Driving Regenerative Medicine to the Market and Clinic

An Exploration of Enablers, Impediments and Ethical-Legal Challenges

ORGANIZING COMMITTEE

Tania Bubela, *School of Public Health, University of Alberta*
Timothy Caulfield, *Health Law Institute, University of Alberta*
Robyn Hyde-Lay, *Health Law Institute, University of Alberta*
Shannon Gibson, *Faculty of Law, University of Toronto*
Christopher McCabe, *Department of Emergency Medicine, University of Alberta*
Richard Gold, *Faculty of Law, McGill University*
Trudo Lemmens, *Faculty of Law, University of Toronto*

The organizers would like to thank the Stem Cell Network, the Cancer Stem Cell Consortium, Genome Canada, Genome Quebec, Genome Alberta, the Ontario Genomics Institute, the Canadian Institutes for Health Research, and Alberta Innovates-Health Solutions for their generous support of both this event and the following projects:

- *Translation Challenges, Science Policy and Stem Cell Research*
- *Enhancing Translational Stem Cell Research: Innovative Models for Multi-Sectoral Collaboration*
- *From the Lab to the Clinic: ELS Issues in Cancer Stem Cell Research*
- *Ethical, Legal, and Social Issues of Cancer Initiating Cell and Translational Medicine Research*
- *PACE-'Omics: Personalized, Accessible, Cost Effective Applications of 'Omics Technologies*
- *Leading Clinical Trials in Islet and Stem Cell Transplantation, Restoration of Self-tolerance and Beta Cell Regeneration – Solving the Supply and Survival Problem in Type 1 Diabetes*
- *Promoting Rare-Disease Innovations through Sustainable Mechanisms*
- *Personalized Genomics for Prenatal Aneuploidy Screening Using Maternal Blood*

Stem Cell Network
Réseau de cellules souches

Cancer Stem Cell Consortium (CSCC)

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GenomeAlberta

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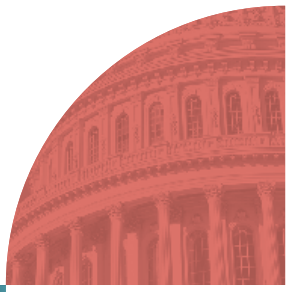
Driving Regenerative Medicine to the Market and Clinic

An Exploration of Enablers, Impediments and Ethical-Legal Challenges

This workshop will investigate a broad range of legal, management, ethical, economic, and social issues associated with the translation and commercialization of regenerative medicine technologies and services. Topics include the source and impact of pressures to commercialize research outputs; how decisions are made and reviewed with respect to moving from pre-clinical to clinical research; an examination of the whos, whys, whens and wheres of multi-sectorial collaborations; an exploration of current and potential governance mechanisms related to research and product development; and decision-making and considerations of health system markets that have adopted methods for health technology assessment to ensure that novel therapies are more cost effective than the ones they replace.



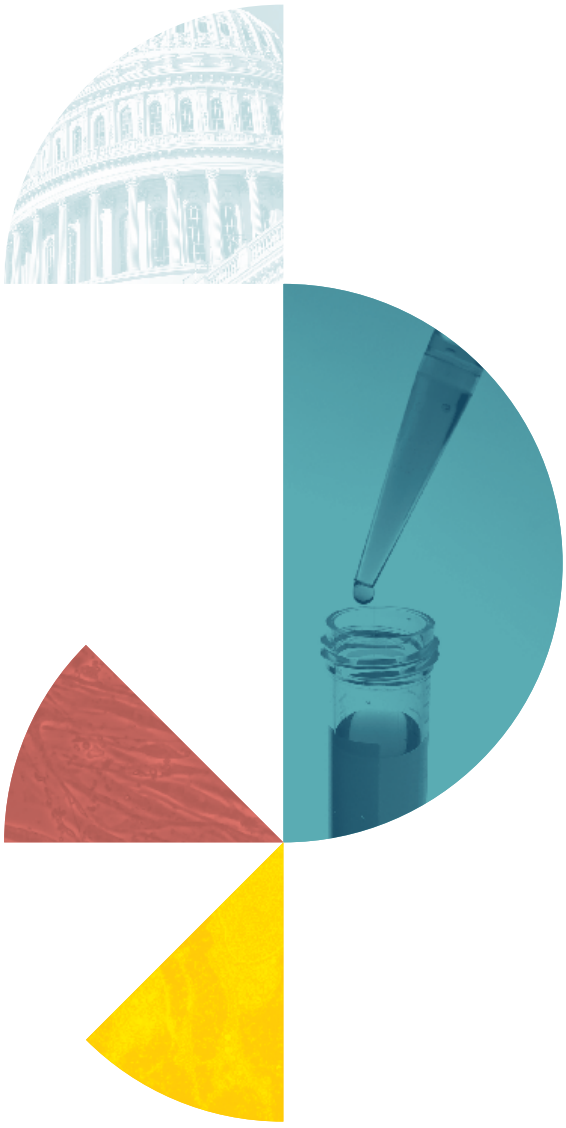
NOVEMBER 5 TO 7 | SHERATON CENTRE | TORONTO, ON

Driving Regenerative Medicine to the Market and Clinic

An Exploration of Enablers, Impediments and Ethical-Legal Challenges

WEDNESDAY EVENING November 5th

7:00 pm — **WELCOMING RECEPTION**
PINNACLE ROOM



THURSDAY November 6th

7:00 am — **BREAKFAST**
SHERATON HALL C

8:15 am — **OPENING REMARKS**
Timothy Caulfield, *University of Alberta*

8:30 am — **SESSION 1**
The Commercialization Environment
SESSION CHAIR: Christopher Scott, *Stanford University*

10:00 am — **BREAK**

10:30 am — **SESSION 2**
The Challenge of Striking the Right Balance
SESSION CHAIR: Eric Meslin, *Indiana University*

12:00 pm — **LUNCH**

1:00 pm — **SESSION 3**
Value-Engineered Translation for Regenerative Medicine: Meeting the Needs of Health Systems
SESSION CHAIR: James Piret, *University of British Columbia*

2:30 pm — **BREAK**

3:00 pm — **SESSION 4**
Understanding the Niche Market Context: Incentives, Evidence and Decision-Making
SESSION CHAIR: Amy Zarzeczny, *University of Regina*

FRIDAY November 7th

7:00 am — **BREAKFAST**
SHERATON HALL C

8:30 am — **SESSION 5**
Collaborative Research Consortia: When are They more Effective than Market Contracting?
SESSION CHAIR: Richard Gold, *McGill University*

10:00 am — **BREAK**

10:30 am — **SESSION 6**
Between Collaboration and Commercialization: Reconciling the Profit Motive and Publicly-Funded Biomedical Research
SESSION CHAIR: Michael Szego, *University of Toronto*

12:00 pm — **FINAL DISCUSSION & WORKING LUNCH**

THURSDAY November 6th

8:30 am – **SESSION 1**

The Commercialization Environment

Governments throughout the world are increasingly emphasizing the need for economic impact of academic research and the need to facilitate rapid translation. This session will explore the commercialization environment and its possible impact on the research environment, public perceptions of research, and how research is represented in the popular press.

SESSION 1 CHAIR: Christopher Scott, *Stanford University*

SPEAKERS:

- Science Powers Commerce: Mapping Language and Justifications for the Push to Commercialize Scientific Research
  Ubaka Ogbogu, *University of Alberta*
- Public Perceptions on the Commercialization of Research
  Zubin Master, *Albany University*
- Media Representations of Translational Stem Cell Research
  Kalina Kamenova, *Univesity of Alberta*

RESPONDERS:

Judy Illes, *University of British Columbia*
Rosario Isasi, *McGill University*

10:30 am – **SESSION 2**

The Challenge of Striking the Right Balance

The faster emerging technologies move to the clinic, the faster they can have an impact on the health of individuals. It is no surprise, then, that there is often intense pressure to rapidly translate potentially useful technologies and to create policies that facilitate the move to the clinic. This session will build on the morning panel and explore a range of issues associated with the translation process.

SESSION 2 CHAIR: Eric Meslin, *Indiana University*

SPEAKERS:

- Pressure to Market Stem Cell Interventions
  Douglas Sipp, *RIKEN Center for Developmental Biology*
- Challenges in the Translation of Regenerative Medicine and the Rise of Unproven Stem Cell Therapies
  Aaron Levine, *Georgia Institute of Technology*
- Ethical Considerations in Translating High-Expectation Technologies
  Jennifer Fishman, *McGill University*

RESPONDERS:

Kirstin Matthews, *Rice University*
Bernadette Richards, *University of Adelaide*

1:00 pm – **SESSION 3**

Value-Engineered Translation for Regenerative Medicine: Meeting the Needs of Health Systems

Research and development for novel bio-therapeutics must be driven by considerations of value to healthcare payors. In an era of cost-constrained health systems, investment decisions in research and development for novel bio-therapeutics need to closely consider market needs and clearing market access hurdles. Using stem cell therapies for diabetes as an example, this session will consider models for evaluating technologies as these progress from pre-clinical through clinical testing to ensure they represent a good investment from both commercial and health system perspectives.

SESSION 3 CHAIR: James Piret,
University of British Columbia

SPEAKERS:

- Enablers and Barriers to Cost-Effective Translation of Regenerative Medicine
  Tania Bubela, *University of Alberta*
- Value Engineered Translation for Regenerative Medicine: Case Study of Diabetes Cell Therapies
  Christopher McCabe, *University of Alberta*
- Do Social Values Transform the Value-Based Translational Calculus for Regenerative Medicine?
  Mike Paulden, *University of Alberta*

RESPONDERS:

Geoffrey Lomax, *California Institute for Regenerative Medicine*
Mark Rohrbaugh, *National Institutes of Health*

3:00 pm – **SESSION 4**

Understanding the Niche Market Context: Incentives, Evidence and Decision-Making

This panel will consider issues related to and arising from the pharmaceutical industry's increasing interest in pursuing high-value niche markets. Topics discussed will include the merits and drawbacks of orphan drug policies to incentivize research into rare diseases, evidentiary challenges in niche markets, and the importance of transparency in decision-making for rare diseases.

SESSION 4 CHAIR: Amy Zarzeczny,
University of Regina

SPEAKERS:

- Why the Shift? Taking a Closer Look at the Pharmaceutical Industry's Growing Interest in Niche Markets
  Shannon Gibson, *University of Toronto*
- Involvement of Patients and Patient Organizations in Orphan Drug Regulation
  Barbara von Tigerstrom, *University of Saskatchewan*
- The Data Transparency Battle in the Context of Drug Reforms
  Trudo Lemmens, *University of Toronto*

RESPONDERS:

Joel Lexchin, *York University*
Matthew Herder, *Dalhousie University*

FRIDAY November 7th

8:30 am – **SESSION 5**

Collaborative Research Consortia: When are They more Effective than Market Contracting?

Policy-makers and academics alike have highlighted the benefits of collaborations in advancing research and development. This session will discuss various forms of collaboration— from formal research agreements, to informal market transactions—and their likely impact on innovation in the life sciences.

SESSION 5 CHAIR: Richard Gold,
McGill University

SPEAKERS:

- Collaborative Research Inside and Outside the Innovation Wetlands
  Andrew Torrance, *University of Kansas*
- Paradigm Shifts for Innovating Collaborative Research
  Richard Johnson, *Global Helix*
- Collaborations and Open Science: Strategies to Accelerate Innovation
  Benedicte Callan, *Arizona State University*

RESPONDERS:

Michael May, *Centre for Commercialization of Regenerative Medicine*
Samuel Abraham, *BC Cancer Agency*

10:30 am – **SESSION 6**

Between Collaboration and Commercialization: Reconciling the Profit Motive and Publicly-Funded Biomedical Research.

This session will consider issues related to and arising from the commercialization of publicly-funded biomedical research and collaboration and data/sample sharing with private, for-profit industry. Topics discussed will include what types of policies should govern industry access to data and biological samples contained in publicly-funded biobanks and the merits and risks of encouraging biomedical researchers to promote the commercialization of their research, to collaborate with the health products industry, or more generally, to engage in 'entrepreneurial' activities.

SESSION 6 CHAIR: Michael Szego,
University of Toronto

SPEAKERS:

- Commercialization and Conflict of Interest: Institutionalizing Academic Entrepreneurship in Biomedical Science in Canada
  Renata Axler, *University of Toronto*
- Reflections on the 'Entrepreneurial Hospital': Patients as Assets in Hospital-based Research and Innovation Systems
  Fiona Miller, *University of Toronto*
- Qualitative Study on the Legal Relationship between Custodians and Researchers Applying for Access to Biobanks
  Michiel Verlinden, *KU Leuven*

RESPONDERS:

Tania Bubela, *University of Alberta*
Monique Albert, *Ontario Institute for Cancer Research*

BIOGRAPHIES

Samuel Abraham, PhD (Genetics), Vice President Research, BC Cancer Agency; Vice President Strategic Relationships, BC Cancer Agency; Executive Lead, Business and Intellectual Property Development, Provincial Health Services Authority.

As VP Strategic Relationships and VP Research, Dr.. Abraham works to enable high quality discovery research and to create linkages between the BC Cancer Agency (BCCA) and both the public and private sectors that will help the BCCA to achieve its mandate of cancer control for the province of British Columbia. Both sets of responsibilities are involved in the development of intellectual property arising from research activities at the BCCA and its partner institutions, and the translation of those discoveries into clinical practices or products that will benefit patients. Dr. Abraham works closely with senior scientific, clinical and administrative staff to provide both scientific, business and policy expertise in supporting targeted, high-value research and determining patient-focused development strategies.

BCCA is a branch of the Provincial Health Services Authority, where Dr.. Abraham has an additional role as Executive Lead, Business and Intellectual Property Development. In this expanded role, he is instrumental in advising branches of the PHSA on issues related to IP development and commercialization for technologies resulting from research programs at member agencies. These agencies include the BC Cancer Agency, BC Centre for Disease Control, BC ChilDr.en's and Women's Hospitals, Mental Health & Addiction, Renal, Transplant and Cardiac Services.

Dr. Abraham received his PhD in Genetics from the University of British Columbia. He joined Inflazyme Pharmaceuticals as a Senior Scientist in 1996 and later became Project Leader for the Transplant Program, as well as Division Leader for Cell and Molecular Biology. He has been with the BC Cancer Agency since 2000 and also serves as a member of the Scientific Advisory Board of Quest Pharma. Dr. Abraham has been VP Strategic Relationships for the BCCA since 2007 and was appointed Executive Lead, Business and Intellectual Property Development for PHSA in 2010 and Interim VP Research in 2011.

Dr. Abraham also serves as a Director on the boards of the BC Cancer Foundation; the Centre for Dr.ug Research and Development; and the British Columbia Aquatic Food Resources Society.

Monique Albert, M.Sc., PMP, is the Director of the Ontario Tumour Bank, which is a not-for-profit biorepository that serves both the academic and commercial sectors in Ontario and worldwide. She has also contributed to the development and launch of the MaRS Excellence in Clinical Innovation and Technology Evaluation ("EXCITE") program as its first manager. Her experience spans the healthcare research, biotech, and pharmaceutical sectors, having held a variety of management and research roles at MaRS, OICR, the STTARR Innovation Centre at the Princess Margaret Cancer Centre and the Microarray Centre (both at University Health Network) and in the corporate sector at Cangene Corporation and Affinium Pharmaceuticals. Her academic background combines a M.Sc. in biological sciences with project management certification/professional designation.

Renata Axler is a PhD candidate in the Institute of Health Policy, Management and Evaluation in collaboration with the Joint Centre for Bioethics at the University of Toronto. Renata's research focuses on academic entrepreneurship and the commercialization of academic biomedical research. Using critical social science methodologies, her work examines how these initiatives are reshaping the landscape of academic health research, and how they might entail

specific conflict of interest related harms. Renata's research and doctoral work has been supported by CIHR and the Health Care, Technology and Place strategic training initiative, and she has received several awards for her research. Renata has also been involved in the development of a public engagement strategy for the Ontario Health Technology Advisory Committee. Her research interests include science and research policy, health technology assessment, research ethics, and the application of empirical methods to areas of bioethical concern.

Tania Bubela, (PHD, JD), is Associate Dean for Research in the School of Public Health at the University of Alberta. Before joining the University of Alberta, Dr. Bubela clerked for the Honourable Louise Arbour at the Supreme Court of Canada. Her doctoral research was in the biological sciences, and she taught biology and genetics as a faculty member at the University of Toronto at Mississauga. From 2004-2008, she was an assistant professor at the School of Business, University of Alberta. Dr. Bubela's research interests include intellectual property law and policy, health law, biotechnology, genomics, technology transfer, commercialization of biomedical research and science communication. Her current research focuses on intellectual property issues and other legal and ethical issues in health biotechnology and biomedical research more broadly. Her interdisciplinary research has been published in high-impact journals including *Nature, Nature Biotechnology, Science Translational Medicine*, and *Cell Stem Cell*. She co-leads the Genome Canada funded PACEOMICS project and the Alberta Ocular Gene Therapy Team funded by AI-HS, CIHR and disease foundations. Her research on regenerative medicine is funded by the Canadian Stem Cell Network as Principal Investigator.

Benedicte Callan is a Clinical Professor in the College of Health Solutions and in the School of Public Affairs at Arizona State University. She is also a researcher at the Center for Policy Informatics at ASU. Dr. Callan's research interests focus on how new technologies challenge existing polices, institutional structures or business models, primarily in the field of health care. She is also interested how interest groups influence the direction or rate of change of new technologies. Dr. Callan has worked on the scientific and industrial policies that facilitated the rise of biotechnologie; the debates around intellectual property right policies for genetic inventions and pharmaceuticals; the promise of personalized medicine; the privacy and research implications of the digitization of health information; the search for new and more efficient research models in the life sciences. Prior to ASU, Dr. Callan was the Sid Richardson Fellow and Lecturer at the LBJ School of Public Affairs at the University of Texas, Austin. For over twelve years Dr. Callan was an Administrator at the Organization of Economic Cooperation and Development in Paris, France, serving in a variety of positions including as Head of the Biotechnology Unit and as Executive Assistant to the Deputy Secretary General. She has been a lecturer at Princeton University, a Fellow for the Center for Information Technology and Policy at Princeton University, and a Fellow for Political Economy at the Council on Foreign Relations in New York. Dr. Callan got her PhD at UC Berkeley in Political Science and her BA from Yale University in Biology & East Asian Studies.

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 medi-

cine 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: the 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).

Jennifer Fishman is Assistant Professor in the Biomedical Ethics Unit and the Department of the Social Studies of Medicine at McGill University. She holds a Ph.D. in Sociology from the University of California, San Francisco. She uses empirical qualitative methods to describe and analyze the emergence of new medical knowledge and technologies, from the early stages of development to their integration into clinical practice. Often referred to as "empirical ethics," she analyzes the oft unexamined and presumptive values and ethical frameworks within new scientific enterprises and how these impact biomedical research trajectories and ultimately patient care. She has studied new pharmaceutical drug development, anti-aging science and medicine, direct-to-consumer genetic risk susceptibility tests, prenatal genetic carrier testing panels, and the promise of personalized genomic medicine. Her recent work has been published in venues including *PLoS ONE, CMAJ, Trends in Genetics, Sociology of Health and Illness, Science, Technology and Human Values, Personalized Medicine*, and *New Genetics and Society*. She has also co-edited a volume entitled *Biomedicalization: Technoscience, Health, and Illness in the U.S.* (Duke University Press, 2010).

Shannon Gibson (BSc, LLB, LLM) is a Research Associate at the University of Toronto Faculty of Law where she is managing a research project on the ethical, legal and social dimensions of pharmacogenomic drug development. She recently completed her Master of Laws at the University of Toronto focusing on Health Law and Policy where she was a Canadian Institute for Health Research Fellow in Health Law, Ethics and Policy and a fellow with the Pharmaceutical Policy Research Collaborative. Her thesis explored the impact of the Internet and social media technologies in the direct-to-consumer marketing of prescription drugs. She received a B.Sc. in Health Information Science and a law degree from the University of Victoria, as well as completing an exchange term at the National University of Singapore. She articled in Toronto at the Ontario Ministry of Health and Long-Term Care and the Ministry of Health Promotion and Sport. During law school, she also completed an internship with the Patient Safety Department at the World Health Organization in Geneva, Switzerland.

Richard Gold is a James McGill Professor at McGill University's Faculty of Law where he was the founding Director of the Centre for Intellectual Property Policy. He teaches in the area of comparative intellectual property and innovation. His research centers on the nexus between innovation, development and commerce, with an emphasis on the life sciences. Professor Gold has provided advice to Health Canada, Industry Canada, the Canadian Biotechnology Advisory Committee, the Ontario Ministry of Health and Long-Term Care, the Organisation for Economic Cooperation and Development (where he was the lead author of the OECD Guidelines on the Licensing of Genetic Inventions and a report on Collaborative Mechanisms in Life Science Intellectual Property), the World Health Organization, the World Intellectual Property Organization and UNITAID. His research has been published in high-impact journals in science, law, philosophy and international relations including *Nature Biotechnology, The Lancet, PLoS Medicine, the McGill Law Journal, Public Affairs Quarterly, the European Journal for International Relations* and *International Studies Quarterly.*

Matthew Herder is an Assistant Professor in the Faculties of Medicine and Law at Dalhousie University. He is also a member of Dalhousie's Health Law Institute and the Novel Tech Ethics research group. Prior to arriving at Dalhousie, Matthew was the Ewing Marion Kauffman Foundation Legal Research Fellow at New York University School of Law. He holds a Master of the Science of Law degree from Stanford Law School as well as LLM and LLB degrees from Dalhousie. Currently, Matthew is the Principal Investigator on a three-year operating grant entitled "Emerging health researchers and the commercialization of academic science" funded by the Canadian Institutes of Health Research.

Judy Illes, PhD, FRSC, FCAHS, is Professor of Neurology and Canada Research Chair in Neuroethics at the University of British Columbia. She is Director of the National Core for Neuroethics at UBC, and faculty in the Centre for Brain Health at UBC and at the Vancouver Coastal Health Research Institute. She also holds affiliate appointments in the School of Population and Public Health and the School of Journalism at UBC, and in the Department of Computer Science and Engineering at the University of Washington in Seattle, WA. USA, and is a Life Member of Clare Hall, Cambridge University. Dr. Illes' research focuses on ethical, legal, social and policy challenges specifically at the intersection of the neurotechnology and biomedical ethics. This includes studies in stem cells and regenerative medicine, neurogenetics, aging and neurodevelopmental disorders, and the commercialization of neuroscience. She also leads a robust program of research and outreach devoted to improving the literacy of neuroscience and engaging stakeholders on a global scale.

Dr. Illes is an internationally recognized author, lecturer, and mentor. She is a Founder and Governing Board Member of the International Neuroethics Society, founder and Executive Committee Member of Women in World Neuroscience of IBRO, a member of the Dana Alliance for Brain Initiatives, and a Canadian representative to the National Academy of Sciences/IBRO US-Canada Committee. She is a member of the Standing Committee on Ethics for CIHR, and of the Scientific Advisory Committee on Expert Panels for the Royal Society of Canada. Dr. Illes was elected to the Royal Society (Life Sciences) in 2012, to the Canadian Academy of Health Sciences in 2011, and to the American Academy for the Advancement of Science (Neuroscience) in 2013.

Rosario Isasi is currently a Research Associate at the Centre of Genomics and Policy, Faculty of Medicine, at McGill University. Mrs. Isasi has built an international reputation as a scholar with particular expertise in the area of comparative law and ethics regarding regenerative medicine.

Closely related to her academic work is her role as an ethics and policy adviser to government, professional and international bodies, such as the United Nations, where she played an active role in the adoption of the UN Declaration on Human Cloning. Most recently, she contributed to the development of harmonized ELSI and educational tools for Canadian Blood Services' National Public Cord Blood Bank, the Centre for the Commercialization of Regenerative Medicine (CCRM) and to the Bioethics Education Project of the Royal College of Physicians and Surgeons of Canada.

Rosario Isasi holds many leadership roles in major international initiatives. She is the Academic Secretary of the International Stem Cell Forum Ethics Working Party and the Ethics/Policy Adviser of the European Human Pluripotent Stem Cell Registry (hESCREG). She leads the Governance Working Group of the International Stem Cell Banking Initiative (ISCBI). Mrs. Isasi is a member of the Legal and Human Rights Advisory Board of the Genetics Policy Institute (GPI), a member of the Bioethics and Legal Advisory Board of an EC-FP7 project on Biomaterials for Tracheal Replacement in Age-related Cancer via a Humanely Engineered Airway (BIOtrachea) and on regenerative medicine legislation (RegMedLaw, Translational Centre for Regenerative Medicine, Leipzig University).

Mrs. Isasi was the first post-doctoral fellow at the Canadian Program on Genomics and Global Health at

the Joint Centre for Bioethics, University of Toronto. She received further post-doctoral training at the Genetics and Society Project, Centre de Recherche en Droit Public, Université De Montréal. She holds her J.D. from the Pontifical Catholic University of Peru, where she practiced corporate and health law. She received her Masters of Public Health from Boston University, USA.

Richard A. Johnson is the CEO and founder of Global Helix LLC, a thought leadership and innovative strategic positioning firm for governments, foundations, university research centers, and high growth enterprises. This year he also will be serving as a Visiting Scholar at Stanford University. After 30 years, Rick retired as Senior Partner at Arnold & Porter LLP in Washington, D.C., where he represented many of the leading American research universities and foundations, and several high growth companies, about enabling basic research, creating societal value from research, and creating public-private partnerships through innovative approaches to law and policy. He created a number of path-breaking university-industry collaborations, pre-competitive consortia, and multi-stakeholder collaboration platforms; and helped to develop a number of platform technologies, flagship innovations, and new S&T models.

Johnson is a member of the Board on Life Sciences at the U.S. National Academy of Sciences (NAS) and the NAS Synthetic Biology Leadership Forum. He is a member of several, current NAS national initiatives: biomedical innovation and precision medicine; enabling global infrastructure for convergence; synthetic biology and the industrialization of biology; and global collaborations for neuroscience and healthy aging. Rick serves as the Chairman of the OECD/BIAC Science & Technology Committee and its Working Party on Biotechnology and Biomedicine; Brown's Biology & Medicine Council; the Stanford Biofab and BioBricks Foundation; and the International Advisory Council of the Innovation Knowledge Centre at Imperial College (London). He also is a member of the boards for UC-Berkeley/MIT and SynBerc; the MIT Bio Initiative; Brown Institute of Brain Sciences and U.S. BRAIN initiatives; the INCF at the Karolinska Institute; and the Human Genome Organization's Global Council. For many years, Rick served on the MIT Corporation Committee and global visiting committees for research enterprises.

Kalina Kamenova is a Research Associate with the Health Law Institute in the Faculty of Law at the University of Alberta. She received her PhD in 2012 from York University's Graduate Programme in Social and Political Thought with a dissertation titled "The Public Communication and Biopolitics of Human Embryonic Stem Cell Research in the United States and the European Union." Dr. Kamenova also holds Master's degrees in Comparative Literature, Gender Studies, and Cultural Studies. In 2012-2013 she held a Post-Doctoral appointment as the Inaugural Research Director of the newly established Centre for Public Involvement at the University of Alberta and was appointed as Adjunct Professor at the Faculty of Extension. Her research interests are interdisciplinary and include deliberative democracy and participatory governance, public engagement with science and technology, science communication, comparative science policy, and conceptual, ethical and legal issues related to new and emerging biomedical technologies. Prior to her appointment at the University of Alberta, Dr. Kamenova taught courses in the sociology of scientific controversies and scientific and technical communication at York University and the University of Ontario Institute of Technology.

Trudo Lemmens is a Professor and Scholl Chair in Health Law and Policy at the University of Toronto Faculty of Law, with cross appointments in the Faculty of Medicine and the Joint Centre for Bioethics. Professor Lemmens holds a Licentiate in Law from the K.U.Leuven (Belgium) and both an LLM (bioethics) and Doctorate in Law (DCL) from McGill University. Since joining the Faculty of Law, he has been a member of the School of Social Science of the Institute for Advanced Study in Princeton, a visiting

fellow of the Royal Flemish Academy of Belgium for Science and the Arts, a visiting professor at the KU Leuven and the University of Otago (New Zealand), a Plumer Visiting Fellow at Oxford's St. Anne's College, and an academic visitor at the Faculty of Law and the HeLEX Center for Health, Law and Emerging Technologies at the University of Oxford. His research sits at the interface of law, ethics, and professional governance. His current research focuses on the complex interaction between law, other governance tools, and ethical norms and values in the context of health care, biomedical research, health product development, and–more generally–knowledge production.

Aaron D. Levine is an Associate Professor in the School of Public Policy at Georgia Tech. His research explores the intersection between public policy, bioethics and biomedical research and focuses on understanding how the policy environment influences the development of ethically contentious new technologies, such as stem cell research and nanotechnology. Much of his recent work has focused on the development of stem cell science, particularly research using human embryonic stem cells, and the oversight of contentious areas of medicine, such as assisted reproductive technologies. In 2012, he received a five-year NSF CAREER award to examine the impact of ethical controversy on graduate science education and the development of scientific careers. He is the author of *Cloning: A Beginner's Guide* (Oneworld Publications, 2007), an accessible introduction to the science of cloning and embryonic stem cells and the ethical and policy controversies this science inspires. Aaron completed his Ph.D. in Public Affairs at Princeton University, where his dissertation research examined the impact of public policy on the development of human embryonic stem cell science. He also holds an M. Phil. from the University of Cambridge, where, as a Churchill Scholar, he studied computational biology at the Sanger Centre and developed algorithms to help analyze the human genome sequence.

Joel Lexchin received his MD from the University of Toronto in 1977 and for the past 32 years has been an emergency physician at the University Health Network. He is currently a Professor in the School of Health Policy and Management at York University and an Associate Professor in the Department of Family and Community Medicine at the University of Toronto. From 1992-94 he was a member of the Ontario Drug Quality and Therapeutics Committee and he was the chair of the Drugs and Pharmacotherapy Committee of the Ontario Medical Association from 1997-99. He has been a consultant for the province of Ontario, various arms of the Canadian federal government, the World Health Organization, the government of New Zealand and the Australian National Prescribing Service. He is the author or co-author of over 145 peer-reviewed articles on topics such as physician prescribing behaviour, pharmaceutical patent issues, the drug approval process and prescription drug promotion. He is currently working on a book tentatively entitled *The Pharmaceutical Industry and the Canadian State*.

Geoffrey Lomax is the Senior Officer for the Medical and Ethical Standards and the Manager for Collaborative Funding Partnerships at the California Institute for Regenerative Medicine. He oversees development and implementation of standards governing CIRM-funded research. As the Manager for Collaborative Funding, he works with state, national and international partners to develop support for development of collaborative research initiatives. He worked previously as the Research Director with the California Environmental Health Investigations Branch to publish and implement a strategic plan for the development of an Environmental Health Surveillance System in California. Through his professional career Dr. Lomax has continually worked to bridge issues of scientific policy and ethics in the development of state-based public health programs and research. His DrPH research and M.P.H. work were performed within the Division of Environmental Health Sciences at the University of California at Berkeley and his BS in Environmental Toxicology was conferred by the University of California at Davis.

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* on several laboratory assisted reproductive technologies and embryo research. During his tenure in government, Dr. Master maintained academic ties, continuing research as Affiliate Investigator at the Sprott Centre of Stem Cell Research and the Ottawa Hospital Research Institute, University of Ottawa, and held a short post as Guest Researcher at the National Institute of Environmental Health Sciences, National Institutes of Health. 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 over 50 articles in top-tier science, bioethics and law journals.

Kirstin R.W. Matthews, Ph.D., is a fellow in science and technology policy at the Baker Institute. She is also joint faculty and a lecturer in the Wiess School of Natural Sciences and an adjunct lecturer in the Department of Sociology at Rice University.

Matthews manages the activities of the Baker Institute Science and Technology Policy Program, which include overseeing events, conducting policy research, and writing policy reports and briefs. Her research focuses on the intersection between traditional biomedical research and public policy, which she publishes both through the Baker Institute and in peer-reviewed journals. Current projects include the Baker Institute International Stem Cell Policy Program, the Civic Scientist Lecture Series and Outreach Program, and policy studies in research and development funding.

Matthews came to Rice University as a postdoctoral research associate in the Department of Physics and Astronomy and a research assistant at the Baker Institute in 2003. From 2004 to 2006, Matthews was also the project director for the task force Access to Health Care in Texas: Challenges of the Uninsured and Underinsured. The task force released the report "Code Red: The Health of Texas" in April 2006, followed by an update, "Code Red 2008," in March 2008.

Matthews has a B.A. in biochemistry from The University of Texas at Austin and a Ph.D. in molecular biology from The University of Texas Health Science Center at Houston.

Michael H. May completed his PhD in Chemical Engineering at the University of Toronto in 1998 as an NSERC Scholar and was awarded the Martin Walmsley Fellowship for Technological Entrepreneurship.

Michael May is currently President and Chief Executive Officer of the Centre for Commercialization of Regenerative Medicine (CCRM), a Canadian, federally incorporated, not-for-profit organization dedicated to supporting the development of foundational technologies that accelerate the commercialization of stem cell- and biomaterials-based technologies. Prior to CCRM, Michael was the President, and co-founder, of Rimon Therapeutics Ltd., a Toronto-based regenerative medicine company developing novel medical polymers that possess drug-like activity. Michael sits on a number of boards and advisory committees including: MaRS Innovation; 20/20 Vision, a centre of excellence for biomaterials in ophthalmology; the Industry Committee of the International Society for Stem Cell Research(ISSCR); the 2014 ISSCR Programme Committee; the Rick Hansen Institute Commercialization Program Advisory Committee; Toronto Region Board of Trade Life Sciences Steering Committee; the Biozone Commercialization Committee; and, the Department of Chemical Engineering and Applied Chemistry at the University of Toronto.

Christopher McCabe has worked on methodological and applied research for evaluating new technologies to inform health reimbursement decisions for the last 20 years, primarily in the United Kingdom, but also working for governments in Europe, North America and Australasia. He was co-author of the 2004 edition of the UK National Institute for Health and Clinical Excellence (NICE) Guide to the Methods of Health Technology Assessment, and an expert advisor to its update in 2008. With others McCabe has made key contributions to the application of Decision Analytic Modelling and Value of Information methods to health care resource allocation decisions. He was founding Director of the NICE Decision Support Unit, an academic collaboration of 4 Universities providing methodological support and expert peer review to the NICE Technology Appraisal programme and was first author on one of the first papers to argue that regulatory authorities needed to consider cost effectiveness in order to incentivise manufacturers to design R&D processes to develop cost effective new technologies. Prior to moving to the University of Alberta, McCabe was the EPSRC Translational Research Professor in Health Economics at the University of Leeds, in the UK, as well as a founder member of the NICE Medical Technology Advisory Committee; which appraises non-drug technologies; including biomarkers, for the UK National Health Service. He is currently the senior health economist and Co-Investigator on two UK NIHR funded biomarkers trials, and Lead Investigator on the Genome Canada project *PACE-'Omics: Personalized, Accessible, Cost Effective Applications of 'Omics Technologies* (PACE-'Omics) and the Canadian Institutes for Health Research project *Promoting Rare-Disease Innovations through Sustainable Mechanisms* (PRISM).

Eric M. Meslin, Ph.D. is founding Director of the Indiana University Center for Bioethics and Associate Dean for Bioethics in the Indiana University School of Medicine. He has academic appointments in the Schools of Medicine, Liberal Arts, and Law. In 2012 he was appointed Indiana University's first endowed Professor of Bioethics.

Among his other leadership positions at IU, Meslin directs the Indiana University-Moi University Academic Research Ethics Partnership, an NIH-funded bioethics training program in Eldoret, Kenya; the Bioethics and Subject Advocacy Program of the Indiana Clinical and Translational Science Institute; and the Indiana University Center for Law, Ethics and Applied Research in Health Information (CLEAR).

Born in Canada, Dr. Meslin has a B.A. from York University, and an M.A. and Ph.D. from Georgetown University. Prior to coming to Indiana, he was director of bioethics research for the ELSI program at the National Human Genome Research Institute, and then Executive Director of the U.S. National Bioethics Advisory Commission appointed by President Bill Clinton.

He has held academic positions at the University of Toronto; at Green College, University of Oxford; and the University of Western Australia. During 2012-2013 he was on sabbatical leave at the Université de Toulouse as the *Pierre de Fermat Chaire d'Excellence* awarded by the Région Midi Pyréenées.

Dr. Meslin has more than 150 published articles and book chapters, is a co-editor of the *Cambridge University Press Bioethics and Law Series*, and is a member of several boards and committees in the U.S. and Canada including the Science and Industry Advisory Committee of Genome Canada.

Fiona Alice Miller, PhD, is an Associate Professor in the Institute of Health Policy, Management and Evaluation at the University of Toronto, and holds a New Investigator award from the Institute of Health Services and Policy Research of the Canadian Institutes of Health Research (CIHR). Miller leads a broadly based research program centred on health technology policy, particularly for genetic and genomic diagnostic and screening technologies. Miller is also involved in policy development in these areas, through the Ontario Maternal-Child Screening Committee and the Ontario Expert Panel on Pharmacogenetics, and the Institute Advisory Board of the CIHR Institute of Genetics.

Ubaka Ogbogu is an Assistant Professor cross-appointed to the Faculties of Law and Pharmacy & Pharmaceutical Sciences. He teaches and researches in the areas of health law and science policy studies, law and bioethics, legal history of science/medicine, pharmacy law and ethics, and the law of torts. He previously taught at the Universities of Nigeria, York and Minnesota, and his academic publications have appeared in numerous law and science journals, including the Health Law Journal, Constitutional Forum, Journal of International Biotechnology Law, Medical Law International, Cell Stem Cell, Nature Biotechnology, EMBO Reports, Regenerative Medicine, Canadian Medical Association Journal, and Canadian Pharmacists Journal. Professor Ogbogu is a member of the Faculty's 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 was previously a Research Associate at the Toronto Health Economics and Technology Assessment Collaborative at the University of Toronto, and a Research Fellow at the Centre for Health Economics at the University of York. He holds an MA in Economics from the University of Cambridge and an MSc in Health Economics from the University of York.

Mike's research interests are in the economic evaluation of health care technologies. He has worked on Health Technology Assessment projects for the National Institute for Health Research (NIHR) and the National Institute for Health and Care Excellence (NICE) in the UK, and for the Ministry of Health and Long-Term Care in Ontario. He has contributed to models evaluating the cost-effectiveness of a variety of health technologies and interventions, including formal screening programs for post-natal depression, neuromise inhibitors for the treatment of influenza, and gene expression profiling tests for guiding chemotherapy decisions in early stage breast cancer. His current research focuses upon developing methods for the economic evaluation of orphan drugs and personalized medicine technologies; this work is supported by the PRISM and PACEOMICS research projects at the University of Alberta.

Mike's theoretical work concentrates upon a number of issues which carry implications for social decision making in health care, including research into the most appropriate perspectives on social choice, cost-effectiveness thresholds, and rates of time preference to be adopted by decision makers. This work has addressed a long-running dispute over the use of differential discounting in cost-effectiveness analysis and has challenged current methodological practice in the UK and elsewhere.

James Piret, Sc.D., FCIC, is a Professor in the Michael Smith Laboratories and Associate Head of the Department of Chemical & Biological Engineering at the University of British Columbia. He graduated with an Applied Math to Biochemistry Bachelors from Harvard University in 1981, followed by Chemical Engineering master's and doctoral degrees from MIT in 1986 and 1989. Since 1989, at the University of British Columbia, his research focus has been on process and device technology for mammalian cell culture protein or stem cell production. This multi-disciplinary research ranges from bioreactor engineering to molecular biology, often including collaborative work with biologists and industry. Dr. Piret's contributions and expertise were recognized by the 2012 Cell Culture Engineering Award from the Engineering Conferences International.

Bernadette Richards comes from the Law School at the University of Adelaide and is an active researcher in the areas of Tort Law, Medical Law, and Bioethics. She has written a text book on Tort Law (*Tort Law Principles*,) has contributed to a collaborative text, *Health Law in Australia* and has recently completed a new text, *Medical Law and Ethics: A Problem Based Approach*. Bernadette is Deputy Chair of a major clinical research ethics committee, Associate Editor (Law) of the *Journal of Bioethical Inquiry* and provided advice to the Minister of Health as a member of the South Australian Council of Reproductive

Technology. She is the Director of the Centre for Law, Ethics and Society (CELS, an international collaboration with the Cardiff University) and Deputy Director, Research Unit for the Study of Society, Law and Religion (RUSSLR). Bernadette is the President of the Australasian Association of Bioethics and Health Law (AABHL). Her current research projects include a major grant project considering innovative surgery, the misapplication of the Australian Human Tissue Acts to posthumous donation of reproductive material and the role of ethical dialogue in popular entertainment.

Mark L. Rohrbaugh serves as the Director, Office of Technology Transfer (OTT), National Institutes of Health (NIH), US Department of Health and Human Services (HHS). OTT manages the patenting and commercial licensing of inventions made by NIH, FDA, and CDC intramural scientists and serves as the lead office within the HHS for technology transfer policy. Licensee companies have brought 27 FDA approved products to market and currently conduct clinical trials on 50 products under development. OTT's licenses for in vitro diagnostics have led to more than 100 commercial products and services in the last 20 years. In 2013, OTT licensees reported a combined total of $7B in sales of licensed products. Mark serves on the National Science and Technology Council Technology Committee and the White House Office of Science and Technology Policy (OSTP) Lab-to-Market Committee. He has represented the HHS at the Organization for Economic Cooperation and Development (OECD) and the World Health Organization (WHO). Mark has led intellectual property policy implementation for embryonic stem cells, pandemic flu, low-income country access, and use of the government's march-in authority.

Prior to joining the NIH, Mark conducted molecular and cell biology research at the University of Minnesota and two start-up companies. He received his Ph.D. in biochemistry from The Pennsylvania State University and a degree in law from The George Washington University.

Christopher Thomas Scott, MLA, PhD, is Director of the Stanford University Program on Stem Cells in Society, a faculty and senior research scholar at the Stanford Center for Biomedical Ethics, and a member of the Stanford Institute for Stem Cell Biology and Regenerative Medicine. He is a faculty affiliate of the University of British Columbia's National Core on Neuroethics.

His academic interests focus on the social, economic, political and ethical dimensions of new biotechnologies and regenerative medicine. Scott is widely published in journals such as *Cell, Cell Stem Cell, Nature Methods, Nature Biotechnology*, and the *American Journal of Bioethics*. His introductory text, *Stem Cell Now* (Penguin/Plume) has been translated into four languages. He directs several Stanford graduate and undergraduate courses. He is a contributing editor at *Nature Biotechnology* and serves on the editorial boards of several journals.

A former cell biologist, Scott was the Assistant Vice Chancellor at the University of California, San Francisco (UCSF), and co-founded Acumen Sciences, a research consulting company based in San Francisco. He was past President and CEO of The Stem Cell Advisors, a public benefit non-profit company providing stem cell research oversight for biotechnology and research institutions. He is one of only a handful of senior officials awarded for their contributions to Stanford's research enterprise.

He is regularly featured in national and local coverage of ethics and policy, including ABC, BBC, NBC, PBS, *The New York Times*, *The Boston Globe*, *Time, U.S. News and World Report, Boston Globe, The Atlantic Monthly, Nightline,* UPI, Fox, and *NPR's Fresh Air with Terry Gross, Talk of the Nation*, and *TechNation*.

Douglas Sipp graduated from Rutgers University in 1991. After working in the software and publishing industries, he joined the RIKEN Center for Developmental Biology as head of the CDB communications office in 2002. From 2009 to 2014, he led a research unit studying policy and ethics issues in the translation and commercialization of stem cell research. He

has published more than 40 research papers, reviews, and book chapters, presented his work at dozens of international meetings, and has been extensively interviewed by the international scientific and mass media. He serves on task forces addressing the problem of the marketing of unproven stem cell treatments for both the International Society of Stem Cell Research and the International Society for Cell Therapy. He serves as managing editor for the journals *Zoological Science* and the *International Journal of Hematology*, and as business manager of the International Society for Developmental Biology and the Asia-Pacific Developmental Biology Network.

Michael Szego is currently a clinical ethicist with the Centre for Clinical Ethics (a joint venture of St. Michael's Hospital, St. Joseph's Health Centre and Providence Healthcare), a Research Ethics Consultant with the Centre for Applied Genomics at the Hospital for Sick Children, and an Assistant Professor in the Department of Family and Community Medicine at The University of Toronto.

Prior to joining the Centre for Clinical Ethics, he completed an academic fellowship in clinical and organizational ethics at the University of Toronto Joint Centre for Bioethics. Michael earned both a Master of Health Science in Bioethics and a Doctorate in Molecular Genetics from the University of Toronto.

He is a course director in the MHSc in Bioethics program and has a research interest in the ethical issues associated with genomic research.

Barbara von Tigerstrom is Professor in the College of Law at the University of Saskatchewan, where she teaches in the areas of health law and ethics, public health law, administrative law, and international law. She holds a law degree from the University of Toronto and a Ph.D. in law from the University of Cambridge. Her current research focuses on legal issues in chronic disease prevention and the regulation of drugs and medical devices. She has acted as principal investigator on CIHR-funded projects in public health law and as an investigator and collaborator on several Stem Cell Network-funded projects relating to ethical, legal, and social issues in stem cell research. As part of a current project funded by Genome Canada ("CARE for RARE" led by Dr. Kym Boycott and Dr. Alex MacKenzie), she is examining legal and regulatory issues in the development of drugs for rare diseases. Her recent publications include articles and book chapters on the regulation of regenerative medicine products and on public health law and policy. She is a member of the CIHR Stem Cell Oversight Committee and an external research fellow of the University of Alberta Health Law Institute.

Andrew W. Torrance received his Ph.D. in Biology from Harvard University in 1997, J.D. from Harvard Law School in 2000, and Bachelor of Science from Queen's University (Canada) in 1991. He joined the University of Kansas School of Law in 2005 as Associate Professor. In 2009 he was named a Docking Faculty Scholar and in 2011 was promoted to tenured Full Professor. At KU Torrance served as a member of the Faculty and University Executive Councils (2010-2013), and as the elected President of the Faculty Senate (2012-2013). Prior to his arrival at KU, Torrance taught at Harvard University, was a Fellow in Law, Innovation, and Growth at the Searle Center at Northwestern University Law School (2009-2010), a Manza Scholar at the DePaul University College of Law School (2010), a Visiting Professor at the University of Washington School of Law (2011-2012), a Visiting Distinguished Professor at the University of Toronto Faculty of Law (2014), and a Visiting Scholar in Behavioral and Policy Sciences at the MIT Sloan School of Management (since 2011). In 2008, Torrance served as a policy advisor to presidential candidate Barack H. Obama on his Technology, Media, and Telecommunications Committee and in 2012 he was commissioned by the U.S. National Academies to write a report on patents and standards-setting in synthetic biology.

Professor Torrance teaches and conducts research in patent law, intellectual property, innovation, food and drug regulation, biotechnology law, biodiversity law, biolaw, and empirical, experimental, and big data

approaches to the law. He presents his research at universities, research organization, governments and intergovernmental agencies throughout the world, and has his scholarship published in journals such as as the *Yale Journal of Law and Technology*, the *Stanford Technology Law Review*, the *Columbia Science and Technology Law Review* and the *Berkeley Technology Law Journal*. As well, Torrance's research is regularly featured in the media, including *NPR*, *Forbes*, the *Seattle Times*, the *San Francisco Chronicle* and *Voice of Russia*.

Michiel Verlinden studied Law, with a specialization in European law, at the University of Ghent (Belgium) in 2003. Afterwards, he completed an LLM Program in International Legal Cooperation, focusing on European and International law at the Vrije Universiteit Brussels (Belgium) and a Postgraduate Master in Intellectual Property Law at the KU Leuven/KU Brussels. From February until October 2005, he worked as a Legal Researcher in the framework of the FP6 project "Safeguards in a World of Ambient Intelligence" at the interdisciplinary Research Group on Law, Science, Technology and Society at the Vrije Universiteit Brussels. From October 2005 until March 2011, he worked as an attorney at law in the Practice Group 'IP and Life Sciences' at the law firm Stibbe. He specialized in the domains of intellectual property rights, know-how protection, life sciences, protection of personal data and technology transfer and obtained practice experience providing advice on an optimal legal and contractual protection as well as litigating in these domains. In March 2011, Michiel joined the Research Center for Clinical Pharmacology and Pharmacotherapy at the KU Leuven to work on a PhD project on the legal framework applicable to access to biobanks under the supervision of Prof. Isabelle Huys, Prof. Herman Nys and Prof. Nadine Ectors.

Amy Zarzeczny is an Assistant Professor with the Johnson-Shoyama Graduate School of Public Policy, University of Regina campus, and Program Director of its Master of Health Administration program. She is also an External Research Fellow with the University of Alberta's Health Law Institute. Zarzeczny served as Crown Counsel with the Ministry of Justice and Attorney General of Saskatchewan in the Policy, Planning and Evaluation Branch, and previously practiced law with the firm of Reynolds, Mirth, Richards & Farmer LLP in Edmonton, Alberta. She is currently a Pro Bono member of the Law Society of Saskatchewan. Zarzeczny's research focuses on legal, bioethical and policy challenges associated with emerging biotechnology, medical innovations and biomedical research. She is currently involved in a number of interdisciplinary research collaborations and is funded by CIHR, Genome Canada and the Stem Cell Network. Zarzeczny currently teaches courses in Health Law, Health Policy and Health Care Organization and Administration.

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