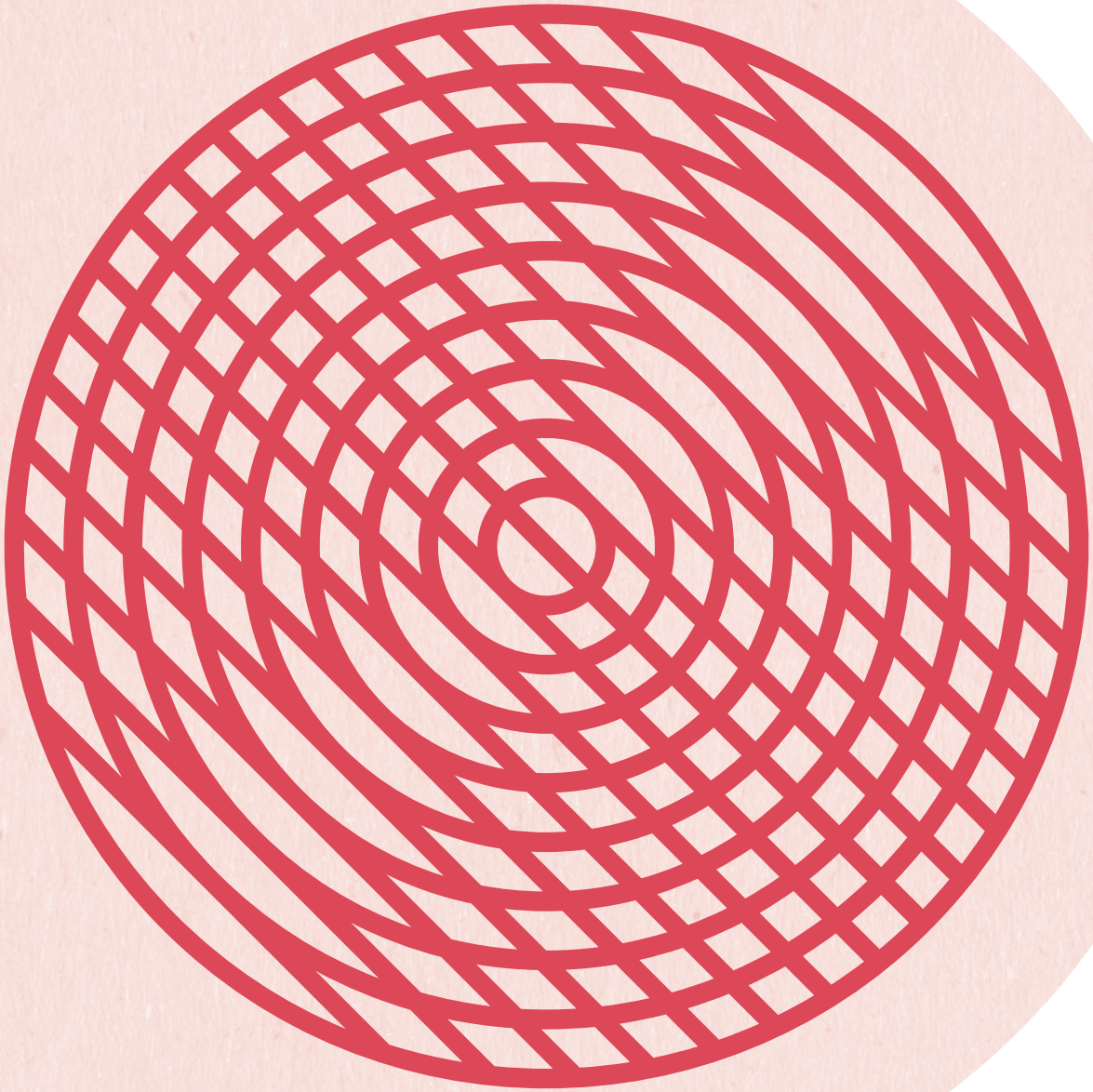
COMMERCIALIZATION OF NIPT: PAST, PRESENT & FUTURE

FEBRUARY 11 & 12, 2016

MONTRÉAL, QC



Event organizers would like to thank the funders of the PEGASUS and PACEOMICS projects, as well as the Trudeau Foundation for their generous support of this event. Specifically funders of the PEGASUS project include: Génome Québec, Genome Canada, the Government of Canada, and the Ministère de l'enseignement supérieur, de la recherche, de la science et de la technologies du Québec and those supporting PACEOMICS include: Genome Canada, Genome Alberta, the Canadian Institutes for Health Research, and Alberta Health & Wellness.

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This event will explore a variety of issues associated with the commercialization of non-invasive prenatal testing (NIPT), such as the desire to innovate, commercialization pressure, patient access to new technologies, and the development of new health policy concerns.

Specific goals are to:

1) explore the history and unique issues associated with the IP and commercialization of NIPT;
2) analyze the commercialization impact of and future challenges associated with NIPT; and
3) produce a policy document on point.

THURSDAY, FEBRUARY 11, 2016

7:30 BREAKFAST

8:45 **Setting the Stage**

Timothy Caulfield,
University of Alberta

9:00 SESSION ONE

NIPT: The Science and Clinical Applications

CHAIR: **Timothy Caulfield**,
University of Alberta

SPEAKERS:

The Rapidly Changing Landscape of Prenatal NIPT
François Rousseau, Université Laval

Incorporating NIPT into BC
Julie MacFarlane, Perinatal Services BC

10:30 BREAK

11:00 SESSION TWO

Commercialization Issues and Challenges

CHAIR: **Zubin Master**,
Albany Medical College

SPEAKERS:

Commerce Powers Science? NIPT Commercialization and the Innovation Ecosystem
Ubaka Ogbogu, University of Alberta

Commercialization Issues and Challenges for MPGI
Ross Duncan, Public Health Agency of Canada

12:30 LUNCH

1:30 SESSION THREE

Patents and NIPT/Translation Innovation Models

CHAIR: **Blake Murdoch**,
University of Alberta

SPEAKERS:

The Paradox of IP in Open Innovation Strategy
Jeremy deBeer, University of Ottawa

IP and Innovation: of Tangled Webs and Deception
Richard Gold, McGill University

Universities as Patent Litigants: Preliminary Analysis of the Past Decade
Tania Bubela, University of Alberta

3:00 BREAK

3:30 SESSION FOUR

Relevant, Legal, Ethical and Social Issues

CHAIR: **Sarah Ali-Kahn**,
McGill University

SPEAKERS:

NIPT: Ethical and Social Issues, with a Focus on Cost and Access
Vardit Ravitsky, Université de Montréal

Does NIPT Bring New Challenges to the Scientific Governance Conundrum
Yann Joly, McGill University

The Emerging Media Discourse on NIPT
Kalina Kamenova, Trent University

FRIDAY, FEBRUARY 12, 2016

7:30 BREAKFAST

8:45 **Next Steps**

Timothy Caulfield,
University of Alberta

9:00 SESSION FIVE

NIPT: Tension Between Commercialization, Innovation, Patient Access, Health Policy

CHAIR: **Bryn Williams Jones**,
Université de Montréal

SPEAKERS:

Brenda Wilson, University of Ottawa

Daryl Pullman, Memorial University

Juan Andrés León, Public Health Agency of Canada

Michael Paulden, University of Alberta

10:30 SESSION SIX

Paper Discussion

Timothy Caulfield,
University of Alberta

11:45 LUNCH

Sarah Ali-Khan, PhD, is a Research Associate at the Centre for Intellectual Property Policy (CIPP) in the Faculty of Law at McGill University. She holds a Ph.D in Pharmacology and Therapeutics, also from McGill. Sarah uses qualitative empirical methods to study GE3LS issues raised in the context of health biotechnology and biomedical research more broadly. Her current research focuses on intellectual property management, including public policy issues raised by gene patenting in Canada. She recently developed with Prof. Richard Gold, an Open Science policy framework for the Montreal Neurological Institute. She also leads knowledge translation for the PACEOMICS Genome Canada-funded research project. Previously, Sarah was at the Centre of Genomics and Policy, McGill University, and a Post-Doctoral Fellow at the McLaughlin-Rotman Centre for Global Health (now the Sandra Rotman Centre/Grand Challenges Canada) at the University of Toronto. There she focused on GE3LS issues raised by clinical translation of whole genome analysis in Autism Spectrum Disorder patients, genomics and ethnicity research, and associated issues with the 'genomics divide'. She has authored a chapter on global bioethics, organized and reported on international workshops on 'Ancestry in Health and Medicine', and 'Genomics and the Bioeconomy' with the OECD and HUGO, and was the 2010 winner of the 'SIG' Society Impact of Genomics prize for research excellence from the Ontario Genomics Institute. Her recent work can be found published in the HUGO Journal, Genome Medicine, the International Journal of Technology Assessment in Health Care, and PLoS One.

Tania Bubela (BSc (Hons), PhD, JD) is Professor and Associate Dean (Research) in the School of Public Health and Adjunct Professor in the Alberta School of Business at the University of Alberta, Canada. She joined the faculty of the U Alberta in 2004 after clerking for The Honourable Louise Arbour at the Supreme Court of Canada, articling at Field Law LLP in Edmonton, and being called to the bar (Law Society of Alberta) in 2005. Her research program in intellectual property and health law related to translational biomedical research brings together her legal training and a PhD in biology and expertise in genetics and molecular biology. Her research program focuses on large collaborative science networks in genomics, gene therapy, and stem cell biology, addressing barriers to the effective translation of new technologies. These are varied and include ethical issues, effective communication of risks and benefits among stakeholder groups, commercialization and regulation. She provides advice for Government Health and Science agencies as well as life sciences research communities, and patient organisations. Her research is funded by the Canadian Institutes of Health Research, the Canadian Stem Cell Network, Genome Canada, and Alberta Innovates – Health Solutions, among others. She co-leads the PACEOMICS program on the development of cost-effective personalized medicine and the Alberta Ocular Gene Therapy Team, which is developing novel gene therapies and conducting a phase I clinical trial of the NightaRx AAV2-REP1 product for choroideremia. She has nearly 100 publications in law, ethics and science policy journals including *Nature*, *Nature Biotechnology, Cell Stem Cell, PLoS Biology, Trends in Biotechnology, American Journal of Bioethics* and *Science Translational Medicine.*

Timothy Caulfield is a Canada Research Chair in Health Law and Policy and a Professor in the Faculty of Law and the School of Public Health at the University of Alberta. He has been the Research Director of the Health Law Institute at the University of Alberta since 1993. Over the past several years he has been involved in a variety of interdisciplinary research endeavours that have allowed him to publish over 300 articles and book chapters. He is a Fellow of the Trudeau Foundation and the Principal Investigator for a number of large interdisciplinary projects that explore the ethical, legal and health policy issues associated with a range of topics, including stem cell research, genetics, patient safety, the prevention of chronic disease, obesity policy, the commercialization of research, complementary and alternative medicine and access to health care. Professor Caulfield is and has been involved with a number of national and international policy and research ethics committees, including: Canadian Biotechnology Advisory Committee; Genome Canada's Science Advisory Committee; the Ethics and Public Policy Committee for International Society for Stem Cell Research; and the Federal Panel on Research Ethics. He has won numerous academic awards and is a Fellow of the Royal Society of Canada and the Canadian Academy of Health Sciences. He writes frequently for the popular press on a range of health and science policy issues and is the author of The Cure for Everything: Untangling the Twisted Messages about Health, Fitness and Happiness (Penguin 2012) and Is Gwyneth Paltrow Wrong About Everything?: When Celebrity Culture and Science Clash (Penguin 2015).

Jeremy de Beer is a world-leading expert on technology innovation, intellectual property, and global trade and development. He is a tenured Full Professor of law at the University of Ottawa's Centre for Law, Technology and Society. As co-founder and director of the Open African Innovation Research (Open AIR) partnership, a multi-disciplinary group of international experts, Professor de Beer and his colleagues are helping to improve innovation and knowledge governance systems in both developed and developing countries. He co-author/editor of five books, including Intellectual Property and Innovation: Collaborative Dynamics in Africa. As a practicing lawyer and legal expert, he has argued numerous cases before the Supreme Court of Canada, advised businesses and law firms both large and small, and consulted for numerous agencies from national governments and the United Nations. He is online at: www.JeremydeBeer.com.

Ross Duncan's professional experience spans 27 years in the federal government with an emphasis on science policy in relation to a wide range of health related fields/areas of interest. These have ranged from supporting the re-engineering of specific elements within Canada's public health laboratory to past activities in managing public health genomics research activities. Beyond the public health field his work has also focussed on: support to independent panels reviewing science and innovation policy in Canada (for the Clerk of the Privy Council) and abroad (at the World Health Organization); health policy issues dealing with the interface between health and trade policy at the multilateral, regional and bilateral level; and, a broad range of pharmaceutical and health care policy issues including Direct-To-Consumer-Advertising of prescription medicines.

Richard Gold is Associate Dean (Graduate Studies) and a James McGill Professor at McGill University's Faculty of Law where he founded the Centre for Intellectual Property Policy. He teaches in the area of intellectual property and innovation. His research crosses boundaries between: science, social sciences and humanities; law, management, international relations and economics; policy and theory; academy and practice. Bringing this interdisciplinary approach to his research, he examines innovation – even if seemingly technological – as a social phenomenon involving governments, private firms and civil society. He is an Associate Member of McGill's Centre of Genome Policy and of the University of Alberta's Health Law Institute.

Yann Joly Ph.D. (DCL), Ad.E. is a Lawyer Emeritus from the Quebec Bar and the Research Director of the Centre of Genomics and Policies(CGP). He is an Associate Professor at the Faculty of Medicine, Department of Human Genetics and, at the Bioethics Unit, at McGill University. He is a research fellow from the Fonds de recherche du Québec- Santé (FRQS) and an Associate Researcher at the Centre de recherche en droit public (Université de Montréal). His research activities lie at the interface of the fields of intellectual property, health law (biotechnology and other emerging health technologies) and bioethics.

Kalina Kamenova is an Assistant Professor in the Bachelor of Arts and Science Program at Trent University in Peterborough, where she teaches courses in science communication, science and technology studies, and biomedical ethics. Her research interests are broadly interdisciplinary, spanning communication and cultural studies, social and political theory, deliberative democracy, bioethics, science and health policy, and conceptual, ethical and legal issues related to new and emerging technologies in biomedicine. She has published on diverse topics such as media representations of contemporary scientific and health controversies, science policy and stem cell research, stem cell tourism, public deliberation, and bioethics.

Juan Andrés León is the manager responsible for maternal, child and youth health surveillance with the Public Health Agency of Canada. His line of work involves maternal, fetal and infant health; congenital anomalies, childhood cancer, autism spectrum disorder and rare pediatric conditions surveillance at the national level. Prior to joining the federal government, Juan Andrés worked in the non-governmental sector mainly in international health and development. His areas of interest include public health surveillance and maternal, child and youth health epidemiology

Zubin Master is currently an Assistant Professor at the Alden March Bioethics Institute, Albany Medical College and Research Associate at the University of Alberta's Health Law Institute. He holds an undergraduate degree in genetics from York University and a PhD in cell and molecular biology from the University of Toronto. He transitioned into bioethics and health policy as a post-doctoral fellow at Dalhousie University and the University of British Columbia. Previously, Dr. Master worked as Senior Policy Advisor at Health Canada where he led the development of Health Canada's Scientific Integrity Framework and beforehand, developed regulations under the Assisted Human Reproduction Act. Dr. Master has previously held adjunct or visiting professor positions with the University of Montreal, the National Institute of Environmental Health Sciences, National Institutes of Health, and University of Ottawa. His research interests focus on the ethics, policy and commercialization of stem cell research, ethical and policy issues of biobanking, and the responsible conduct of research including authorship and publication ethics. Dr. Master serves on several governmental and non-governmental committees and journal editorial boards and has published about 60 articles in science, bioethics and law journals.

Julie MacFarlane, MSc, CCGC, Provincial Lead, Screening Programs , Perinatal Services BC, an agency of the Provincial Health Services Authority. Julie joined Perinatal Services BC in 2009 when funding had just been approved by the BC Ministry of Health, and along with Medical Director Dr. Sylvie Langlois, established a centralized and coordinated provincial program for prenatal genetic screening. BC's integrated screening program includes serum collection anywhere in the province, transported to one centralized lab in Vancouver, and coupled with certified Nuchal translucency ultrasounds performed at 20 different facilities, risk calculations and results are all reported out by genetic counsellors to health care providers. Now with the recent government funding announcement for NIPT, Julie and Dr. Langlois are once again quickly establishing a provincial coordinated effort to be able to educate, offer, and perform NIPT for those eligible women.

Over the past 7 years at Perinatal Services BC, Julie's screening portfolio has grown to also managing the BC Newborn Screening Program and the Biliary Atresia Home Screening Program. Julie has had extensive experience managing large-scale clinical genetic and pharmaceutical programs from her previous years at Xenon Pharmaceuticals Inc. in Burnaby, BC, and was part of the genetics team who identified the genes for Juvenile Hemochromatosis and Congenital Insensitivity to Pain with the help of DNA collections from Canadian families. She is a Canadian certified genetic counsellor, with a Master of Science from the University of British Columbia, and a Biotechnology Graduate Diploma from the University of Melbourne, Australia . She is the author of two book chapters and numerous research publications in clinical and molecular genetics. She is also a very proud Mum to amazing 5 and 8 year old girls.

Blake Murdoch is a research Associate at the Health Law Institute in the Faculty of Law at the University of Alberta. His research interests include the legal and ethical issues associated with clinical research, genetics, alternative medicine, and health, as well as public perceptions surrounding fitness and diet, biotechnology and medicine. Blake is currently examining intellectual property issues surrounding non-invasive prenatal testing, the ethics of clinical research on vulnerable populations, and issues with alternative medicine.

Prior to joining the Health Law Institute, Blake received his B.A., J.D., and M.B.A. from the University of Alberta, and is a member in good standing of the Law Society of Alberta. He has spent time as a business broker and a real estate agent, and uses his perspectives and knowledge of business to inform the Institute's research.

Ubaka Ogbogu is an Assistant Professor in the Faculties of Law and Pharmacy & Pharmaceutical Sciences and the Katz Research Fellow in Health Law and Science Policy at the University of Alberta. He holds bachelor's and graduate degrees in law from the Universities of Benin (Nigeria) and Alberta, and he completed his doctoral work on the legal history of vaccination policies in Canada in the Faculty of Law at the University of Toronto. His scholarly work is focused broadly on the ethical, legal and societal implications of novel and emerging biomedical research and health care technologies, primarily stem cell research, and on the ethical, legal and social challenges associated with existing medical and public health systems, practices and infrastructures. He has held and worked on numerous stem cell and cell therapy research grants, and he was a member of the now defunct Canadian Stem Cell Network. His academic publications have explored a diverse range of issues in health care and science policy, including health information privacy protections, genetic testing, bio-banks, stem cell research, ownership of the human body, genetic discrimination, global health, public health, vaccination, infectious diseases and research ethics, and ethical and legal issues surrounding complementary and alternative medicine. Dr. Ogbogu is the recipient of the 2015 Confederation of Alberta Faculty Associations Distinguished Academic Early Career Award and a member of the University of Alberta's prestigious Health Law Institute.

Mike Paulden, MSc, MA (Cantab.) is a Senior Research Associate at the Faculty of Medicine and Dentistry at the University of Alberta. He is a health economist with an interest in health technology assessment. His current research focuses upon developing methods for incorporating social values into economic evaluations of health technologies.

Daryl Pullman is Professor of Medical Ethics in the Faculty of Medicine at Memorial University in St. John's, Newfoundland & Labrador. He serves on numerous national and international ethics bodies, and is involved in a wide range of interdisciplinary health research projects. He has published widely on a variety of issues in research and clinical ethics.

Vardit Ravitsky, PhD, is Associate Professor at the Bioethics Programs within the Department of Social and Preventive Medicine of the School of Public Health at the University of Montreal. She is Director of the Ethics and Health Branch of the CRE, an interuniversity research center in ethics. She is a Board Member and Ethics Designate of the CIHR's Institute of Genetics (IG) and a member of the CIHR Standing Committee on Ethics. She is also a member of the University of Montreal's Public Health Research Institute (IRSPUM) and of the Quebec Reproduction Network (RQR). Previously, she was faculty at the Department of Medical Ethics of the University of Pennsylvania. She was also a Senior Policy Advisor at CIHR's Ethics Office and a GE3LS consultant to Genome Canada.

Prof. Ravitsky's research focuses on reproductive ethics and the ethics of genetic and genomics research. She is particularly interested in the various ways in which cultural frameworks shape public debate and public policy in the area of bioethics. Her research projects are funded by CIHR, FRQSC, SSHRC, and Genome Canada.

Born and raised in Jerusalem, Ravitsky brings international perspectives to her research and teaching. She holds a BA from the Sorbonne University in Paris, an MA from the University of New Mexico in the US, and a PhD from Bar-Ilan University in Israel. She was a post-doctoral fellow at the Department of Bioethics of the NIH and at the National Human Genome Research Institute (NHGRI).

François Rousseau is a medical biochemist subspecialized in molecular genetics. He obtained a BSc in medicine (1983), a MD in medicine (1984) and a MSc in Molecular Ontogeny (1987), all from Université Laval. He completed a three-years post-doctoral fellowship in Human Molecular Genetics at Université Louis-Pasteur in Strasbourg (1989-1991), where he contributed to the discovery of the fragile-X syndrome gene, the most frequent cause of inherited mental retardation. His research focuses on the translation of discoveries stemming from the Human Genome Project into the health care system, as well as in evidence-based laboratory medicine. He is an expert member of several national and international committees on diagnostic tests, including for the Québec Health Technology Assessment Agency (INESSS) where he is Chair of committee on laboratory testing. He was the designated principal investigator of the CIHR-funded Canadian APOGEE-Net/CanGeneTest research consortium on health services research in genetics, that focuses on transferring clinically useful and cost-effective genetic innovations to the health care system. He is also the Leader of the Genome-Canada-funded PEGASUS Project on real-life comparative effectiveness of genomic technologies for non-invasive prenatal testing. He has over 120 peer-reviewed publications and is a Fellow of the Canadian Academy of Health Sciences. He is also an auditor in clinical laboratory accreditation for Accreditation Canada since 2009.

Bryn Williams-Jones, PhD, is Associate Professor and Director of the Bioethics Program, Department of Social and Preventive Medicine, School of Public Health (ESPUM) at the University of Montreal. An interdisciplinary scholar trained in Bioethics, Dr Williams-Jones is interested in the socio-ethical and policy implications of health innovations in diverse contexts. His work examines the conflicts that arise in academic research and professional practice with a view to developing ethical tools to manage these conflicts when they cannot be avoided. Current projects focus on issues in professional ethics, public health ethics, research integrity and ethics education. Dr Williams-Jones heads the Research Ethics and Integrity Group and is Editor-in-Chief of the open access journal BioéthiqueOnline.

Brenda Wilson is Professor in the School of Epidemiology, Public Health and Preventive Medicine at the University of Ottawa. She trained in medicine at St Andrews and Edinburgh, with residency training in internal medicine and public health medicine. Following clinical and health board appointments, she joined the Department of Public Health at Aberdeen University in 1991. She moved to Ottawa in 2002. She has served on a number of national and provincial committees relating to research strategy and policy issues in genetics, research ethics, and research integrity.

Dr Wilson's research interests centre on public health and health system aspects of emerging genetic technologies, including 'personal genomics'. Her goal is to generate a robust evidence base to promote the implementation of effective genomic interventions, and to facilitate informed decision making about their use by practitioners, patients, policy-makers, and citizens.

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