EMERGING RESEARCH METHODS AND THE CONSENT CHALLENGE

SEPTEMBER 25–27, 2016
RIMROCK RESORT HOTEL
BANFF, ALBERTA

UNIVERSITY OF ALBERTA
FACULTY OF LAW
Health Law Institute

The Health Law Institute would like to thank the teams of the Canadian National Transplant Research Program, the Interdisciplinary Chronic Disease Collaboration, and the PACEOMICS project, in addition to the following funding agencies for their generous support of this event: Alberta Innovates -- Health Solutions, Canadian Blood Services, the Canadian Institutes of Health Research, the Kidney Foundation of Canada, Genome Alberta, Genome Canada, and the Pierre Elliott Trudeau Foundation.

Canadian National TRANSPLANT Research Program | Programme national de recherche en TRANSPLANTATION du Canada

ICDC interdisciplinary chronic disease collaboration

PACEOMICS

UNIVERSITY OF ALBERTA FACULTY OF LAW Health Law Institute

Alberta Innovates Health Solutions

Canadian Blood Services Société canadienne du sang

CIHR IRSC Canadian Institutes of Health Research | Instituts de recherche en santé du Canada

The Kidney Foundation of Canada

GenomeAlberta

GenomeCanada

FONDATION TRUDEAU FOUNDATION

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There are many emerging and established biomedical research methods that have the potential to produce useful scientific data, improve clinical practice and lead to new therapies. Many of these methods are relevant to and being used in organ donation and transplantation research. However, they also create profound legal and research ethics challenges. For example, there has been an ongoing debate about the legally appropriate way to obtain consent. This event will focus on this consent challenge. We will explore what the existing law and regulations say — that is, what can be done under existing norms — and what the evidence says about public perceptions and policy challenges. The goal is to produce a paper (or several) with specific recommendations about possible policy reforms in the context of consent.

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SUNDAY, SEPTEMBER 25, 2016

7:00pm **WELCOME RECEPTION**

MONDAY, SEPTEMBER 26, 2016

8:30am **Setting the Stage: Research & the Consent Challenge**
Timothy Caulfield, University of Alberta

Topic I: Biobanks and Cohort Studies

Chair: Karine Morin
Alberta Innovates – Health Solutions

Biobanking has become an important resource for biomedical research, including research on organ donation and transplantation. The debate about broad versus specific consent of research participants providing biological samples has been going on for over a decade. And while there has been huge public and private investment in biobanking and the establishment of a large number of biobanking initiatives (usually using some version of the broad consent approach), the law remains unsettled. This session will explore:

9:15 **Existing Legal Challenges**
Timothy Caulfield, University of Alberta

9:45 **Can Access to Information Law Help Us Escape the "Consent Maze"?**
Ubaka Ogbogu, University of Alberta

10:15 **Stakeholder Perceptions on Biobanking: Informed Consent and Beyond**
Zubin Master, Albany Medical College

10:30 COFFEE

10:45 **Biobanking in Transplantation: Issues from the Clinical Researcher Perspective**
Donna Wall, The Hospital for Sick Children (SickKids)

11:00 **Updating Consent: What the Participants Think**
Harriet Teare, University of Oxford

11:15 DISCUSSION
The Needed Policy Reform
Timothy Caulfield, University of Alberta

12:00 LUNCH

1:00 **The Finnish Approach to Competitive Biobanking and Consent Issues**
Sandra Liede, The National Supervisory Authority of Welfare and Health

Topic II: Pragmatic Clinical Trials (PCT)

Chair: Marcello Tonelli
University of Calgary

Pragmatic Clinical Trials are becoming an increasingly common research tool. However, given the unique approach — the use of real life clinical settings — they create many consent dilemmas. This session will explore:

1:30 **Pragmatic Trials: Why and Why Now?**
Braden Manns, University of Calgary

2:00 **Examples of Pragmatic Trials**
Natasha Wiebe, University of Alberta

2:15 **Pragmatic Trials and Informed Consent: Ethical and Legal Issues in a Canadian Context**
Blake Murdoch, University of Alberta

2:45 COFFEE

3:00 DISCUSSION
The Needed Policy Reform
Timothy Caulfield, University of Alberta

3:30 **Select TCPS 2 Guidance**
Wendy Burgess, Secretariat on Responsible Conduct of Research

4:00 DISCUSSION

TUESDAY, SEPTEMBER 27, 2016

Topic III: Deceased Organ Donor Research

Chair: Lori West
University of Alberta

Deceased organ donor research has the potential to increase the quality and supply of donated organs by identifying interventions that could be used in the donation process to enhance organ function in recipients. These trials, however, raise consent challenges respecting both donors and recipients. This session will explore:

8:30am **Deceased Donation Intervention Research Landscape In Canada**
Maureen Meade, McMaster University

8:50 **Deceased Donor Intervention Research: Law and Ethics**
Maeghan Toews, University of Alberta

9:20 **Consent Considerations for Deceased Donor "Participants"**
Sonny Dhanani, Children's Hospital of Eastern Ontario

9:40 **Consent Considerations for Recipients**
Greg Knoll, University of Ottawa

10:00 COFFEE

10:15 **Barriers to Research in Deceased Donors: The U. S. Situation**
Sandy Feng, University of California San Francisco

10:45 **Canadian Blood Services: Our ongoing role in Donation and Transplantation Research**
Kimberly Young, Canadian Blood Services

11:00 **Toward a New Research Framework in Organ Donation Medicine in Canada?**
Frederick D'Aragon, Université de Sherbrooke

11:20 DISCUSSION
The Needed Policy Reform
Maeghan Toews, University of Alberta

12:00 **Mapping the Way Forward**
This working lunch will synthesize the discussions and information presented at each session and identify emerging themes and ideas for policy reform.

PARTICIPANTS

Wendy Burgess joined the Secretariat on Responsible Conduct of Research as a policy analyst in 2010. She provides interpretations of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2), develops ethics guidance in emerging areas and develops and delivers research ethics training. She also provides interpretations and develops guidance for the *Tri-Agency Framework: Responsible Conduct of Research* (Framework). Wendy is the lead staff in the areas of research involving human biological materials, clinical trials, research involving the secondary use of information, and publication guidelines. She holds an Ethics degree from Saint Paul University and an MBA from England's University of Warwick. Prior to joining the Secretariat, Wendy worked in the semiconductor industry in product line and business management. She is an Electrical Engineering Technology graduate from Algonquin College and has served on its Board of Governors.

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).

Frederick D'Aragon is an anesthesiologist and critical care consultant at *Centre Hospitalier Universitaire de Sherbrooke* (CHUS), Quebec. He is an assistant professor at University of Sherbrooke and a clinical scientist at le *Centre de Recherche du Centre Hospitalier Universitaire de Sherbrooke*.

Dr. D'Aragon has unique clinical expertise. First, he completed a residency training in anesthesiology (University of Sherbrooke) and a fellowship in critical care medicine (McMaster University). He refined his knowledge in organ donation with a one year fellowship in organ donation and transplantation at the *Hospital Clinic de Barcelona* (University of Barcelona) in Spain. This country is recognized as the world leader in organ donation. On a research perspective, Dr. D'Aragon completed a three years fellowship in clinical research and a master degree in Health Research Methodology (McMaster University) under the supervision of Dr. Maureen Meade. The primary focus of his thesis was on the foundation work of a National Research Program in critical pre-donor care. As a junior clinical investigator, Dr. D'Aragon designed and co-leads a multicentre pilot study on deceased donor management called DONATE.

Sonny Dhanani is the chief of the pediatric intensive care unit at the Children's Hospital of Eastern Ontario (CHEO) in Ottawa and Associate Professor (Pediatrics) at the University of Ottawa. He has trained at the Hospital for Sick Children in Toronto. He has recently been the chief medical officer- donation for Trillium Gift of Life, Ontario's organ procurement organization. He is also leading national research pertaining to practices and standards for determining death after cardiac arrest for the purposes of donation.

Sandy Feng is a graduate of Harvard College, where she received the prestigious Marshall Scholarship. She utilized this fellowship to pursue graduate studies in molecular biology and received a doctorate from Cambridge University. Her medical training began at Stanford University School of Medicine, followed by general surgery residency at the Brigham and Women's Hospital, Harvard Medical School and abdominal transplant fellowship at the University of California, San Francisco. As Professor of Surgery, Dr. Feng performs liver, kidney and pancreas transplants. Her teaching and mentoring responsibilities include leading the Abdominal Transplant Surgery fellowship program and guiding medical students, residents, fellows, and junior attendings in clinical and translational research.

With respect to research, Dr. Feng's interests center on exploring mechanisms of spontaneous tolerance and approaches to induce tolerance in adult and pediatric liver transplant recipients. She is the overall principal investigator for numerous NIH-funded multi-center tolerance trials and serves as a site principal investigator for a diverse portfolio of other trials in both kidney and liver transplantation. She serves in a leadership capacity on the Executive and Steering Committees of the Immune Tolerance Network with responsibility for overseeing the Transplant portfolio.

Within the transplantation community, Dr. Feng serves as one of 8 worldwide Deputy Editors for the American Journal of Transplantation. She has held numerous leadership roles for the American Society of Transplant Surgeons, American Society of Transplantation, and American Association for the Study of Liver Disease. Recently, she has spearheaded a successful effort engaging the Institute of Medicine to conduct a study examining the ethical, regulatory, and logistical challenges that obstruct innovative research in deceased donors that can improve the quality and increase the quantity of organs available for transplantation.

Greg Knoll is Vice-Chair of Research, University of Ottawa Department of Medicine, Ottawa, Canada. He is Professor of Medicine in the Division of Nephrology and Medical Director of Renal Transplantation at the Ottawa Hospital. He currently holds the University of Ottawa Chair in Clinical Transplantation Research and is a Senior Scientist with the Clinical Epidemiology Program of the Ottawa Hospital Research Institute. He is a Past-President of the Canadian Society of Transplantation. He is on the Editorial Boards of the American Journal of Kidney Diseases, Clinical Journal of the American Society of Nephrology and the Canadian Journal of Kidney Health and Disease. He is involved in ongoing studies related to the measurement of renal function in kidney transplant recipients, cardiac screening in kidney transplant candidates, systematic reviews on immunosuppressive strategies, and measuring quality in transplantation. He is the Co-Chair of the international KDIGO guidelines on the Evaluation and Management of Candidates for Kidney Transplantation.

Sandra Liede works as Senior Officer of Legal Affairs at the National Supervisory Authority of Welfare and Health in Finland. She specializes in legal and ethical issues relating to biomedical research and biobanking. She is responsible for the supervision, guidance and oversight of the Finnish biobanking field, including international affairs.

She is a member in various working groups aiming to implement the Finnish health sector growth strategy (Ministry of Health and Social Affairs). The work is ongoing and has resulted in new legislative proposals (f.ex. secondary use of social and health care databases) as well as a proposal for a national genome strategy for Finland.

Her other responsibilities include legal support in issues such as organ donation and transplantation,

organ, tissue and cell research, medical training activities during autopsies and genetic engineering. Alongside legal practice, she is engaged in various research and collaboration projects both in Finland and the Nordics. Her pending doctoral dissertation at the Faculty of Law, University of Helsinki, studies commercialization issues of biobanking and personalized medicine. She currently chairs the Finnish Association for Medical Law and Ethics.

Braden Manns is the Svare Professor in Health Economics and a Nephrologist at the University of Calgary in the Departments of Medicine and Community Health Sciences and an Alberta Innovates – Health Solutions Health Scholar. He is the Scientific Director of the Alberta Health Services Kidney – Strategic Clinical Network and holds a CIHR Foundation grant. He has expertise in Applied Health Economics and clinical research in Nephrology and is co-PI for an inter-disciplinary team grant investigating chronic diseases (www.icdc.ca/) and a CIHR strategy for patient-oriented research network grant in kidney disease (Can-SOLVE CKD). Dr Manns' current research interests include examining the implications of patient-borne costs on care and outcomes in chronic disease, examining the cost effectiveness of strategies and health care policies for managing patients with chronic disease, and conducting trials assessing the impact of novel strategies on care and outcomes in chronic disease. He has experience in pharmaceutical priority setting, having served on provincial and national committees for drug evaluation, including a term as Chair of Canadian Expert Drug Advisory Committee from 2006-2008. Dr. Manns is the Past-President of the Canadian Society of Nephrology, and supervises graduate students at all levels of training.

Zubin Master is an Assistant Professor at the Alden March Bioethics Institute of Albany Medical College. A biomedical scientist by training, he transitioned into bioethics and health policy as a postdoctoral 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 developed regulations under the *Assisted Human Reproduction Act*. Dr. Master has previously held adjunct or visiting professor appointments at the University of Montreal, the National Institute of Environmental Health Sciences of the National Institutes of Health, and the University of Ottawa. Dr. Master teaches a range of bioethics, research integrity and better doctoring courses to graduate and medical students. His research interests focus on research ethics and policy of stem cell research, biobanking, and the responsible conduct of research including authorship and publication, mentorship and peer review among others. Dr. Master serves on several committees and journal editorial boards and has published about 70 articles in science, bioethics and law journals.

Maureen Meade is a critical care consultant in the neurotrauma ICUs at Hamilton Health Sciences, a senior investigator of the Canadian Critical Care Trials Group, and a professor of Medicine at McMaster University. She is a Hospital Donation Physician with the Trillium Gift of Life Network of Ontario and director of the new Canada-DONATE research program.

Karine Morin joined Alberta Innovates – Health Solutions in 2015, as Director, Ethics Innovations and was promoted Executive Director, Platforms in March 2016. She moved from Ottawa where she had served as Genome Canada's Director, National GE3LS Program for four years, overseeing activities related to the ethical, environmental, economic, legal and social aspects of genomics research.

Prior to joining Genome Canada, she was a Senior Ethics Policy Advisor at the Canadian Institutes of Health Research (CIHR). She also conducted research on ethical, legal and social issues related to genomics at the University of Ottawa's Institute of Science, Society and Policy.

Karine worked in the US for several years as the Director of Ethics Policy at the American Medical Association, and previously as an Ethics and Health Pol-

icy Associate at the American College of Physicians. Before leaving Canada, she had worked for the Commission of Inquiry on the Blood System in Canada (Krever Commission).

Karine holds a Masters in Law (LLM) from the University of Pennsylvania and is a graduate of McGill University School of Law, where she obtained a joint degree in civil (B.C.L.) and common law (LL.B).

Over the years, she has published widely in bioethics and law, and has taught as an adjunct at several universities in the US and Canada.

Blake Murdoch is a research associate who joined the Health Law Institute in 2016. He has a JD and an MBA from the University of Alberta. Blake is involved in research on various bioethics and policy topics, including but not limited to legal challenges with the alteration of consent for pragmatic clinical trials, management of complementary and alternative medicine and stem cell advertising claims, problems with the translation and implementation of non-invasive prenatal testing technologies, and protection of participants' rights in infectious disease and vaccine research.

Ubaka Ogbogu is an Assistant Professor and the Katz Research Fellow in Health Law and Science Policy in the Faculties of Law and Pharmacy & Pharmaceutical Sciences at the University of Alberta. His teaching and research interests are in the areas of health law, biomedical law, legal history of medicine and public health law. His academic achievements include the Confederation of Alberta Faculties Association Distinguished Academic Early Career Award.

Harriet Teare's research interests relate to the role of participants in medical research, and improving governance infrastructure to support communication and interactive engagement. She contributes to a number of specific research projects, including providing research governance and ethical support to the DIRECT project – an IMI-JU funded collaboration exploring stratification in Type 2 diabetes, the Rudy project – a research network for rare diseases of the bones, joints and blood vessels, and leads a work package focusing on consent in the Genetics Clinic of the Future – a Horizon 2020 project mapping the complex challenges that will need to be tackled to introduce genome sequencing more widely into the clinic. Harriet obtained a DPhil in Chemistry from Merton College, University of Oxford, and previously worked as a senior policy advisor at Cancer Research UK, focusing on policy issues relating to science and research, and public health

Maeghan Toews is a Research Associate at the Health Law Institute in the Faculty of Law at the University of Alberta. Her research interests include examining the legal and ethical issues associated with genetics and genomics, organ donation and transplantation, rare diseases, and biomedical research. She currently teaches Law and Medicine at the Faculty of Law and holds the prestigious James Kreppner Fellowship awarded by Canadian Blood Services for her project examining legal strategies to increase organ donation in Canada. Prior to joining the Health Law Institute, Maeghan completed her BA, JD, and LLM degrees, and spent several years in private practice as a commercial litigator.

Marcello Tonelli is a graduate of the University of Western Ontario's Faculty of Medicine (1995), and completed his postdoctoral training at the University of Western Ontario (1998), Dalhousie University (2002) and the Harvard School of Public Health (2002). He spent 12 years with the University of Alberta's Department of Medicine as a professor in the faculties of medicine and public health sciences, and a staff nephrologist at the University of Alberta Hospital. He joined the University of Calgary Cumming School of Medicine in 2014, taking on the role of Senior Associate Dean (Health Research). He was named Associate Vice-President (Research) in July 2014.

Dr. Tonelli's primary research focus is improving the care of people with chronic kidney disease and other chronic health conditions. He has partnered with regional, provincial and national decision-mak-

ing bodies to inform clinical practice and impact health policy in this area. He is currently a co-lead for the Alberta-based Interdisciplinary Chronic Disease Collaboration, chair of the Canadian Task Force on Preventive Health Care, and an Alberta Innovates-Health Solutions Population Health Scholar.

Dr. Tonelli was the recipient of the 2013 United States National Kidney Foundation Medal for Distinguished Service and the Kidney Foundation of Canada's 2013 Medal for Research Excellence for changing nephrology practice in Canada and beyond. Along with the two other team co-leads, he received a Top Canadian Achievements in Health Research Award from the CIHR-CMAJ in 2013 for his work with the Interdisciplinary Chronic Disease Collaboration. He was elected a fellow of the Canadian Academy of Health Sciences in 2012 and a member of the American Society for Clinical Investigation in 2014. He was named a "Highly Cited" researcher in 2015 by Thomson-Reuters, corresponding to a rank in the top 1% by citations of all researchers worldwide for field and publication year.

Kimberly Young is the Director of Donation & Transplantation with Canadian Blood Services, the agency responsible for leading the national services to advance organ and tissue donation and transplantation (OTDT) in Canada. Since 2008 Kimberly has played a principal role in the development of interprovincial patient programs and services, working in partnership with national and international donation and transplantation programs. In 2011 her portfolio expanded to include Stem Cell programs and services, OneMatch and the Stem Cells National System Solutions registry.

Kimberly is a recognized leader in donation and transplantation; she continues to serve on a number of national and international boards, advisory groups and committees including: the Canadian Society of Transplant Education Committee, Canadian Organ Replacement Register, and Canadian Standards Association Technical Committee for Organs and Tissues. Kimberly is the past President of the International Society for Organ Donation and Procurement and continues to lead the development of workshops to advance leadership in donation and transplantation globally.

While Kimberly's current focus involves administrative and transformative leadership she is also a registered nurse, with a Bachelor of Science and a Master's degree in Health Studies.

Donna Wall, after graduating from the University of Manitoba, received pediatric and pediatric hematology/oncology/transplant training in New York and Boston. She has established/led transplant programs and cord blood banks in St. Louis, San Antonio, and Manitoba.

Currently she is a Professor in Pediatrics and Child Health, Internal Medicine, and Immunology, the director of the Cellular Therapy Laboratory, and member of the Regenerative Medicine program at the University of Manitoba. She will be joining the transplant/cellular therapy program at SickKids Hospital/University of Toronto in the fall. Her research interests include allogenicity as therapy for malignancy, cord blood transplantation, and cellular therapy laboratory support for hematologic and regenerative medicine applications.

Lori West is Professor of Pediatrics, Surgery and Immunology at the University of Alberta and holds a Canada Research Chair in Cardiac Transplantation. She is a world leader in pediatric cardiac transplantation and transplant immunology, including translation of basic concepts and findings from animal models to clinical application in organ transplantation. She pioneered a strategy for increasing donor availability for infants by crossing the ABO blood group barrier, leading to global impact on infant heart transplantation. Her investigations of the immune development of infants after ABO-incompatible transplantation led to the first demonstration of neonatal transplantation tolerance in humans. Director of the Alberta Transplant Institute, Dr. West is also the founding Director of the Canadian National Transplant Research Program (CNTRP), a coalition of more than 300 investigators at 30 sites across Canada funded by the Canadian Institutes of Health Research and partners. The CNTRP network integrates basic science, clinical and policy researchers in solid organ transplantation,

hematopoietic cell transplantation and organ/tissue donation, with the overall goal of increasing access to transplantation and improving long-term transplant outcomes. Dr. West is Past-President of both the International Society for Heart and Lung Transplantation and the Canadian Society of Transplantation, and served on the Board of Directors of the American Society of Transplantation. She is a Fellow of the Canadian Academy of Health Sciences and currently serves on Governing Council of the Canadian Institutes of Health Research.

Natasha Wiebe is a Research Associate with the University of Alberta in the Department of Medicine, Division of Nephrology. She manages the Kidney Health Research Group which staffs statisticians, economists, GIS analysts, study coordinators and other research assistants. She is the Senior Statistician and with expertise in a wide array of analytical techniques, they carry-out cohort studies, systematic reviews, surveys and randomized controlled trials. She has over 100 peer-reviewed journal articles. She is professionally accredited with the Statistical Society of Canada. She had studied Statistics at the University of Waterloo. She is currently conducting a CIHR-funded systematic review of alternative designs for randomized controlled trials.

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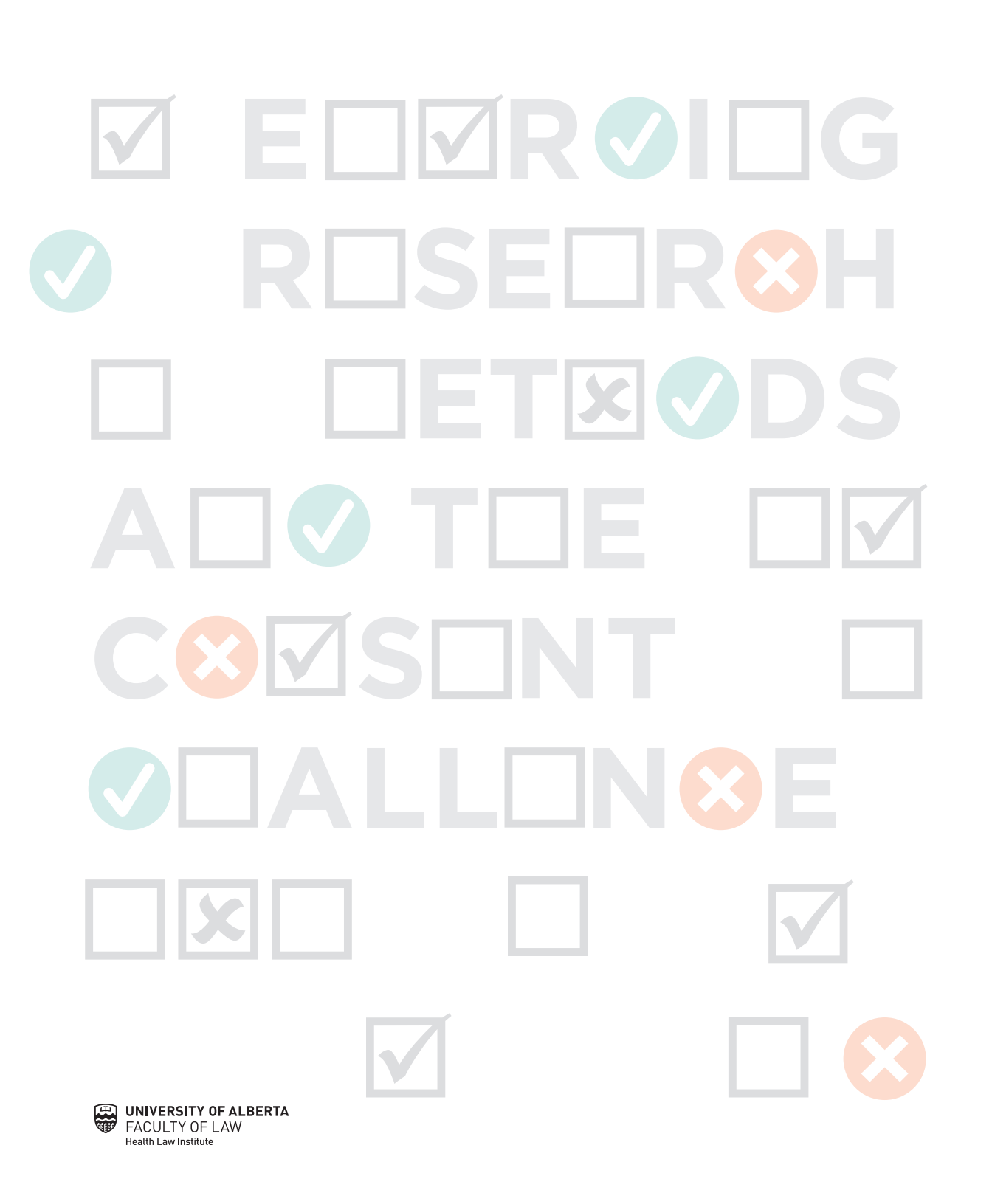

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