Michael Smith Health Research BC
RESEARCH ETHICS BC

# 2021 Clinical Research Ethics Symposium

## Program Day One


### Updates on COVID-19 Research: How Research Conduct Has Pivoted

9:30am-12:00pm PST

Join the discussion with insights from the experience of conducting research during the COVID-19 pandemic, including reflections on the following, and more:

- Disconnect between institutional/regulatory requirements and patient needs, for informed consent of an interventional study
- Data linkages between inpatient and administrative datasets, and Broad Consent
- The strengths and weakness of multi-jurisdictional approaches for review, and where implementation gaps remain
- Increasing requirements for clinical trial data sharing and the informed consent encounter

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## The Ethics of Genomics Research: Real-World Practice

### 2:00pm-4:00pm PST

Join the discussion with insights from a patient perspective, clinical care, genetic counselling, and more:

- Lived experience of a patient with diagnosis of cancer, and then a genetic syndrome
- Challenges of relaying information to family as the patient
- Evolution of genomic events in personalized onco-genomics (POG) over 10 years
- Harmonizing consent between research and clinical care
- Privacy above all else – problematic?
- Informed consent and the value of plain language

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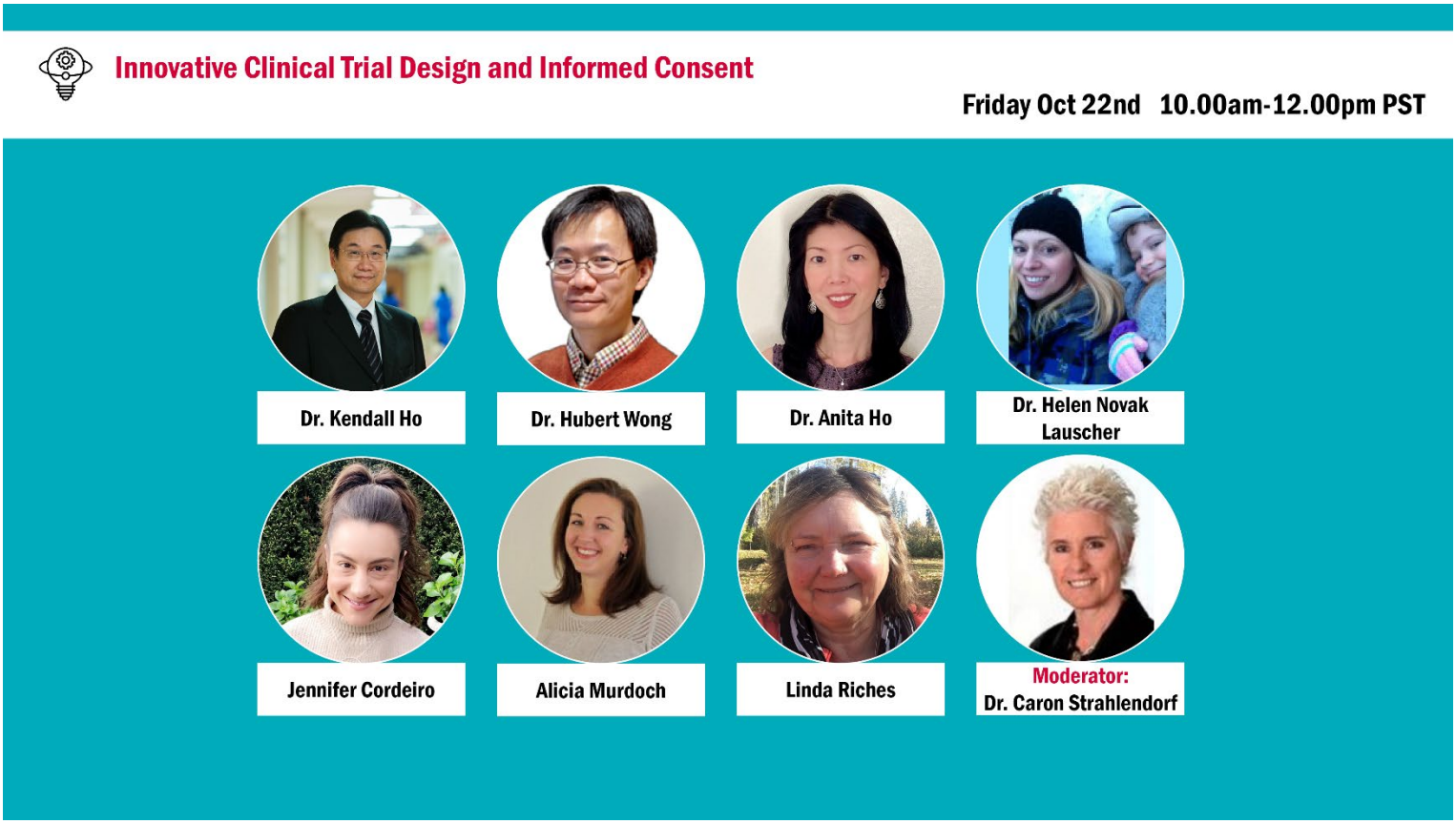
# Program Day Two




## Innovative Clinical Trial Design and Informed Consent

### 10:00am-12:30pm PST

Join the discussion with insights from researchers using innovative clinical trial designs, research coordinators and managers describing the challenges/solutions for true informed consent, and patient partners' lived experience of clinical trials, and more:

- Adaptive clinical trial design and the ethics of response adaptive randomization model
- Potential for differential recruitment bias in cluster-randomized trials
- What should the informed consent cover for access to health care records?
- Step-wedge trial design and concealment of group allocation from participants
- Benefits of decentralized trial designs and remote informed consent
- How much information should be in the consent form to respect autonomy of decision-making by participants and still protect recruitment bias?
- Have we been relying too much on informed consent to do the real ethical work of respecting participants? Blurring the requirements of consent and data access for clinical care with those for research

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# Speaker Bios:

## Updates on COVID-19 Research: How Research Conduct Has Pivoted

### Dr. Adeera Levin

Dr. Levin is a Professor of Medicine, Head Division of Nephrology at the University of British Columbia, and Consultant nephrologist at Providence Health Care/St Paul's Hospital, in Vancouver Canada. She has been appointed Sr Medical Lead, Integration Clinical and Academic Networks at PHC. She is the Executive Director of the BC Renal Agency, which oversees the care, planning and budgets for Kidney services in the province of British Columbia.

She is active in international activities across the spectrum of kidney education, research and administrative activities, and was past President of International Society of Nephrology (ISN), from 2015-17), and a founding member of the Declaration of Istanbul Custodian Group (DICG). She advocates for patient rights to equitable access to care, and in the prevention of exploitation of vulnerable populations.

Her major research interests include CVD in CKD patients, variability in the progression of CKD and optimal models of care. She has over 300 peer reviewed publications, and numerous book chapters. She is the Principal Investigator on a patient-oriented network grant CAN SOLVE CKD.

### Dr. Srinivas Murthy

Dr. Srinivas Murthy is Board certified in Pediatric Critical Care and Pediatric Infectious Diseases. He is interested in innovative clinical trials and international collaborations, with a specific focus on improving the management of patients with severe infections and managing critically ill patients in under-resourced settings. He is currently an investigator at University of British Columbia and Clinician at BC Children's Hospital.

### Dr. Corinne Hohl

Corinne is an Associate Professor in UBC's Department of Emergency Medicine, Scientist at the Centre for Clinical Epidemiology and Evaluation, and an Associate Member of UBC's School of Population and Public Health. She practices Emergency Medicine at Vancouver General Hospital. Her main research interests are in emergency medicine, patient safety, health systems innovation and critical appraisal. In 2020, she became the Chair of the Canadian COVID-19 Emergency Department Rapid Response Network (CCEDRRN), which is generating evidence to inform decision-making during the COVID-19 pandemic.

### Tony Lanier

Tony Lanier is a patient partner and a co-chair of the Community Stakeholders Committee at Legacy for Airway Health. As an asthma sufferer, Tony is involved in programs where his lived experiences help guide research for improved delivery of health services in British Columbia.

### Brayden Griffiths

My name is Brayden Griffiths and I am a research assistant in the Post-COVID Recovery Clinic at Jim Pattison Outpatient Care & Surgery Centre. I hold a Bachelor of Science in Biology with concentrations in Pre-Medicine and Cellular, Molecular, and Genetic Biology.

Previously, I have held research assistant positions at Surrey Memorial Hospital, B.C. Children's Hospital, and Langley Memorial Hospital. I have had the pleasure of working on various research studies such as TEC4Home, MyHEARTSMAP, ACAP, and MagNUM. Most recently, I was a part of B-EPIC, a clinical trial involving COVID-19 patients receiving a monoclonal antibody treatment called bamlanivimab.

In my spare time, I volunteer with local non-profits. I am currently on the board of Langley Pos-Abilities Society: a non-profit organization focused on improving the quality of life for individuals living with disabilities. I also enjoy staying active through various activities such as hiking, swimming, running, and resistance training.

### Moderator: Anika Patel

For the past 20 years, Anika Patel has participated in the research landscape in a variety of roles. Having held roles including Research Nurse Coordinator, Business and Regulatory Coordinator, Global Lead Clinical Operations, Manager of Research to Chair of the Clinical Research Ethics Board for the past 7 years she has a perspective and understanding that spans from the researcher to the regulatory levels. She is currently employed as Manager, Clinical Services at BC Cancer Victoria. A few monumental accomplishments include leading Island Health's application and ultimately successful MOU to hold CIHR funds along with facilitating and collaborating a 'blue sky idea' with a physician to a successful award of a large scale genome project of 9.6 million. Anika holds a BSN from University of Victoria and is currently finishing her MSc: Bioethics Policy at Clarkson University in New York. With a love for adventure and seeing the world, she looks forward to the ability to travel again soon!

## The Ethics of Genomics Research: Real-World Practice

### Dr. Howard Lim

Dr. Howard Lim is a Medical Oncologist at B.C Cancer - Vancouver Centre and Clinical Associate Professor in the Faculty of Medicine at the University of British Columbia. He specializes in gastrointestinal malignancies and is also actively involved in clinical trials, ethics and genomic based research.

### Dr. Sophie Sun

Dr. Sophie Sun is a medical oncologist, co-Medical Director of the BC Hereditary Cancer Program, and Chair of the BC Cancer Lung Systemic Policy Group at BC Cancer - Vancouver. Her clinical and research interests span cancer genetics, precision oncology, and novel cancer therapies, with a focus on breast and thoracic malignancies. She is actively involved in several therapeutic clinical trials as well as studies aimed to implement new genetic testing approaches for personalized therapies and improve hereditary cancer identification, with a focus on ethical implications with tumour and germline genetic testing. She also mentors medical students, residents, and fellows, including facilitating communication workshops for oncology trainees. She was previously Chair of the BC Cancer Breast Systemic Policy Group (2015-2019) and is a prior member of the University of British Columbia/BC Cancer Research Ethics Board (2009-2018).

## Dr. Nadine Caron

Dr. Nadine Caron is a member of the Sagamok Anishnawbek First Nation. She is a practising surgical oncologist in northern British Columbia where she provides cancer screening, diagnosis and surgical care for individuals in rural, remote, and northern BC - a large percentage of whom are Indigenous. Dr. Caron is the sole Indigenous physician within BC Cancer, the only Indigenous academic faculty member within the University of BC's Faculty of Medicine, a Professor at UBC Northern Medical Program and Department of Surgery as well as a Senior Scientist at Canada's Michael Smith Genome Sciences Centre at BC Cancer. Dr. Caron is the inaugural First Nations Health Authority Chair in Cancer and Wellness at the University of British Columbia. She is also a founding co-Director of the UBC Centre for Excellence in Indigenous Health and Consultant in development of BC's first-ever Indigenous Cancer Strategy to improve Indigenous cancer outcomes and experiences in BC. "Improving Indigenous Cancer Journeys: A Road Map". Dr. Caron currently leads the development of the Northern Biobank Initiative, including a First Nations-governed and controlled biobank in partnership with the FNHA that aims to provide safe access to cancer research for First Nations people in Northern BC. She is also co-Lead investigator on the Silent Genomes project which aims to address the genomic divide by reducing access barriers to diagnosis of genetic disease in Indigenous children and facilitating a governance framework to inform policy in fields of data sovereignty, genomic research, Indigenous research processes, among others.

## Jennifer Nuk

Jennifer Nuk is a genetic counsellor, clinical coordinator and clinical assistant professor based in Victoria, British Columbia (BC Cancer Hereditary Cancer Program; University of British Columbia Faculty of Medicine Department of Medical Genetics). She holds a Bachelor of Science in Biology from the University of Victoria and a Master of Science in Genetic Counselling from the University of British Columbia.

Current interests include integrating the evolving landscape of hereditary cancer genetic testing in to contemporary service delivery models, enhancing public and health care provider education and increasing access to inclusive genetic services for underserved and diverse populations.

## Claudia Pavao

My name is Claudia Pavao. I am a mom to a 12 year old daughter named Elizabeth and a 9 year old son named Christopher. I have been a Registered Psychiatric nurse for 20 years and currently work at St. Paul's Hospital, downtown Vancouver. I got diagnosed with colo-rectal cancer at the age of 33, when my kids were 18 months and nearly 4. I had radiation, took chemo pills and had surgery. Shortly after this, I found out that I had the lynch syndrome. Luckily I am surrounded by amazing friends and family who have all been a major support to me from day 1! I love life and live it to the fullest! Despite having had cancer at 33, I feel so blessed for this life.

## Moderator: Dr. Karen Gelmon

Karen Gelmon is a Professor of Medicine at the University of British Columbia and a medical oncologist at the BC Cancer, Vancouver Centre. She is Chair of the UBC/BC Cancer Research Ethics Board and a fellow of the Canadian Academy of Health Sciences. She combines clinical care with research focusing on improving outcomes of patients including translational research into prognostic and predictive markers, new therapies and supportive care.  She has been Chair of the BCC Breast Tumour Group, CoChair of the Canadian Clinical Trials Group Breast Site Committee, Chair of the CCTG Investigational Drug Committee and CoChair of the Ontario Institute of Cancer Research Scientific Advisory Board (SAB). She was a member of the SAB of the Susan G

Komen Foundation, the Breast International Group Executive Board and the North American Breast Cancer Group. She is involved in a number of international consensus boards as well as community boards.

## Innovative Clinical Trial Design and Informed Consent

### Dr. Kendall Ho

Dr. Kendall Ho is a practicing emergency medicine specialist and lead, Digital Emergency Medicine. Dr. Kendall Ho was the founding Director of the eHealth Strategy Office until 2015, and was the immediate past Associate Dean of the Division of Continuing Professional Development and Knowledge Translation (CPD/KT) up until February 2008, when CPD/KT was transitioned to two units: Continuing Professional Development (CPD) and the eHealth Strategy Office (eHealth). Dr. Ho is a member of the Royal College of Physicians and Surgeons of Canada's Professional Development Committee and a collaborator with the World Health Organization eHealth Observatory.

He is the executive director of the Technology Enabled Knowledge Translation Investigative Centre (TEKTIC) interdisciplinary research team in BC and the Vice President of the International Association of Humanitarian Medicine. Dr. Ho's academic and research interests fall into the domain of technology enabled knowledge translation (TEKT) – the use of information technologies to accelerate the incorporation of latest health evidence into routine practice. Specific directions within TEKT include telehealth, information and communication technologies (ICT) and patient safety, ICT and public engagement, and evidence-based policy translation in eHealth. He is a recipient of a number of provincial, national, and international research grants in eHealth and eLearning, and has published related papers and textbook chapters in these subjects.

### Dr. Helen Novak Lauscher

Helen has a Doctorate in Educational Psychology with particular focus on human learning, development and culture. Her work at the eHealth Strategy Office involves leading an interdisciplinary research team working on projects in the areas of technology-enabled knowledge translation in health professional practice and education, participatory community-based health research, and program evaluation. Her SSHRC-funded PhD research explored youth empowerment through creative expression and media production.

### Dr. Anita Ho

Anita Ho (PhD, MPH) is currently Clinical Associate Professor at the Centre for Applied Ethics at UBC and a Scientist at the Centre for Health Evaluation and Outcome Sciences (CHÉOS). She is also a faculty member at the UCSF Bioethics Program and the Regional Director of Ethics (Northern California) for Providence St. Joseph Health. She has extensive experience serving on research ethics board, served as a Section Editor on research ethics for BMC Medical Ethics, and directed a Responsible Conduct for Research course at UCSF for the past two years.

An international scholar and author of more than 70 publications, Anita's current research focuses on ethical dimensions of utilizing innovative and artificial intelligence technologies in health care, research and trial design ethics, supportive decision making, and end-of-life care decisions (supported by the Canadian Institutes of Health Research, BC SUPPORT Unit, and St. Paul's Foundation). Her broader research focuses on trust and decision making in clinical and research medicine, particularly around how to ensure equitable research benefits and

burdens among different populations. She is currently completing a book manuscript on AI health monitoring ethics, to be published by Oxford University Press.

### Dr. Hubert Wong

Dr. Wong is the Real-World Clinical Trials Methods Cluster Lead at the BC SUPPORT Unit, an Associate Professor in the UBC School of Population & Public Health. He has over 20 years experience as the lead Biostatistician in clinical trials. His research focuses on developing statistical methodology for pragmatic clinical trials, with a special interest in how clinical trials can be embedded within a Learning Health System and used to support personalized medicine.

### Alicia Murdoch

Alicia is a certified Clinical Research Professional (ACRP-CP) with over 12 years of clinical research experience. Prior to joining Can-SOLVE CKD, she worked as a research coordinator, review manager at a Research Ethics Board (REB) and ethics and regulatory coordinator. Her past employment experiences have given her a wide breadth of knowledge about the research process. In her current role as a Can-SOLVE CKD Network project manager, she is responsible for the Canadian Nephrology Trials Network and Can-SOLVE CKD Network Pediatric Committee, helping these core infrastructures move their initiatives and ideas forward in the pursuit of improving the lives of those affected by chronic kidney disease.

### Linda Riches

Linda is a semi-retired high school performing arts and mindfulness teacher. In addition to volunteering as a patient partner, she volunteers for the RCMP Restorative Justice Program. Linda's first patient partner experience was with Tec4Home. That project has informed subsequent patient partner experiences, including her current one with a focus on pharmacogenomics.

### Jennifer Cordeiro

Jen Cordeiro is a senior research coordinator with Digital Emergency Medicine at UBC. In this role, she translates vision into action by directing the implementation of research studies. Her current portfolio of projects includes evaluating the use of digital health technologies to support patients during the transition of care from hospital to home.

### Moderator: Dr. Caron Strahlendorf

Dr. Caron Strahlendorf is Head of the Division of Pediatric Hematology/Oncology/BMT at BC Children's Hospital and Clinical Professor at the University of British Columbia. She is presently Interim Head of Pediatrics. Caron's research interests include clinical and research bioethics, both cooperative clinical trials and investigator driven quantitative and qualitative clinical research. Additionally, she co-chairs the Children's and Women's Research Ethics Board.