirusSeq) to address topics unique to each. CanCOGeN-VirusSeq had 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 of the VirusSeq Implementation Committee. Overall, as a part of CanCOGeN-VirusSeq, the CGP team addressed essential ethical and legal issues derived from the CanCOGeN project.

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JUN 2020**MAR 2023**

ETHICS AND POLICY PILLAR-HOSTSEQ (CANCOGEN)

Genome Canada

In response to the ongoing COVID-19 pandemic, CanCOGen 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 leveraged existing biobanking and sample collection efforts, as well as invited 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 identified 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 also performed 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 provided ongoing policy consultation to the HostSeq databank.

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JUL 2020**MAR 2024****ETHICAL LEGAL EXPERTISE
– COVID-19 IMMUNITY TASK
FORCE (CITF)**

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

The COVID-19 Immunity Task Force (CITF) collected 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 coordinated numerous local and multi-centre seroprevalence studies, and collaborated 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 was 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 was actively involved in the CITF's efforts to ensure the normative interoperability of its cohorts, through direct engagement with study coordinators and CITF leadership.

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SEP 2020**JAN 2023****TOWARDS AN
EPIDERMOLYSIS BULLOSA
CLINICAL TRIAL WITH
TISSUE-ENGINEERED SKIN
AFTER EX VIVO GENE
THERAPY CORRECTION**

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)

This project demonstrated via 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 was 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) assisted in preparing the necessary requirements for research ethics approval (including preparing standardized recruitment procedures and protocols, consent forms and information pamphlets). The CGP was involved in preparing documentation for the pre-CTA meetings and for the regulatory approval with Health Canada.

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NOV 2020**MAR 2026****SECURE DATA 4 HEALTH**Canadian Foundation for
Innovation (CFI)

Data has the potential to dramatically transform biomedical research and health care. In particular, we are now in an era where genomes can be systematically sequenced and provide fundamental insights into our predisposition to diseases, our response to therapies and how our health can be affected by our environment. Recognizing this, Canada has been at the forefront of the genomic revolution, making a combined investment of more than \$2.4 billion in this field. However, as a global scientific community, our ability to interpret and utilize this type of information is still only at a nascent stage. Specifically, to fully realize the benefits of genomic and health data, we need infrastructure to securely store, analyse and employ this information without compromise. Moreover, when appropriately consented, we need tools to share these data both nationally and internationally, since a critical mass of samples is needed for advanced machine learning approaches and to enable key biomedical discoveries. Our SecureData4Health proposal creates the computational and software infrastructure needed to safely store, interpret and share the genomic and health information that is rapidly expanding within our centres and hospitals. It also facilitates access to the wealth of complementary information being made available across the world. The SecureData4Health infrastructure is deployed within the existing host sites of Compute Canada, allowing our team of scientists and users easy access to the technologies needed to reap the full benefits of their data, without the need to duplicate resources. Finally, our project provides innovative data sharing modalities where the security and confidentiality of participants' data will be paramount. It enables Canada to play a leading role in the challenging but critically important movement towards international health data sharing. The CGP will contribute leadership, expertise, and coordination to develop a variety of policies, best-practices, and standards on behalf of the SecureData4Health Initiative. Additionally, the CGP, will provide guidance on privacy, security, and data governance.

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JAN 2021**DEC 2023**

**SMARTPHONE
CROWDSOURCED MEDICAL
DATA FOR BIOMEDICAL
RESEARCH:
ADDRESSING THE ETHICAL,
LEGAL AND HEALTH POLICY
CONCERNS**

Fonds de Recherche du Québec
(FRQ)

Smartphone applications for health are being increasingly used as a platform to collect and share large volumes of crowdsourced personal health data for biomedical research and algorithm training. Consumer genetics products are similarly allowing individuals to have direct access to their own genetic data and to share such data with researchers. Using smartphone and genetic data in these ways presents numerous opportunities to expand biomedical knowledge, though it also raises certain risks. Some of these include risks to personal privacy and risks associated with unclear ethical and legal obligations on the part of app developers and researchers. In this project, the CGP collaborated with Belgian partners to mitigate these risks. We did so by determining how smartphone applications and other mobile tools that collect health data work in practice and by addressing legal, ethical, and regulatory uncertainty in both Canada and the European Union. We used this evidence to develop health policy guidelines that will enable smartphone data to be used safely, in a manner that protects users and the public. In doing so, we assured that such data will contribute to improved health outcomes by expanding biomedical knowledge and making health more effective and efficient.

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JAN 2021

JUN 2024

THE QUEBEC SMARTCARE CONSORTIUM

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

The Quebec SmartCare (Soins intelligents) Consortium is an innovative research project centred on the Opal patient portal (opalmedapps.com) at the Research Institute of the McGill University Health Centre (RI-MUHC) that is designed to address the challenges caused by the siloing of data in the Quebec healthcare system. It comprises a unique group of public and private partners with expertise and interest in patient-centered care, mHealth technology, and AI research. Working together, the consortium partners will strengthen the patient-centered technology of the existing Opal patient portal, enable secure data flow from wearable devices into Quebec hospitals, and collect real-world data for artificial intelligence and real-world evidence research.

The Centre for Genomics and Policy will: (1) Examine specific ethico-legal issues associated with access to data, (2) Develop a governance framework for access, (3) Develop with stakeholders a "Collaboration with Industry" policy, a Code for Collaboration with Industry, and a go/no-go checklist for agreements with industry, and (4) Implement an Access system and coordinate review/adjudication of access requests by researchers.

The work will put in place solid frameworks for data governance and commercialization/technology transfer that are expected to persist well beyond the lifetime of the QSCC and will help foster continued collaboration amongst the partners.

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JAN 2021

DEC 2024

ARTIFICIAL INTELLIGENCE AND DIGITAL HEALTH (PERSONNEL HAUTEMENT QUALIFIÉ : INTELLIGENCE ARTIFICIELLE ET SANTÉ NUMÉRIQUE)

Fonds de Recherche du Québec - Santé (FRQS)

The Centre of Genomics and Policy along with the MUHC Data Governance Task force will develop an MUHC/MUHC-RI Data Governance Framework encompassing the use of clinical and administrative data from MUHC information systems and other sources by researchers at the RI-MUHC. The Framework will clearly define the ethical and legal foundations for, and limits on, the use of clinical and administrative data for research within and outside of the MUHC in the province of Quebec. The Framework will facilitate legal and ethical conformity in domains including privacy, data access, research ethics and information systems. The Framework will also consider, when possible, the use of these data by clinicians and administrators for quality assurance of healthcare. The use of clinical and administrative data for research and quality assurance are well aligned under the concept of a learning healthcare system, in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation with new knowledge being captured as an integral by-product of care delivery.

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APR 2021**MAR 2024****PARADIGM SHIFT IN
THE CONDUCT OF
CLINICAL TRIALS**Ministère de l'Économie et de
l'Innovation (MEI)

Innovations in digital technologies and the onset of the COVID-19 pandemics have accelerated the implementation of new approaches to the conduct of clinical trials. Funded by the MEI's Fonds d'accélération des collaborations en santé (FACS) initiative, the "Paradigm Shift in the Conduct of Clinical Trials" project aims to develop and deploy a multi-faceted informatics framework to support the conduct of high-quality, low-cost digital and virtual clinical trials using innovative strategies for patient recruitment, retention, and follow-up at performance thresholds well beyond conventional approaches. The CGP is responsible for drafting access policies to facilitate the sharing of clinical trial data, is providing ongoing support with the management of emerging ethico-legal questions, including informed consent, participant confidentiality, and the responsibilities of nurses and physicians when remotely monitoring patients.

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APR 2021**MAR 2025****CANDIG: DISTRIBUTED
INFRASTRUCTURE
FOR GENOMICS DATA
SHARING AND ANALYSIS
– INFRASTRUCTURE
OPERATING FUND (IOF)**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 Application Programming Interface 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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JUL 2021

JUL 2024

GA4GH GENOMIC DATA SHARING TOOLS AGAINST COVID-19 FUNDING OPPORTUNITY

Canadian Institutes of Health Research (CIHR)

The COVID-19 outbreak has highlighted the need for genomic data standards to share high-quality genomic and health data rapidly. Researchers have started to share viral and host sequence data at an unprecedented pace, a first step in creating vaccines in record time. Sharing this data is necessary to understand human diseases and eventually help patients. Doing so requires the community to agree on standard methods for collecting, storing, transferring, accessing, and analyzing data.

The Global Alliance for Genomics and Health (GA4GH) brings together 1,000+ individual contributors and 660+ organizational members across 35+ countries to accelerate progress in genomic research and human health by cultivating a common framework of standards and harmonized approaches for effective and responsible data sharing.

GA4GH will develop, refine, and adapt GA4GH standards and open-source tools to facilitate research data sharing for COVID applications and the greater infectious disease community. This project will support the GA4GH to bring in additional personnel, support the existing team, and drive engagement with the Canadian COVID research community. Collectively, these efforts will ensure the rapid and timely research response to the current phase of the COVID-19 pandemic in Canada and around the globe, which emerging variants of concern will heavily impact. The CGP will contribute leadership, expertise, and coordination to develop a variety of policies, best-practices, and standards surrounding to facilitate better COVID-19 Genomic Data Sharing.

PRINCIPAL INVESTIGATOR
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KÉKESI-LAFRANCE Kristina

MASTER'S STUDENT
LIU Hanshi

COLLABORATOR
JOLY Yann

JUL 2021

JUL 2025

CANADA FOUNDATION FOR INNOVATION (CFI)'S INNOVATION FUND: "A CGMP FACILITY FOR PERSONALIZED TISSUE ENGINEERING"

Université Laval

Rapid advances in stem cell research and tissue engineering have put regenerative medicine at the forefront of innovation in the area of patient-oriented therapeutic applications. Combining stem cells cultured from patient biopsies with tissue engineering has the potential to revolutionize grafting practices by offering viable and feasible solutions not only to healing complex wounds but also to the shortage of donated organs. However, the clinical translation, from bench to bedside, of these personalized tissue engineering products is slow and often hampered by both a lack of resources and access to appropriate facilities that meet the safety and quality standards required for clinical research. Therefore, the CGP will provide Canada with the governance and guidance policies for a certified Good Manufacturing Practice (cGMP) facility that will conduct the clinical research essential in concretizing the applications of personalized tissue engineering for regenerative medicine.

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ACADEMIC ASSOCIATE
NGUYEN Minh Thu

JAN 2022

DEC 2023

THE CANADIAN OPEN NEUROSCIENCE PLATFORM (CONP)

Brain Canada

The Canadian Open Neuroscience Platform (CONP) is a first Canadian effort to host neuroscience data (e.g., brain imaging data, behavioral data, etc.) in full-open access. The Centre of Genomics and Policy coordinates the ethical-legal work package of the CONP. In this respect, the CGP has led the refinement of its data governance framework, privacy and de-identification policy, and consent policy, as well as the development of a pioneering Citizen Science Portal enabling citizen scientists to deposit their data in full open access on the CONP Community Server.

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RESEARCH ASSISTANT
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ACADEMIC ASSOCIATE
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MAR 2022**APR 2023****FEDERATED DATA ACCESS COMMITTEES FOR HARMONISED PAN-CANADIAN CANCER DATA STEWARDSHIP (CANFED)**

Canadian Cancer Society - Data Transformation Grant

Non-harmonized data access processes are a barrier to the cost-effective use of existing oncology data to derive population-level insights. To this end, CanFED was launched as a common effort across multiple cancer and population health data repositories that operate Data Access Committees (DACs). It explored technical, organisational, and private law measures that increase the interoperability and scalability of DACs and generated empirical evidence of the distinct data governance processes that different repositories have implemented. Participating infrastructures included the International Cancer Genome Consortium (ICGC), the Canadian Partnership for Tomorrow's Health (CanPath), the Marathon of Hope Cancer Centres Network, and dbGaP. The CGP was leading the drafting and development of a policy document to provide actionable guidance to new data stewards that are developing their own data access processes. This document described the established best practices in the operation of data access committees, and assessed the relative merits of distinct approaches to achieving further standardisation and automation of access processes.

PRINCIPAL INVESTIGATOR
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BERNIER Alexander**MAR 2022****MAR 2024****THE 2022 GENETIC DISCRIMINATION OBSERVATORY SCIENTIFIC CONFERENCE**

Social Sciences and Humanities Research Council - Individual Connection Grants

The Genetic Discrimination Observatory (GDO) is a unique international network of researchers and stakeholders from more than 27 countries dedicated to researching and preventing genetic discrimination worldwide. Genetic discrimination (GD) involves the differential, negative treatment or unfair profiling of an individual relative to the rest of the population based on actual or presumed genetic characteristics that can infringe upon or have the effect of infringing human rights, fundamental freedoms, and human dignity. For decades, it has been a global problem associated with genetic testing, data-intensive genetic research, and direct-to-consumer DNA testing services. With rapid technological advancements in today's postgenomic era, GD is a persistent issue associated with the use of genetic and genomic data. Many countries have adopted legal frameworks to prevent GD that offer a certain degree of protection. However, many legislation and policies overlook essential aspects of GD, and vulnerable individuals may remain at risk of discrimination. Furthermore, genetic information from patients, data-sharing research, and genetic services (such as 23andMe, Ancestry.com) are increasingly moving across national borders or transcending them, thus limiting the effectiveness of protections built solely around national approaches.

It is vitally important to advance the debate and research regarding novel solutions to counter GD at the national and international level by building on both foundational international ethics and human-rights texts. The GDO was launched in 2020 and has since achieved a significant presence on a global scale. The GDO is looking to have a two-day in-person international conference on genetic discrimination. This conference will be invaluable to gather together a group of interdisciplinary experts in law, bioethics, genetics, sociology and economics from different world regions. The GDO conference will address recent normative framework developments worldwide and the many novel forms of GD deriving from today's rapidly evolving genetics and biotechnology.

The GDO conference will be instrumental in generating the following deliverables in 2022-2024: publications of the conference proceedings in an open-access journal, lay summaries adapted for healthcare professionals, genetic counsellors, patient associations and the lay public, and video capsules. The GDO online platform (<https://gdo.global/en>) and its international team of expert collaborators will provide a unique edge in disseminating the GDO conference outputs to researchers and knowledge users (KUs) in Canada and draw the international community's attention to recent developments in the field of GD.

PRINCIPAL INVESTIGATOR
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APR 2022

MAR 2023

**PSILOCYBIN TO RELIEVE
EXISTENTIAL DISTRESS
AT THE END OF LIFE/
LA PSILOCYBINE POUR
SOULAGER LA DÉTRESSE
EXISTENTIELLE EN FIN DE VIE**

Fonds de la recherche du
Québec - Society and Culture
(FRQSC)

Psilocybin is the psychoactive element found in hallucinogenic mushrooms or “magic mushrooms”. Although the production, possession and sale of these mushrooms are illegal in Canada, the potential therapeutic uses of psilocybin are attracting growing interest internationally. Randomized clinical trials have demonstrated that a moderate single dose of psilocybin combined with psychotherapy produces rapid, robust and long-lasting anxiolytic and antidepressant effects in patients with advanced cancer and suffering from cancer-related psychological distress.

This project aimed to 1) assess the social and professional acceptability of psilocybin-assisted therapy to relieve existential distress at the end of life, 2) identify the issues to consider for access to this innovative therapy and 3) propose recommendations establishing guidelines for the use of psilocybin for therapeutic purposes in the Quebec forensic context. In addition to the recommendations that were presented to decision-makers in the form of a memorandum, this work lay the foundations of a community resource which, together with the care settings, has the mission of informing and supporting patients considering using assisted therapy with psilocybin to alleviate their existential distress.

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APR 2022

SEP 2023

**ALL FOR ONE HEALTH
DATA ECOSYSTEM (HDE)**

Genome Canada

Breakthroughs in precision health, which harnesses the power of genome sequencing for diagnosis and treatment of genetic conditions, are revolutionizing healthcare. But access to clinical genomic testing is inconsistent across Canada. The All for One Health Data Ecosystem (HDE) initiative aims to advance precision health across the country through the creation of a pan-Canadian variant database and promote access to precision health research for rare disease patients through the creation of a patient registry. Ultimately, the All for One HDE initiative aims to improve the health and wellness of Canadians by building regional genomics capacity, promoting the equitable and ethical uptake of precision health tools and addressing barriers to data sharing. The CGP is responsible for the development of governance tools for the database and registry, including frameworks and model consent clauses. The CGP also provides input on the ethical, legal and social implications of the sharing of health data in Canada.

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APR 2022

JAN 2025

**ENGINEERED
HEMATOPOIETIC STEM
CELLS (EHSCS) AS VEHICLES
FOR NEXT GENERATION
THERAPIES**

Stem Cell Network - Horizon
Awards Program

Modern cancer therapies increasingly rely on antibody-based drugs or genetically engineered immune cells that are programmed to recognize specific proteins on the surface of cancerous cells while not attacking their healthy counterparts. The goal of this project is to better target leukemia cells while sparing the normal blood by engineering blood stem cell grafts as a next-generation therapy for treating aggressive blood cancers. Further, establishing an improved delivery method for genetically engineered anti-leukemia immune cells into leukemia patients by completely modifying blood stem cells would allow for the regeneration of engineered immune cells for life. Overall, this research has the capability to vastly improve therapeutic prospects for leukemia patients.

Our role is to investigate potential liability for race-associated precision medicine interventions. We will review and document how North American courts have considered medical liability when adjudicating claims of medical negligence for the race-disparate effects of clinical interventions. We will also engage in a systematic review of legal scholarship on race-based or race-influenced medical care and document the degree to which legal scholars predict that such interventions will affect the professional and clinical obligations of individuals engaged in providing care of this kind.

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APR 2022

JAN 2025

TISSUE ENGINEERING TO TREAT CANADIAN BURN PATIENTS: THE SELF-ASSEMBLED SKIN SUBSTITUTES (SASS)

Stem Cell Network -
Clinical Trial Awards

Skin autografts are used to treat burn wounds, but they take on a strategic role when the area that needs to be covered is greater than 50% of the total body surface area. Autologous Self-Assembly Skin Substitutes (SASS) can be made from just a little skin biopsy using tissue engineering techniques established in Dr. Moulin's lab (Université Laval), and they might be used to permanently cover all the patient's wounds. Health Canada had approved this early-stage clinical trial, and only a small number of patients have received care in Quebec. By extending the study to burn units in other Canadian provinces, this project will serve as a model treatment approach. This trial's objective is to assess this cutting-edge therapeutic strategy for treating Canadian patients with extensive burns to promote skin regeneration. Preliminary findings have shown that treatment reduces morbidity brought on by current treatments and improves patients' quality of life, suggesting that treatment should have economic and societal benefits. Dr. Moulin's lab will be the first in Canada to routinely treat patients with autologous rebuilt skin after the clinical trial and approval by Health Canada.

The CGP will help with the preparation of the requirements needed for research ethics coordination and approval (including preparing standardized recruitment procedures and protocols, consent forms and information pamphlets). Documentation for the clinical trial application meetings and for regulatory approval with Health Canada will be prepared by the CGP.

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JUN 2022

JUN 2025

EXPLAINING THE RIGHT TO EXPLANATION: DATA PROTECTION LEGISLATION AND CLINICAL AUTOMATED DECISION-MAKING

Observatoire International sur les
Impacts Sociétaux de l'IA et du
Numérique (OBVIA)

Quebec's National Assembly adopted a right to explanation for automated decision-making in late 2021. This is the first such right implemented in Canada, with as yet unknown consequences for the practice of medicine. Automated decision-making tools for the diagnosis, management, and treatment of disease are being applied across the healthcare system, and these newly adopted rights might have significant legal consequences for clinicians. This project will address how statutory rights to explanation for automated decision-making adopted in Quebec and elsewhere are likely to affect the legal obligations of clinicians providing care that is facilitated by automated medical devices. We are conducting a comparative legal analysis to understand the effects of rights to explanation adopted in other jurisdictions, with particular focus on European Union member states. We will also define the potential scope of rights to explanation by surveying automated decision-making tools presently being used in Canada, hold a virtual deliberative exercise with relevant stakeholders (including clinicians and patient representatives), and prepare policy tools outlining how rights to explanation will affect the use of clinical automated decision making.

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JUL 2022

JUN 2025

RESPONSIBLE PATHWAYS FOR PEDIATRIC CELL THERAPIES

Stem Cell Network (SCN)

This project will concentrate on the lack of guidance for researchers designing cell therapy clinical trials, especially at the first-in-human stage. It will address the lack of guidance and educational resources for REBs and regulatory bodies assessing such trials, along with the paucity of guidance for research participants considering the risks and benefits of their participation. Further, it will tackle the ethical, legal and social issues associated with these gaps, in order to facilitate the ethical and responsible clinical translation of cell therapies, via ethically conducted clinical trials, with a specific focus on minors and their parents/families.

Issues addressed by this project will include: criteria to be used by researchers/clinicians, REBs and regulatory bodies to select which potential therapies should move towards clinical trials; review criteria for REBs to assess such proposals; clarification of the legal and ethical duties and professional liabilities of researchers/clinicians; specific considerations regarding the participation of minors in clinical trials; and concerns perceived as important by minors, their parents/families, and their pediatricians, regarding cell therapies. Addressing these issues will allow us to better understand how to overcome challenges and barriers to clinical translation.

The CGP will analyze the legal roles and ethical responsibilities of researchers/clinicians in the context of clinical trials using cell therapies, with an emphasis on first-in-human trials in minors, and to understand the perspectives of clinicians and researchers on how to operationalize the high-level principles of the Stem Cell Charter (2009) (<https://doi.org/10.2217/rme.09.84>) relevant to their practice and covering their interactions with participants.

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AUG 2022

JUL 2024

CANADIAN PEDIATRIC CANCER CONSORTIUM (CPCC)

Canadian Institutes of Health
Research (CIHR)

The Canadian Pediatric Cancer Consortium (CPCC) is the largest-ever Canadian pediatric cancer research project. It is performing a broad array of distinct research activities, including both clinical data generation, and public policy work in areas such as health economics, law, and other fields. The Centre of Genomics and Policy leads its ethical-legal and data governance work-package, which includes the development of policies and procedures to enable the stewardship of the data that the CPCC generates. The CPCC raises a plethora of public policy challenges that lie at the intersection of pediatric bioethics and data governance. Building on prior research in the PROFYLE project, governance proposals arising from this initiative could serve as a template for future Pan-Canadian efforts to generate and share pediatric oncology data.

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JAN 2023**MAR 2024**

**AUTHENTIC LIVES AND
THE RIGHT TO GENDER
AFFIRMING CARE FOR
YOUTH: ACTORS, VALUES,
AND LEGISLATIVE
APPROACHES IN THE US
AND CANADA**

Social Sciences and Humanities
Research Council - McGill
Internal Funds

While new avenues for gender diversity are opening, politically motivated legal battles are increasingly impeding access to gender affirming care (GAC) for trans and non-binary (TNB) youth. These legal developments will have substantial repercussions for the wellbeing of TNB minors and implicate many stakeholders including their families, clinicians, community organizations, health and social services, schools, researchers, policymakers, and legislators. This seed project will be a critical interdisciplinary legal and social-scientific analysis to capture an overview of current trends and biases in the legal arena and their influence on the provision of and access to GAC for TNB youth in Canada and the U.S. over the past five years. We will conduct and integrate three modes of analysis: (1) Network analysis of key actors in cases and legislation; (2) Thematic analysis of values presented implicit to GAC; (3) Comparative analysis of the approach to GAC in Canada and the US. This seed project will lay the foundation for a larger interdisciplinary research program on ELSI in access to and provision of GAC for youth.

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JAMALI Narges

COURSES

HGEN 660B

GENETICS, ETHICS, AND LAW

Instructor Prof. Yann Joly, D.C.L. (Ph.D.), Ad.E.

The objectives of this course are to:

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

The classes 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 counseling, personalized medicine, privacy and confidentiality, population genetics, regenerative medicine, commercialization and intellectual property, genetic discrimination, and genetic analysis of social and behavioral traits. Through class lectures, case studies and discussions on a series of selected readings, students are asked to reflect on the complex relationships between science, law, and ethics. Each member of the class participates and contributes to the learning experience. The collaborative learning experience is reflected in the way that the course is structured and the way in which the student’s work is evaluated.

HGEN 674

RESEARCH INTERNSHIP IN GENOMICS AND POLICY

Instructor Prof. Ma’n H. Zawati, D.C.L. (Ph.D.)

The Research Internship in Genomics and Policy course aims to provide graduate students in the Human Genetics program with an opportunity to do research on the ethico-legal and policy issues in human genetics. More specifically, graduate students 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 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 area of interest. Specific areas of research at the Centre of Genomics and Policy included but were not limited to: population genomics, biobanks, stem cells, reproductive technologies, paediatric genetic research, data protection, direct-to-consumer genetic testing, gene therapy, personalized medicine, and genetic counseling. Interested students are encouraged to explore the CGP website (www.genomicsandpolicy.org) to identify areas of interest. Undertaking an internship at the Centre of Genomics and Policy allows students to benefit from a close collaboration with experts at the crossroads of the ethico-legal, medical, and policy fields.

INTERN STUDENTS

The CGP offers internship opportunities for law students via the McGill Legal Clinic Course and undergrad students at the Department of Human Genetics via HGEN 396. Through these internships, students have the opportunity to be involved in various research activities and projects relating to the multidisciplinary work at the Centre.

AMY FERNANDO

INTERN | MCGILL UNDERGRADUATE RESEARCH TRAINEE PROGRAM

"Interning at the CGP under Dr. Joly has been the highlight of my academic career. My traineeship has given me an appreciation for the wide breadth of research at the intersection of genomics, health, and policy. I can't think of a more welcoming environment or group of people to learn under."



NATALIE KELLER

INTERN | MCGILL LEGAL CLINIC COURSE

"I absolutely enjoyed my research internship at the Centre of Genomics and Policy. Many employees are fellow students or recent graduates making for a very friendly work environment. Opportunities to exchange ideas and learn abound, as the projects and research conducted by the CGP are varied, multidisciplinary, and current."

DYLAN YAN

INTERN | MCGILL LEGAL CLINIC COURSE

"During my research internship with the McGill Legal Clinic, I had the opportunity to work on projects associated with ancestry, genetic discrimination and forensic DNA databases. I am indebted to my wonderful colleagues at the CGP for their acuity, guidance and compassion."





VISITING SCHOLAR PROGRAM

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.

As the pandemic gradually abates, the Centre of Genomics and Policy, in collaboration with the WYNG Foundation and the Centre for Medical Ethics and Law (CMEL) of the University of Hong Kong, are pleased to announce the resumption of the Visiting Scholars Program. The CGP is working to ensure both that this collaboration will blossom and for the sharing of ideas on emerging genomics topics with dedicated scholars from Hong Kong to resume.

CGP INTERNATIONAL COLLABORATIONS



Brandeis School of Law
and School of Medicine,
University of Louisville

• United States

Québec

CGP

Tanenbaum Open
Science Institute,
Montreal Neurological
Institute-Hospital

HCA | HUMAN CELL ATLAS

IHEC | INTERNATIONAL HUMAN
EPIGENOME CONSORTIUM

HeLTI | HEALTHY LIFE
TRAJECTORIES INITIATIVE

ICGC | INTERNATIONAL CANCER
GENOME CONSORTIUM

ICDA | INTERNATIONAL COMMON
DISEASES ALLIANCE

GA4GH | GLOBAL ALLIANCE FOR
GENOMICS AND HEALTH

IRDiRC | INTERNATIONAL RARE DISEASES
RESEARCH CONSORTIUM



G D



GENETIC DISCRIMINATION OBSERVATORY

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.

The Genetic Discrimination Observatory (GDO) is a network of international experts and collaborators from over 23 jurisdictions dedicated to researching and preventing genetic discrimination.

GDO MAIN OBJECTIVES

1.

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

2.

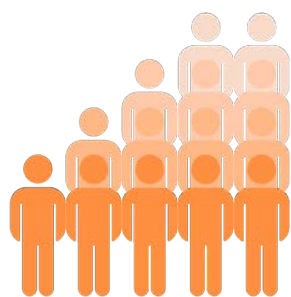
Engage the public, policymakers and other stakeholders in a collective debate about genetic discrimination.

3.

Use this information to assess which existing normative models work best and develop new ones.



- AI
- LAW
- GENETICS
- BIOETHICS
- SOCIOLOGY
- HEALTH POLICY
- PATIENT GROUPS



From January to November 2022,
the GDO website reached
164,000 VISITORS
(an average of 13,700 visits/month)



COLLABORATIVE RESEARCH

GDO is now in collaboration with the Global Alliance for Genomic and Health (GA4GH) to develop tools and policies to address genetic discrimination. The first product of this collaboration is the information brief Genetic Discrimination: Implications for Data Sharing Projects (GeDI).

www.ga4gh.org/wp-content/uploads/Genetic-Discrimination-Dec.-2-2021.docx.pdf

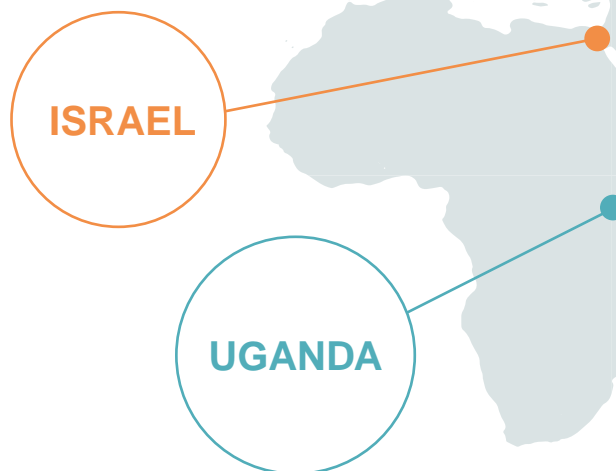
approved by GA4GH/GDO in January 2022

ON JUNE 2
2022



The GDO held
its **3rd Annual
Scientific Meeting**
in a hybrid format
online/in person.

NEW countries
represented in the
GDO in 2022



The GDO  is funded by



GenomeCanada



Global Alliance
for Genomics & Health



COLLABORATIONS



5 REGIONS

26 COUNTRIES

27 JURISDICTIONS



CGP TEAM PUBLICATIONS

ARTICLES

1. Ahmed, Saima, Emmanuelle Lévesque, Garland Rosalind, Bartha Knoppers, Michel Dorval, Jacques Simard, Carmen G. Loiselle. "Women's perceptions of PERSPECTIVE: a breast cancer risk stratification e-platform." *Hered Cancer Clin Pract.* 20 no. 1: (2022): 8. Available from: <https://hccpjournals.biomedcentral.com/articles/10.1186/s13053-022-00214-4>.
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