CMEL
THE UNIVERSITY OF HONG KONG
CENTRE FOR MEDICAL ETHICS AND LAW

10 ANNIVERSARY

Regulatory Governance of Genomics & Reproductive Technologies

4-6 December 2023
Hong Kong & ZOOM

11/F, Cheng Yu Tung Tower, Centennial Campus, HKU
& via ZOOM

With support from the Medical Ethics & Humanities Unit (Faculty of Medicine), the Centre for Medical Ethics and Law is delighted to present an international conference that seeks to examine the nature and implications of the regulatory governance of emerging health technologies, with focus on recent developments in reproductive health and genomic medicine. In this connection, we consider the rise of the regulatory state in promoting biomedical research and development (R&D) through the use of direct and indirect rules, and in the variety of regulatory regimes involving non-state actors (e.g., private regulation, self-regulation and civil regulation) that have emerged. Key questions to be addressed at this conference include:

1. What is the "regulatory state" vis-à-vis biomedical R&D, who are the key actors and what are their roles?
2. What is law in the "regulatory state" and what is its contribution to this phenomenon and to biomedical R&D?
3. What is bioethical in the "regulatory state" and what is its contribution to this phenomenon and to biomedical R&D?
4. To what extent are the goals of (2) consistent with those of (3)? How are conflicts (if any) resolved?
5. What are the normative implications of the rise of the "regulatory state" on global governance of biomedical R&D?

Recent advances in genetics and human reproductive technologies continue to present distinctive ethical and legal challenges. For instance, advances in high-throughput sequencing technologies have enabled the detection of chromosomal abnormalities in a foetus through non-invasive prenatal testing (or NIPT). Expanded testing conducted in NIPT has further raised concerns as to whether a child's right to an open future requires parental freedoms to be curtailed. In a research context, it is as yet unclear whether and when actionable genomic results in a research biobank should be returned to an individual or otherwise shared with third parties who could potentially benefit from having access to these results. In this international conference, leading scholars examine the nature and implications of the regulatory governance of emerging genetic and reproductive technologies, as well as the rise of the regulatory state in promoting biomedical research and development (R&D) through the use of direct and indirect rules, and in the variety of regulatory regimes involving non-state actors (e.g., private regulation, self-regulation and civil regulation) that have emerged.

Simultaneous Interpretation in English and Mandarin will be available.

Monday 4 December 2023

Afternoon 14:15-18:15: Advances in Genomics

Evening 19:00-20:30 WYNG-Hatton Lecture 2023

Tuesday 5 December 2023

10:00-18:15: Reproductive Technologies

Wednesday 6 December 2023

Morning 9:15-13:00: Access to Emerging Technologies

Monday 4 December 2023 – Afternoon
Advances in Genomics

14:15-14:30 **Welcome and Introductory Presentations**

Gilberto K.K. Leung。梁嘉傑
Li Ka Shing Faculty of Medicine & Centre for Medical Ethics and Law, The University of Hong Kong

Calvin W.L. Ho。何維倫
Faculty of Law & Centre for Medical Ethics and Law, The University of Hong Kong

14:30-15:00 **Rethinking Governance: Developing a Technology-Agnostic Ethical Governance Framework for Emerging Technology**
Katherine Littler
Health Ethics & Governance Unit, World Health Organization, Geneva

15:00-15:30 **Interpreting the New Ethical Standards in China for Cutting-Edge Science and Technology**
Xiaomei Zhai。翟晓梅
Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing

15:30-16:00 **The Regulatory Role of 'Sufficiency of Disclosure' in Patent Law for Emerging Medical Technologies**

Kathleen Liddell & Mateo Aboy
Centre for Law, Medicine and Life Sciences, University of Cambridge

16:00-16:15 **Intermission**

16:15-16:45 **How International Comparative Law Can Become a Driver for Legal Reform at the National Level: The Example of the International Genetic Discrimination Observatory**
Yann Joly
Centre for Genomics and Policy, McGill University, Montréal

16:45-17:15 **Are Synthetic Health Data 'Personal Data'? Whether, or in What Circumstances, Synthetic Health Data might be Considered 'Personal Data' under the UK and EU GDPR**
Colin Mitchell
PHG Foundation, University of Cambridge

17:15-17:45 **Participatory Governance in Genomics Research: Return of Results and Group Consent**
Chih-Hsing Ho。何之行
Institute of European and American Studies, Academia Sinica, Taipei

17:45-18:15 **Indigenous Research Ethics Governance in Japan and Its Implications for Genomics**
Momoko Sato。佐藤桃子
Laboratory for Biomedical Ethics and Co-Design, RIKEN, Tokyo

Monday 4 December 2023 – Evening
WYNG-Hatton Lecture 2023

19:00-20:30

Smart Regulation for Medical Innovation

Sir Jonathan Montgomery

Faculty of Laws, University College London

Commentators:

Wei Zhu。朱伟
Applied Ethics Center and Department of Social Sciences, Fudan University

Ping Ji。吉萍
Clinical Research Institute, Shenzhen-PKU-HKUST-Medical Center, Shenzhen

20:30-21:30 Dinner
(for registered attendees of the WYNG-Hatton Lecture)

Tuesday 5 December 2023
Reproductive Technologies

10:00-10:15 **Introductory Remarks**

Gilberto K.K. Leung。梁嘉傑
Li Ka Shing Faculty of Medicine & Centre for Medical Ethics and Law, The University of Hong Kong

Calvin W.L. Ho。何維倫
Faculty of Law & Centre for Medical Ethics and Law, The University of Hong Kong

10:15-10:45 **Exploring Different Approaches to Governance**
Jane Kaye
Centre for Law, Health and Emerging Technologies (HeLEX), University of Oxford

10:45-11:15 **Ethical Framework/Approach for the Hong Kong Genome Project**
Derrick Au。区结成
Honorary advisor, Centre for Bioethics, the Chinese University of Hong Kong / Convenor of EAC, Hong Kong Genome Institute

11:15-11:30 **Intermission**

11:30-12:00 **Governance of Embryo-like structures**
Sarah Chan
The Usher Institute, University of Edinburgh

12:00-12:30 **Embryo Research, 'The 14 Day Rule', and the Political Morality of Legislation**
Sir Jonathan Montgomery
Faculty of Laws, University College London

12:30-14:00 **Lunch**

14:00-14:30 **Regulating Technologies of Reproduction**
Catherine Mills
School of Philosophical, Historical and International Studies, Monash University, Melbourne

14:30-15:00 **Mitochondrial Donation – The Australian Story**
Bernadette Richards
Academy of Medical Education, University of Queensland, Brisbane

15:00-15:30 **Personalist (Dignitarian) Approach to the Governance of Reprogen Medicine**
Joseph Tham。譚傑志
School of Bioethics, Regina Apostolorum Pontifical University, Rome

15:30-15:45 **Intermission**

15:45-16:15 **Implementing New Genomic Sequencing Technologies at the Start of Life: The Importance of Bioethics to Regulatory Processes**
Ainsley Newson
Sydney Health Ethics, Sydney School of Public Health

16:15-16:45 **Confucian reflection on the new Reproductive Model of ROPA**
Yonghui Ma。马永慧
Center for Bioethics, School of Medicine, Xiamen University

16:45-17:00 **Intermission**

17:00-17:30 **The Impossibility and Inevitability of Innovation in Human Reproductive Biology: Norms and Limits**
Peter Mills
PHG Foundation, University of Cambridge

17:30-18:00 **The Future of Human Reproduction**
Sara J. Fovargue
Sheffield Law School

18:00-18:15 **Closing Remarks**

Wednesday 6 December – Morning
Access to Novel Technologies

09:15-09:30 **Introductory Remarks**

Gilberto K.K. Leung。梁嘉傑
Li Ka Shing Faculty of Medicine, & Co-Director, Centre for Medical Ethics and Law, The University of Hong Kong

Calvin W.L. Ho。何維倫
Faculty of Law & Centre for Medical Ethics and Law, The University of Hong Kong

9:30-10:00 **Patient Involvement in Research and Access to Benefits**
Kaori Muto。武藤香织
Institute of Medical Sciences, University of Tokyo

10:00-10:30 **The Evolving Landscape of Novel Technologies in Australia: We know where we're going, but how will we get there?**
Matilda Haas
Australian Genomics, Melbourne

10:30-11:00 **Governance of Reproductive Technologies in Hong Kong**
Olivia Ngan。顏妙融
Medical Ethics & Humanities Unit, Li Ka Shing School of Medicine, The University of Hong Kong

11:00-11:15 **Intermission**

11:15-11:45 **Ethical Issues facing Insurers in the Changing Landscape**
Caitlyn A. Tabor
Center for Law, Brain & Behavior, Harvard Medical School, Cambridge, MA

11:45-12:15 **Ethical and Legal Challenges facing the Translation of Polygenic Scores into Healthcare**
Tanya Brigden
PHG Foundation, University of Cambridge

12:15-12:45 **Challenges to Equitable Sharing of Benefits in mHealth Research**
Barry Solaiman
College of Law, Hamad Bin Khalifa University, Doha

12:45-13:00 **Closing Remarks**

13:00-14:30 **Lunch**

Conference Chair
Gilberto K.K. Leung。梁嘉傑

Tsang Wing-Hing Professor in Clinical Neuroscience & Associate Dean (Teaching & Learning), Li Ka Shing Faculty of Medicine, & Co-Director, Centre for Medical Ethics and Law, Faculties of Law & Li Ka Shing Faculty of Medicine, The University of Hong Kong, Hong Kong

Professor Gilberto K.K. Leung is Tsang Wing-Hing Professor in Clinical Neuroscience at the University of Hong Kong (HKU) and Honorary Consultant Neurosurgeon at Queen Mary Hospital. He graduated from the University of London with M.B.B.S. and Intercalated BSc in Physical Anthropology in 1992. He joined HKU in 2005 where he obtained his MS and PhD. He holds an LLB from the University of London, and an LLM in Medical Law and Ethics with Distinction from the University of Edinburgh. He is currently President of the Hong Kong Academy of Medicine, Associate Dean (Teaching & Learning) of his medical faculty, and Co-Director of the Centre for Medical Ethics and Law at HKU. His clinical and research interests cover endoscopic neurosurgery, molecular biology of brain tumours, neuroprotective therapy, medical education, and medical law and ethics.

Conference Chair
Calvin W.L. Ho。何維倫

Associate Professor of Law & Co-Director, Centre for Medical Ethics and Law, Faculties of Law and Medicine, The University of Hong Kong, Hong Kong

Dr Calvin Ho's research is on global health law and ethics, and the governance of health and biomedical technologies (with focus on health technologies based on Artificial Intelligence and data analytics). He is Co-Chair of the Expert Group on the Ethics of Social Listening and Infodemic Management, as well as a member of the COVID-19 Ethics & Governance Working Group of the World Health Organization (WHO). Calvin is also an Ethics Board member of Médecins Sans Frontières (Doctors Without Borders), and a member of the Regulation and Ethics Work Stream of the Global Alliance for Genomics & Health. He was one of the contributing authors of the WHO's *Guidelines on Ethical Issues in Public Health Surveillance* that was published in 2017.

Rethinking Governance: Developing a Technology-Agnostic Ethical Governance Framework for Emerging Technology

Monday 14:30-15:00

Abstract to follow

Katherine Littler

Co-Lead, Health Ethics & Governance Department of Research for Health Science Division, World Health Organization, Geneva

Katherine Littler is the Co-Unit Head of the Health Ethics & Governance Unit at WHO in Geneva, Switzerland. She focuses on the intersection of ethics, governance and policy in global health. Whilst a lot of her recent focus have been on pandemic-related work, she has responsibility for a broad portfolio, including: realizing the potential benefits of emerging technologies in different settings; research ethics, with a focus on priority setting and advancing equity and inclusion in research; governance, ethics oversight and clinical trial design; and climate change, health, and ethics. Prior to joining WHO in October 2018, Katherine led the Global Policy Team at Wellcome, where she provided strategic advice on regulatory, governance and ethical issues.

Interpreting the New Ethical Standards in China for Cutting-Edge Science and Technology

Monday 15:00-15:30

This presentation will examine the process of institutionalisation and capacity building of scientific research ethics review committees (ERCs) in mainland China. The establishment of ERCs by Chinese research institutions in the mid-1990s was primarily driven by the necessity of international cooperation. It was not until 17 January 2007 that the Ministry of Health (MOH) issued the *Measures for Ethical Review of Biomedical Research Involving Humans (Clinical Trials)*, which advanced the institutionalization of ERCs. With the promotion of the MOH, this institutionalisation process progressed rapidly across the country. However, it is evident there is still a need to further strengthen the capacity of ERCs. This presentation will discuss the findings of a national survey that was conducted in 2009 to evaluate the work and capacity of ERCs. It then considers policy measures that were taken to harmonise standards by various ministries and commissions and to strengthen capacity, with focus on the Ethical Review Requirements jointly signed by four ministries and commissions (including the MOH / the National Health Commission (as it is now known)) in 2022.

Xiaomei Zhai・翟晓梅

Distinguished Professor, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing

Professor by special appointment, Doctor of Philosophy, and PhD supervisor at Peking Union Medical College, Chinese Academy of Medical Sciences. Member of the Chinese Academy of Medical Sciences, Member of the National Science and Technology Ethics Committee, Deputy Director of the Medical Ethics Expert Committee of the National Health Commission, Member of the Science and Technology Ethics Committee of the Ministry of Education, and Chairman of the Life Ethics Professional Committee of the Natural Dialectics Research

Association of the China Association for Science and Technology. Member of the WHO Global Committee on Gene Editing Ethics and the International Society for Stem Cell Research. She is an elected fellow of the Hastings Center in the United States. She is the deputy editor of the magazine "Health Care Science" and also serves as an editorial board member and reviewer for certain academic publications both internationally and domestically. She has a significant influence in the academic field, with publications of academic works, translations, and edited works, as well as numerous academic papers in both Chinese and English.

The Regulatory Role of 'Sufficiency of Disclosure' in Patent Law for Emerging Medical Technologies

Monday 15:30–16:00

Patent law is often thought of as a niche field best left to experts. However, it plays an important role in the regulation of emerging medical technologies. By providing a market-based incentive in return for public disclosure of a new invention, it too is a strategic policy that seeks to influence human behaviour to avoid economic, social and moral problems that result from 'free' unregulated interactions. Understanding how it does that, and influencing its evolution, are key factors for the future of the 'regulatory state' surrounding biomedical R&D and emerging health technologies. The first part of our forthcoming chapter explains the regulatory role of patents. It then examines the intentions behind a particular cluster of patent rules in this regulatory domain known in some countries as 'sufficiency of disclosure' (eg Europe) and 'written description' and 'enablement' in others (eg the United States). These rules have been the subject of considerable debate for emerging technologies including genetic-engineering. This is considered alongside the authors' recent empirical evidence that shows related issues looming in medical AI. Drawing on experiences in genetic engineering, we conclude with two recommendations to improve the regulatory role of disclosure and enablement in patent law for medical AI.

Kathleen Liddell

Professor of Intellectual Property and Medical Law, & Director, Centre for Law, Medicine and Life Sciences, University of Cambridge

Professor Kathy Liddell is the Director of the Centre for Law, Medicine and Life Sciences (LML), and the Herchel Smith Professor of Intellectual Property and Medical Law at the Faculty of Law, University of Cambridge. Her research focuses on innovations in health, medicine and society, with the aim of understanding and improving the legal frameworks that govern and support these fields. Professor Liddell has been a principal investigator in several large projects and consultancies on intellectual property and emerging health technologies, including in relation to genomics, precision medicine, repurposing pharmaceuticals, and antimicrobial resistance. Her expertise also extends to other areas of life sciences including national and international regulation of clinical trials, medical negligence, biomaterials (including human tissue, cells, organs), pharmaceuticals, diagnostics, and regenerative medicine. She studied law and natural sciences at the University of Melbourne before undertaking her doctorate in law at the University of Oxford and a Masters of Bioethics at Monash University. In addition to academia, Professor Liddell has worked in private legal practice and in the civil service.

Mateo Aboy

Director of Research in Biomedical Innovation, AI & Law, Centre for Law, Medicine and Life Sciences, University of Cambridge

Professor Mateo Aboy's multidisciplinary background includes a combination of engineering, law, regulatory science, and management experience. He holds degrees in electrical & computer engineering (PhD ECE), law (SJD/PhD), and international management (MBA), as well as a number of professional licenses and certifications (eg USPTO Patent Bar, CEng, CLP, CIPP/E, CIPM, IAPP FIP). His research investigates the intersection of digital innovation, IP policy and economics of healthcare by exploring the key tenets of innovation with a focus on the digital health, biotech, and pharmaceutical industries. This includes investigating the transformation of medical technology, drug development and healthcare delivery, as well as the associated legal, regulatory, policy and strategy questions raised by the growth of medical AI/ML/QC and biotech innovations for personalised medicine. Professor's Aboy research seeks to understand the drivers of technology-based innovation, IP incentives, and the determinants of how emergent medical technologies are protected, regulated, funded, developed, adopted and used in practice. He is the author of more than 150 scholarly articles published in leading scientific, engineering and legal journals, including Nature Biotechnology, IEEE Transactions of Biomedical Engineering, Medical and Biological Engineering & Computing, Medical Engineering & Physics, and the Journal of Law & the Biosciences.

How International Comparative Law can become a Driver for Legal Reform at the National Level: The Example of the International Genetic Discrimination Observatory

Monday 16:15–16:45

Academic legal scholarship is often critiqued for being disconnected from the reality of legal implementation and 'on grounds' of lacking legal impact. This critique becomes even more poignant when directed at international human rights law, a field that is still not fully recognized by legal positivists. This presentation confronts this critique and argues to the contrary. Drawing upon the experience of the International genetic discrimination observatory (GDO), a recognized comparative legal research network, it will propose that there exists much underexploited potential to use international law and policy to stimulate legal reform at the national level. Since its inception in 2017, the GDO has already achieved much in terms of capacity building and domestic legal reform in several participating member countries. This presentation will review the accomplishments of the GDO, identify some of the key challenges faced, and posit opportunities for legal comparatists to better use the power of human rights law and policy to stimulate legal reform at the national level.

Yann Joly

Professor & Director, Centre for Genomics and Policy, McGill University, Montréal

Yann Joly, PhD (DCL), FCAHS, AdE is the Director of the Centre of Genomics and Policy (CGP) at McGill University. He is a James McGill Professor at the Faculty of Medicine and Health Sciences, Department of Human Genetics. Prof. Joly is also an associate member of the Bioethics Unit and at the Law Faculty at McGill. He was named advocatus emeritus by the Quebec Bar in 2012 and Fellow of the Canadian Academy of Health Sciences in 2017. He is the current Chair of the Bioethics Workgroup of the International Human

Epigenome Consortium (IHEC) and Co-Leads the Regulatory and Ethics Work Stream of the Global Alliance for Genomics and Health (GA4GH). He was Chair (2017–2019) of the Ethics and Governance Committee of the International Cancer Genome Consortium (ICGC). Prof. Joly's research interests lie at the interface of the fields of scientific knowledge, health law (biotechnology and other emerging health technologies) and bioethics. He created the first international genetic discrimination observatory in 2018. He has published his findings in over 200 peer-reviewed articles featured in top legal, ethical and scientific journals.

Are Synthetic Health Data 'Personal Data'? Assessing the Status of Synthetic Health Data in EU and UK Data Protection Law

Monday 16:45–17:15

Synthetic data—artificial data that closely mimic the properties and relationships of real data—have the potential to streamline and empower scientific research and development of novel health technology. However, there is considerable uncertainty about the regulatory status of synthetic data generated from real patient data. In particular whether, or under what conditions, synthetic health data will be considered 'personal data' governed by data protection law (the UK GDPR and EU GDPR). This presentation explores this question, drawing on research working closely with developers at the UK's Medicines and Healthcare products Regulatory Agency (MHRA). We discuss a crystalising cautious regulatory approach which treats synthetic data as presumptively 'personal data' in many circumstances, and question some of the assumptions made and balance struck in adopting such an approach. We make recommendations that regulators and policymakers should prioritise consideration of an appropriate regulatory response for this sector and how it fits within the wider legal framework.

Colin Mitchell

Head of Humanities, PHG Foundation, University of Cambridge

Colin is Head of Humanities at the UK based health policy think tank, the PHG Foundation, which is part of the University of Cambridge. He leads a team addressing legal and ethical issues that arise with genomics innovations. This includes challenges associated with genomic data processing, artificial intelligence and the obligations of health and scientific professionals in the contemporary biomedical landscape. Colin has a PhD in health law from the University of Amsterdam, a Masters of Studies in Legal Research from the University of Oxford and a BA in Law from the University of Cambridge.

Participatory Governance in Genomics Research: Return of Results and Group Consent

Monday 17:15–17:45

This presentation investigates the implementation of participatory governance in genomics research, with a focus on two examples-- the Taiwan Precision Medicine Initiative (TPMI) and the group consent requirement for Taiwanese aborigines involved in biomedical research. As genomics research advances, ethical considerations surrounding the return of individual results and the acquisition of informed consent from participant groups have become increasingly complex. The talk examines the TPMI as a case study for genomics research, exploring its approach to returning results, ethical implications, and impact on individuals and families. Simultaneously, the research

delves into the unique context of Taiwanese aborigines, emphasizing the significance of group consent within this cultural framework. Analyzing the challenges and opportunities presented by participatory governance in this specific context, the study contributes to the ongoing discourse on ethical practices in genomics research.

Chih-Hsing Ho・何之行

Associate Research Fellow, Institute of European and American Studies, Academia Sinica

Dr Chih-hsing Ho holds the position of Associate Professor and Associate Research Fellow at the Institute of European and American Studies, with a joint appointment at the Research Center for Information Technology Innovation, both at Academia Sinica in Taiwan. Her research revolves around the convergence of law, medicine, and data science, with a specific emphasis on genomics and emerging technologies such as biobanks, big data, and artificial intelligence. Leveraging her expertise, she serves in advisory and consulting roles as a legal and academic expert. She has been appointed to the Steering Committee on Digital Health, Technology Policy Advisory Committee, and the Advisory Committee on Biotechnology Regulatory Law and Strategies for the Ministry of Health and Welfare (MOHW) in Taiwan. She is a member on the Ethics and Governance Council of Taiwan Biobank, the Institutional Review Board (IRB) for the Taiwan Centers for Disease Control (CDC) and the Consultation and Review Board of the National Biobank Consortium of Taiwan.

Indigenous Research Ethics Governance in Japan and its Implications for Genomics

Monday 17:45-18:15

Current genomic technologies enable various studies of human remains including ancestry and migration research. In Japan, although past excavations of Ainu human remains have been condemned, Japanese research regulations have not recognized the need to address ethnic minorities. Therefore, the Ainu Association of Hokkaido and three anthropology and archaeology academic societies recently drafted the Ethical Guidelines for Research on Ainu People. In discussions of research on Ainu people, it is consistently claimed that the “dissemination of research results” is necessary. In this presentation, this characteristic concept will be analyzed through the records of these discussions and through comparison with the legal regulations in Taiwan. This presentation will also overview how the current direct-to-consumer genetic ancestry testing and population genetics trend in Japan is, or is not, related to the country’s Indigenous people. Through this outline, the gap between the situation and the draft guidelines will be identified. Although these guidelines address several important components of community-based research, such as consultation with the communities, it remains critical to monitor research practices as it is unclear how genomic researchers will react to the draft guidelines.

Momoko Sato・佐藤桃子

Laboratory for Biomedical Ethics and Co-Design, Center for the Integrative Medical Sciences, RIKEN, Tokyo

Momoko Sato graduated in Interdisciplinary Sciences, College of Arts and Sciences Senior Division, at the University of Tokyo in 2015, and received her

master’s degree in Interdisciplinary Information Studies from the same university in 2017. While she takes a doctoral course at the University of Tokyo, she works for the RIKEN Center for the Integrative Medical Sciences, the Laboratory for Biomedical Ethics and Co-Design. Her main research interest is ethical, legal, and social issues (ELSI) of genomic research on ethnic minorities.

WYNG-Hatton Lecture 2023:
Smart Regulation for Medical Innovation

Monday 19:00-20:30

Medical innovation is desirable for clinical and economic reasons, but there is no consensus on the best regulatory approach to promote it. The paradigm for the regulation of medical research is a gatekeeping system but in the era of increasingly personalised medicine and rapid technological development, this is perceived by some as an anachronistic barrier to scientific advance, an unjustified bureaucratic cost, and a mechanism that frustrates consumer expectations. Yet, in the absence of the regulatory protection that obtaining permission provides, patients may face unacceptable risks and innovators are exposed to unreasonable risk of civil and criminal liability should mishaps occur. A series of UK court decisions on innovative treatments for young people, including Pentosan Polysulphate treatment for nvCJD (Simms), Proton Beam Therapy (King) nucleoside therapy (Gard), puberty blockers (Tavistock) have exposed the vices that undermine trust in innovation but also help us to identify the virtues that responsible innovators should display. Smart regulation is required to promote those virtues without creating unnecessary bureaucratic hurdles. An unwieldy system of prior ethics committee approval can be avoided if we can use markers of trustworthiness as a basis of the licence to innovate.

Sir Jonathan Montgomery

Professor of Health Care Law, Faculty of Laws, University College London;
Chair, Ethics Advisory Committee of Genomics England

As Chair of the Health Research Authority (2012-19) he was responsible for the oversight of research ethics approvals in England; working to reduce regulatory complexity and improve research integrity in order to protect the interests of the public, participants and patients. He was Chair of the Nuffield Council on Bioethics, the UK's national ethics committee, from 2012-17 and of the UK Human Genetics Commission from 2009-12. During the COVID pandemic, he was co-chair of the Moral and Ethical Advisory Group to the UK Chief Medical Officers and chair of the Ethics Advisory Board to NHSX on its Contact Tracing App. He was elected Honorary Fellow of the Royal College of Paediatrics and Child Health in 2005, Honorary Fellow of the Faculty of Public Health in 2023, and Fellow of the Academy of Medical Sciences in 2021. He was made Knight Batchelor for services to Bioethics and Health Care Law in the 2019 New Years Honours.

Commentators:

Wei Zhu · 朱伟

Associate Professor, Applied Ethics Center and Department of Social Sciences, Fudan University

Dr Wei ZHU is Associate Professor at Center for Applied Ethics, Fudan University and Vice-Chair of Shanghai Ethics Committee for Clinical Research (SECCR). She is also Fellow of the Hastings Center, the U. S. A and Guest Professor at Center for Ethical Studies, Renmin University of China. She has a background in bioethics, with specific training and expertise in research ethics and ethical oversight systems for research in developing countries. Her research areas include genetic ethics, informed consent in multi-cultural context, justice in health resource distribution and human rights. She is the member of several ERBs at Fudan University and other major hospitals and research

institutions. She is currently working on two research ethics projects (PREPARED and iRECS), which is sponsored by HORIZON.

Ping Ji・吉萍

Deputy Director, Clinical Research Institute, Shenzhen-Peking University-The Hong Kong University of Science and Technology Medical Center, Shenzhen

Dr Ping Ji began her clinical research career as medical writer and monitor for industry in China after obtaining her PhD in 2006 at Cardiff University, UK. She developed her interests in medical research ethical review and human subjects protection since 2010. She took the role as director of Quality Assurance Office in Peking University Human Research Protection Program by 2016. Since 2016, she moved to Shenzhen for building clinical research support and supervision platforms for education & training, technological support, ethical review, and policy development with the support from the local health authority. Together with her colleagues, her team has made great achievements on developing regional clinical research infrastructure.

Exploring Different Approaches to Governance — Tuesday 10:15–10:45

Adaptive governance is an approach that has been used for environmental issues to bring in a range of stakeholders who have different interests in a shared resource such as water. This paper will discuss how adaptive governance compares with other approaches to governance, and how it might be used in when considering emerging technologies in health. The intention is to provide an outline that can stimulate discussion.

Jane Kaye

Professor & Director of the Centre for Law, Health and Emerging Technologies (HeLEX) in the Faculty of Law, the University of Oxford

Prof Jane Kaye is the Director of the Centre for Law, Health and Emerging Technologies (HeLEX) in the Faculty of Law at the University of Oxford and also has a Professorship at Melbourne Law School at the University of Melbourne, Australia. Professor Kaye obtained her degrees from the Australian National University (BA); University of Melbourne (LLB); and University of Oxford (DPhil). Her research team consist of lawyers and sociologists who use mixed-method empirical approaches to explore the relationships between law, governance and best practice in the field of emerging technologies in health. The main focus of Professor Kaye's research is on digital technologies, AI, personalised medicine, biobanks, privacy, informational governance, dynamic consent and translational research. Professor Kaye is the lead PI on the AIDE project, which is identifying ways to engage stakeholders in the implementation of AI in healthcare (ESRC 2019-23). She is on a number of scientific advisory boards and editorial boards.

Ethical Framework/Approach of The Hong Kong Genome Project, and Selected Issues Addressed — Tuesday 10:45–11:15

In May 2020, the Hong Kong Genome Institute ("HKGI") was established by the HKSAR government to lead and implement the Hong Kong Genome Project ("HKGP"), aiming to cover 20,000 cases and sequence 50,000 genomes in six years. The pilot phase started in mid-2021 after a year of preparation. This presentation looks at the issues addressed by the Ethics Advisory Committee ("EAC"), which together with other 5 committees form the governance structure of the HKGP. In particular, the challenges of informed consent, adolescent assent, and report of secondary findings are discussed. Reflections on the participatory process of the EAC are made from the position of the Convenor of the committee.

Derrick Au・区结成

Centre for Bioethics, Faculty of Medicine, The Chinse University of Hong Kong

Dr Au is Honorary Advisor and Ex-Director of the Centre for Bioethics at The Chinese University of Hong Kong (CUHK), current Convenor of the Ethics Advisory Committee of the Hong Kong Genome Institute. He received medical education at Brown University in the US and postgraduate training in geriatric medicine in Hong Kong. Dr Au has served in clinical service in geriatrics and rehabilitation before taking up various management positions in the Hospital Authority (HA), including Director of Quality & Safety. Dr Au

is also a writer and columnist with publications on bioethics, professional ethics, and history of medicine.

Governance of Embryo-like structures — Tuesday 11:30-12:00

Abstract to follow

Sarah Chan

Chancellor's Fellow in Ethics and Science Communication, The Usher Institute, University of Edinburgh

Dr Sarah Chan is a Reader in Bioethics at the Usher Institute, University of Edinburgh and an Associate Director of the Centre for Biomedicine, Self and Society. Previously, from 2005 to 2015, she was a Research Fellow in Bioethics at the University of Manchester, first at the Centre for Social Ethics and Policy and from 2008 the Institute for Science Ethics and Innovation. Sarah's research focuses on the ethics of new biomedical technologies, including gene therapy and genetic modification; stem cell and embryo research; reproductive medicine; synthetic biology; and human and animal enhancement. Her current work draws on these interests to explore the ethics of emerging modes of biomedicine at the interface of health care research, medical treatment and consumer medicine, including genetics and neurotechnologies; ''big data' and artificial intelligence; the use of human biomaterials in both research and treatment; and access to experimental treatments and medical innovation.

Embryo Research, 'The 14 Day Rule', and the Political Morality of Legislation — Tuesday 12:00-12:30

The UK's '14 day rule' (more accurately the 'primitive streak' rule) is best understood as a political tool that reserves the authority to the legislature to alter the parameters of research that the statutory regulator can authorise. This precludes a case by case approval mechanism for later-stage embryo research and requires arguments for reform that will convince a political rather than scientific or expert audience. As suggested by the Dutch recommendations of October 2023, this makes societal acceptance and public trust essential foundations for legal change. Achieving this requires a strong scientific case that it will lead to knowledge creation of practical implementation and also that robust regulatory boundaries can be maintained. To achieve this, UK law will need to break the connection that it makes between time limits and biological markers of embryo development.

Sir Jonathan Montgomery

Professor of Health Care Law, Faculty of Laws, University College London; Chair, Ethics Advisory Committee of Genomics England

Regulating Technologies of Reproduction — Tuesday 14:00-14:30

The literature around the regulation of reproduction has often focused on the ways that regulation centres and controls the maternal body, usually in inequitable and unjust ways. What I want do in

this paper is focus more specifically on the relationship between regulation and the *technologies* of reproduction: that is, the technologies themselves rather than reproduction, whether as part of broader family-making practices or in terms of the medical assistance of it. To do this, I focus on the highly fragmented regulatory environment in Australia. While most health and family law in Australia is state-based, in the early 2000s, a piece of federal legislation was introduced in response to the birth of Dolly the sheep in Scotland. This legislation, The Prohibition of Human Cloning in Reproduction Act 2002, prohibits certain practices in relation to embryos so as to foreclose the development of certain capacities or technologies, including human cloning, inheritable gene editing and mitochondrial donation. In regards to the last of these, the legislation has recently been amended to allow mitochondrial donation. This legislation is interesting from the perspective of regulating technologies of reproduction, because it exemplifies the multi-layered relationship between regulation and technology, including the role of social norms, bioethics, community interests and commercial interests. In disentangling some of these layers, I suggest that concepts of biopolitics and biocapital may be useful in articulating the role of regulation vis-a-vis technologies of reproduction.

Catherine Mills

Professor & Head of the School of Philosophical, Historical and International Studies, Monash University, Melbourne

Catherine Mills is Head of the School of Philosophical, Historical and International Studies (SoPHIS) at Monash University. She was previously Director of the Monash Bioethics Centre. Her disciplinary background is philosophy, and her research addresses ethical, social and regulatory issues that emerge around biomedical and technology innovation in human reproduction. She also has expertise in feminist philosophy and aspects of Continental philosophy, particularly the work of Michel Foucault, and debates on biopolitics. She is the author of three single author books, as well as numerous articles and book chapters. Her books are: The Philosophy of Agamben (2008), Futures of Reproduction: Bioethics and Biopolitics (2011) and Biopolitics (2018). She was also co-editor of the Routledge Handbook of Feminist Bioethics (2022). She leads the Reproductive Biomedicine and Technology Ethics group in the Monash Bioethics Centre. She has received competitive grant funding from major national and international funding agencies, including ARC, NHMRC, MRFF and Wellcome Trust. Industry funders include Illumina, Monash IVF and Ferring Pharmaceutical.

Mitochondrial Donation, The Australian Story — Tuesday 14:30–15:00

The landscape of healthcare is perpetually changing, with new and innovative treatment techniques constantly emerging. We are also improving the ability to investigate (and prevent) specific inherited conditions through pre-implantation diagnosis and other medical interventions. One such category of medical intervention is mitochondrial donation, which up until recently was prohibited in Australia but is now regulated by a staged licensing scheme and supported by ethical guidelines. This regulatory reform began with an Australian Senate inquiry which led to the National Health and Medical Research Council (NHMRC) being tasked with facilitating public consultation and the canvassing of expert advice on relevant legal, regulatory, scientific and ethical issues. This paper will consider the ethical and regulatory challenges that were addressed during the law reform process and provide insight into the new regulatory framework, thus serving as a practical demonstration of the challenges facing the regulators of emerging health technologies.

Bernadette Richards

Assoc Professor, Academy of Medical Education, University of Queensland, Brisbane

Bernadette is currently Associate Professor of Ethics and Professionalism, and Theme Lead – Kind and Compassionate Professional, in the Academy for Medical Education at the University of Queensland Medical School. Prior to that she was working on the Future Health Technologies Project at the Singapore ETH Centre, exploring trustworthy data governance and Assoc Prof of Law at Adelaide Law School, the University of Adelaide. She is a member of the NHMRC's Australian Health Ethics Committee and Embryo Research Licensing Committee and was a member of the South Australian Voluntary Assisted Dying Taskforce. She Chaired the Mitochondrial Donation Expert Working Committee and was involved in drafting of the new law. Until recently, Bernadette was President of the Australasian Association of Bioethics and Health Law (AABHL), and has completed major projects on organ donation, consent to treatment and legal issues around innovative surgery. She is a chief investigator on three major grants, exploring innovation in Healthcare and her co-authored book, 'Technology, Innovation and Healthcare: An evolving relationship' was published in February 2022 and she has over 90 other scholarly publications.

Personalist (Dignitarian) Approach to the Governance of Reprogen Medicine

Tuesday 15:00-15:30

This paper will first analyze the different notions of personhood and dignity in contemporary debates in philosophy and bioethics. These questions touch on the foundation of identity and selfhood from the viewpoints of essence, nature and metaphysics, and in contrast with those of changing human experience and existence. These two positions, or "Sources of the self" according to Charles Taylor, have great significance on the human reproductive act. The essentialist position conceives dignity as derived from the natural sex act, where love and life are intrinsically bound while rejecting physicalism. The latter existentialist position does not preclude the making of life through technology, where sexuality and gender can take on various expressions. Most traditional religions espouse the essential view of self and generation in contrast with the secular tendency towards existential or ¨liquid¨ understanding of self and reproduction. Regarding the governance of reprogen technologies, the use of embryos is politically linked to the debate on abortion, as we see in the US Hyde amendment. In terms of governance, the unsettled questions are therefore: a) embryo status, human dignity and vulnerability at the beginning of life; b) safety of reporgen technologies at the individual level and potential impact on society and future generations; c) fairness in terms of racial, geographical and economical difference affecting the access of such technologies especially in view of the distribution problem of the COVID vaccine; d) transhumanism and its endpoint in view of perfectionism and ablism; and finally e) the place of religions and traditions in a globalized bioethics. Simply put, the dignitarian approach asks: "What does it mean to be human?" and "What does it mean to love?"

Joseph Tham。譚傑志

Professor, School of Bioethics, Regina Apostolorum Pontifical University, Rome

Fr S. Joseph Tham was born in Hong Kong and immigrated to Canada at the age of fifteen. At the University of Toronto, he first majored in Mathematical

Sciences and then graduated from Medical School. After several years of work as a family physician, he entered the seminary of the Legionaries of Christ and was ordained a priest in 2004. As a part of this preparation, he has obtained his degrees in philosophy and theology at Rome's *Regina Apostolorum* Pontifical university, where he also completed his post-graduate studies in bioethics. He successfully defended his doctoral dissertation with high honours on "The Secularization of Bioethics—A Critical History" under the direction of Dr Edmund Pellegrino, former Chairman of the President's Council on Bioethics. He is former dean of the School of Bioethics in *Regina Apostolorum* where he presently teaches bioethics. He is a Fellow of the UNESCO Chair in Bioethics and Human Rights. He is the author and editor of numerous articles and books, including *Sexuality, Gender and Education* (2018), *Religious Perspectives on Social Responsibility in Health* (2018), *Interreligious Perspectives on Mind, Genes and the Self* (2018) and *Cross-Cultural and Religious Critiques of Informed Consent* (2021), and *Enhancement fit for Humanity* (2022).

Implementing New Genomic Sequencing Technologies at the Start of Life: The Importance of Bioethics to Regulatory Processes

Tuesday 15:45-16:15

Like many countries, Australia is currently seeing a rapid increase in the availability and uptake of genomic sequencing technologies, including at the start of life. A large research trial of reproductive genetic carrier screening has just concluded, and projects are also underway to pilot the use of genomics in newborn screening. Alongside, non-invasive prenatal testing has rapidly gained traction despite no public funding. Central to the successful implementation of new technologies is endorsement from government bodies, such as funding committees. These processes draw heavily on Health Technology Assessment (HTA). While there is a well-established literature on ethics in HTA, this is less focused on genomic sequencing technologies and even less again on their use in a screening context. What should the role of bioethics be here? Drawing on recent determinations in Australia, this paper will reflect on the need for a more robust and more embedded role for bioethics in the regulatory state when it comes to the health system rollout of genomic sequencing technologies such as preconception, prenatal and newborn screening. Embedding ethics in early processes that inform the future rollout of genomic sequencing technologies will help ensure their ethical implementation and mitigate individual and group-level harms.

Ainsley Newson

Professor of Bioethics, Sydney Health Ethics, Faculty of Medicine and Health, University of Sydney

Ainsley Newson is Professor of Bioethics at Sydney Health Ethics, Faculty of Medicine and Health, University of Sydney, Australia. She has been active in the field of bioethics for over 25 years and has worked in Australia and the United Kingdom. Ainsley's research critically considers ethical issues in genomics and human reproduction, specifically how these technologies can be used well across research, clinical and population health settings. Her current research projects are addressing reproductive autonomy in light of expanded genomic testing in pregnancy, ethical governance of genomic data, and ethical issues in genomic newborn screening. Her work has led to over 140 peer-reviewed papers, book chapters and commentaries. Ainsley is a Board member of the International Association of Bioethics, a member of the Australian Health Ethics Committee and Australia's Gene Technology Ethics and Community Consultation Committee. In 2022 Ainsley founded AusGenELSI, a research network that aims to bring people together to consider ethical, legal and social issues in genomics in Australia. Ainsley is a keen supporter of early and mid-career scholars in bioethics.

Confucian reflection on the new Reproductive Model of ROPA

Tuesday 16:15–16:45

An increasing number of countries are legalizing same-sex marriage and allowing assisted reproductive technologies such as ROPA (Reception of Oocytes from Partner) for same-sex couples. In recent years, a case in Xiamen, China, involved a dispute over custody rights between a female same-sex couple who used the ROPA method to conceive a child, bringing this unique reproductive model into the public eye. How can China, where access to ART is exclusively limited to heterosexual married couples as a medical treatment for infertility, and where same-sex marriage is still illegal, respond to this case? Western scholars have argued for the legitimacy and justification of the ROPA method from the perspectives of freedom and rights. Confucian ethics have profound influences on the Chinese people's views on reproduction and family. This paper starts with an overview of the reproductive model of ROPA and comparing it with other reproductive models, such as surrogacy. Next, the paper analyzes the relevant issues of ROPA case based on Confucian views of "filial piety," "naturalness," "benevolence," and the concept of "family." Finally, the article proposes the idea of the "doctrine of the mean" as a solution to reconcile the compatibility between the ROPA method and Confucian ethics. The discussion in this article provides new insights for promoting a harmonious and inclusive social environment and improving the regulation of assisted reproductive technologies. It is also of significant importance for the modern transformation of Confucian ethics.

Yonghui Ma。马永慧

Associate Professor, Center for Bioethics, School of Medicine, Xiamen University

Yonghui Ma is now Associate Professor on medical ethics/bioethics and also the Director of the Interdisciplinary Center for Bioethics at Medical School, Xiamen University. She has a bachelor degree on Medicine from Southeast University, MA from Peking Union Medical College, and obtained her PhD on bioethics from the University of Manchester in the UK on 2013 (under full scholarship and supervised by Prof John Harris). She is also member of International Association of Bioethics (IAB), member of Chinese Bioethics Association, editorial committee member of Nursing Ethics, Accountability in Research, Medicine and Philosophy, and Chinese Medical Ethics Journal. She serves as Institutional Review Board member (IRB, or Ethics consultants) in many tertiary hospitals in Xiamen as well as some other academic Institutions. Dr Ma’s research interests focus on genetic ethics, clinical ethics, ethics of new biomedical technology, cross-cultural bioethics. She has published more than 35 peer-reviewed academic papers in the American Journal of Bioethics (Target Article), BMC Medical Ethics, Nursing Ethics, Bioethics, Cambridge Quarterly of Healthcare Ethics, Journal of Bioethical Inquiry, Asian Bioethics Review, Experimental Dermatology, Protein & cell, as well as Chinese journals, such as, Chinese Medical Ethics, Medicine and Philosophy, Chinese Medical Journal.

The Impossibility and Inevitability of Innovation in Human Reproductive Biology: Norms and Limits

Tuesday 17:00–17:30

In this intervention I will trace the ways in which some recent developments of reproductive technology have been framed in biomedical research, policy development and lawmaking. These different registers inscribe limits of acceptability, which they broach in distinctive ways, contributing to the collective elaboration of norms of technological governance. I will consider what insights this

might offer into more general conditions of innovation in biomedicine, innovation that may seem initially impossible, on reflection, inevitable, but, perhaps, after all, manageable.

Peter Mills

Director, PHG Foundation, University of Cambridge

Pete is the Director of the PHG Foundation. He has spent his career working at the intersection of biomedical science, ethics and public policy. Prior to taking up his current post in June 2023, he was Associate Director at the Nuffield Council on Bioethics and before that he led the Secretariat of the Human Genetics Commission. He has also held senior policy positions at the UK Department of Health and the Human Fertilisation & Embryology Authority, and has served in representative and advisory roles on several national and international bodies dealing with genomics, bioethics and human rights. For his first degree, Pete read Philosophy, Politics and Economics at Trinity College, Oxford, and he has an MA and PhD in Philosophy from the University of Warwick.

The Future of Human Reproduction — Tuesday 17:30–18:00

Several new and emerging reproductive technologies have the potential, within a generation or two, to profoundly disrupt established social practices linked to human reproduction and parenting, as well as the concepts of relatedness and family. Better understanding the cultural, ethical, legal, and social issues that these prospects raise is both important and urgent. Equally significant are new research methods and modes of interdisciplinary working that will help to create a novel research paradigm for the study of disruptive emerging technologies. The Future of Human Reproduction, a Wellcome funded project based at Lancaster University, England, seeks to address these matters. In this presentation, I will explain our project and share our activities and findings to date, along with our plans for the future.

Sara J. Fovargue

Professor, Sheffield Law School

Sara Fovargue is a Professor of Law at the University of Sheffield and specialises in health law and ethics, and family law. She has written on reproductive technologies and emerging biotechnologies (particularly xenotransplantation), consent and capacity, risk and regulation, conscientious objection in health care practice, and decision-making and the 'vulnerable'. With regards to family law, she is interested in legal parenthood and parental responsibility, and other matters relating to children – especially in the health context. Sara is a co-investigator on the Wellcome funded Future of Human Reproduction project, based at Lancaster University, England. Beyond this, her current projects include managing hope and regulating exploitation in experimental treatments, and the use of the therapeutic exception in health care practice.

Patient and Public Involvement/Engagement (PPI/E) in Research and Development

Wednesday 9:30–10:00

Patient and public involvement/engagement (PPI/E) has become more widespread internationally over the past decade. In 2022, the Council for International Organizations of Medical Sciences (CIOMS) proposed the introduction of PPI/E from drug development to the regulation of safe use. In Japan, the promotion of PPI/E in research and development began around 2018, with various initiatives underway in cancer, stem cell therapeutics using iPSCs, allergy, mental health and genomic medicine. However, the COVID-19 pandemic blew away the PPI/E that had been brewing. The core principle of PPI/E is the democratization of science, by involving patients and the public in decision-making at all stages of research, to accelerate research development that they need. However, PPI/E is sometimes misunderstood to refer to a broad campaign for the recruitment of research participants, advocacy for research funding, and negotiations with regulatory authorities by patient advocacy groups. In addition, there may be serious conflicts of interest with some active collaborators, difficulties in ensuring diversity, and the risk of tokenism. Efforts should be continued to avoid both the exploitation of patients and the public and practices that only respect the wishes of a few affluent individuals.

Kaori Muto・武藤香织

Professor, Institute of Medical Sciences, University of Tokyo

Kaori Muto, PhD, is the professor of the Department of Public Policy, Human Genome Center, the Institute of Medical Science, The University of Tokyo. She received B.A. in Human Sciences (1993), M.A. in Sociology (1995) from Keio University, and Ph.D. in International Community Health (2002) from The University of Tokyo. After working as a research fellow at the Department of Community Health, Brown University from 2000 to 2002, she served as lecturer at the Department of Health Sciences, Shinshu University from 2002 to 2007. She joined Human Genome Center as an associate professor in 2007 and became professor in 2013. She has been working in the field of medical sociology and biomedical ethics. Her research interests are patient and public involvement/engagement in research and public health ethics. She has served on the ethics committee of the International Society for Stem Cell Research and the WHO COVID-19 Ethics Working Group. She has also served on several expert committees in the Government of Japan, including bioethics, research ethics and measures against COVID-19. She was newly assigned as a team leader of the Laboratory of Biomedical Ethics and Co-design, at the RIKEN Center for Integrative Medical Sciences.

The Evolving Landscape of Novel Technologies in Australia: We know where we're going, but how will we get there?

Wednesday 10:00–10:30

In Australia healthcare delivery is the shared responsibility of the Commonwealth, State and Territory jurisdictional governments. This means the healthcare system often operates under layered legislation, policy frameworks and funding arrangements – making it a complex landscape. The impact of these complexities on the integration of novel technologies is discussed in this presentation. There has recently been a significant drive by governments toward changing laws and policies so that the adoption of novel health technologies is not impeded. One of Australian Genomics' key objectives is to support Commonwealth, State and Territory health departments in

the implementation of genomics by refining and communicating research evidence to inform policy development. In this role, Australian Genomics advocates for policy change, especially where the current state impacts timely, equitable access to advances in healthcare. In this context, patient consent in clinical genomics and insurance discrimination will be discussed, as well as the inequities experienced by our First Nations peoples and those who live in geographically remote places. In other areas, significant positive progress has been made. For example, the passing of *Maeve's Law* now allows mitochondrial donation technology to progress to clinical trials in Australia.

Matilda Haas

Research Projects and Partnerships Manager, Australian Genomics, Melbourne

Dr Matilda Haas originally trained in biomedical research in the field of neurobiology. Following several postdoctoral fellowships focused on laboratory-based research, she found health genomics research. Matilda is now the Research Projects and Partnerships Manager with Australian Genomics, where she contributes across broad research and policy priorities in genomics. In recent years she has published in the areas of health policy, bioethics, and patient experience research. She leads policy activities for Australian Genomics and contributes widely to public health policy consultation. Matilda is also committed to exploring ways to improve patient consent processes for both research and clinical genomic testing. Consent for secondary use of data is an important part of this and Matilda has led the adoption of international standards for data use for Australian Genomics and has been a member of the Australian Genomics Data Access Committee since its inception.

Governance of Reproductive Technologies in Hong Kong Wednesday 10:30–11:00

Social egg freezing is progressively recognized as a crucial practice for women entering the labour force, and it is also perceived as a potential method to counterbalance decreasing fertility rates. This medical procedure enables a woman's eggs to be preserved for prospective future use, affording an opportunity to postpone childbearing without the stress associated with declining fertility. However, the ethical, social, and cultural implications of egg freezing are intricate and multifaceted. Unlike Taiwan, where indefinite storage of eggs is permitted, Hong Kong imposes a restrictive period depending on circumstances. The law in Hong Kong allows egg freezing for social reasons, specifically enabling single women aged 30 and above to preserve their eggs for a period not exceeding 10 years. For medical reasons, such as anticipated treatments like chemotherapy that could potentially harm fertility, exceptions are made for specific cases like cancer patients, where storage can be extended for 10 years or until the patient reaches 55. These restrictions, although rooted in ethical concerns, are viewed by some as outdated. The presentation aims to probe into the arguments that challenge the legitimacy of these prohibitions, aspiring to advocate for social egg freezing.

Olivia Ngan • 顏妙融

Research Fellow, Medical Ethics & Humanities Unit, LKS School of Medicine, The University of Hong Kong

Dr Olivia Ngan has multidisciplinary training in neuroscience, bioethics, and public health. Her research passion lies in reproductive health, public health genomics, rare diseases, and empirical bioethics. She is deeply engrossed in unraveling ethical

dilemmas linked to the practical implementation of technologies in genomic medicine and healthcare services, focusing on reproductive technologies, prenatal screening and diagnosis, and newborn screening.

Ethical Issues facing Insurers in the Changing Landscape Wednesday 11:15-11:45

In the complex terrain of the United States healthcare system, equitable access to emerging health technologies is a critical concern. This presentation delves into the intricacies of health insurance systems and their impact on access, focusing on pre-implantation genetic testing (PGT) for hereditary cancers and fertility care. Drawing insights gleaned as a participant in Point32Health's multi-stakeholder Ethics Advisory Group (EAG) deliberations, we explore ethical questions related to insurance coverage, institutional and organizational ethics, and equitable access. The presentation examines EAG polling results and reflections, illuminating the ethical dilemmas faced by health plans committed to defining and pursuing equitable access. Discussions encompass issues of inclusivity, transparency, decision-making processes, and the societal implications of coverage choices. The presentation sheds light on the pivotal role of health plans in fostering equity, diversity, and inclusivity in the evolving landscape of healthcare technologies.

Caitlyn A. Tabor

Program Director, Centre for Law, Brain & Behavior, Harvard Medical School, Cambridge, MA

Caitlyn Tabor, JD, MBE is an attorney and neuroethicist who is Program Director of the United Nations International Comparative Neurolaw Curriculum, the Aging Brains/Elder Protection Initiative, and the Trauma-Informed Immigration projects of the Massachusetts General Hospital Center for Law, Brain & Behavior (CLBB). Outside of her work at CLBB, Caitlyn is a Neuroethics Fellow at the Neuroethics Hub at Harvard Medical School, and teaching faculty of bioethics and neuroethics at The Center for Bioethics at Harvard Medical School. Caitlyn's research is driven by a fervent commitment to addressing emerging ethical, institutional, and social challenges in the realms of law and medicine, while steadfastly safeguarding human rights through impactful policy transformation.

Ethical and Legal Challenges facing the Translation of Polygenic Scores into Healthcare Wednesday 11:45-12:15

Polygenic scores (PGS) - which measure disease risk based on the cumulative effect of multiple low-impact genetic variants - are generating significant interest due to the potential for their use for disease prevention. At the same time, however, the translation of PGS into healthcare settings raises a host of social, ethical, legal and clinically relevant questions. These include challenges around communication and possible misinterpretation; challenges around regulating PGS as a medical device; and the lack of diverse genomic datasets underpinning PGS models, generating concerns about the applicability of PGS across ethnic groups. Drawing on findings from our PGS work programme at PHG Foundation, this presentation will highlight some proposed applications of PGS, explore some of the ethical and legal considerations that need to be addressed if PGS are to be implemented into healthcare, and focus in particular on the widely recognised concern around the

lack of diversity and inclusion in genomic research, and the what can be done to minimise and mitigate bias.

Tanya Brigden

Senior Policy Analyst, PHG Foundation, University of Cambridge

Tanya is a Senior Policy Analyst (Biomedical Ethics) at the PHG Foundation, working on ethical and legal considerations arising from biomedical innovation and personalised healthcare. She contributes to a broad portfolio of PHG interests, and has developed expertise in a diverse range of topics including person-centred care, ethical issues raised by novel technologies such as genome editing, and the implementation of polygenic risk scores in healthcare. Beyond her role at PHG Foundation, Tanya is the Ethicist member of the NHS Cambridgeshire and Peterborough Clinical Policies Forum, and is a member of the NHS Cambridgeshire and Peterborough System-wide Ethics Committee. Tanya has an MA in Medical Ethics and Law from Kings College London, a Graduate Diploma in Law, and a BA in Philosophy from Durham University

AI Governance and Precision Medicine — Wednesday 12:15–12:45

This presentation examines the legal implications of using artificial intelligence (AI) in precision medicine. It argues that regulations should account for the specific risks concerning the use of genetic information and other AI-accumulated data. This analysis is presented in three parts. First, a framework is outlined called 'AI to Law', which illustrates a pathway from the rise of AI to the creation of law worldwide. This contextualises the analysis and recommendations offered. Second, it highlights key legal issues in AI, and how those issues manifest in precision medicine, Namely, bias, privacy, data security, and consent. Third, it discusses how existing guidelines and policies can be adapted to account for these risks.

Barry Solaiman

Assistant Professor and Assistant Dean, Hamad Bin Khalifa University, Doha

Barry Solaiman is an expert on regulating AI in healthcare. He completed his PhD in law at the University of Cambridge, and holds a Fellowship in Bioethics from Harvard Medical School. In Qatar, he is the Lead Principal Investigator for a research project at HBKU and Project Investigator on another, both examining AI in healthcare. In addition to his journal publications in this space, he is co-editing a major book on 'Health, AI and the Law' to be released in 2024.

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CENTRE FOR MEDICAL ETHICS AND LAW

10 ANNIVERSARY

The Centre for Medical Ethics and Law (CMEL) develops new ideas and solutions in response to the big ethical, legal and policy questions of medicine and health. CMEL is the first cross-faculty interdisciplinary institution of its kind in the region. It was founded in 2012 by the LKS Faculty of Medicine and Faculty of Law at The University of Hong Kong as a joint inheritor of their vibrant intellectual traditions dating back to 1887 and 1969 respectively.

Today, CMEL brings together bioethicists, academic lawyers, medical scientists, and other scholars to conduct cutting edge bioethical and legal research and contribute to policy development in flagship areas like digital health and emergent technologies, mental health and capacity, and population and global health.

Research, teaching and knowledge exchange—CMEL's core initiatives—aim to ensure that developments in biomedicine and public health will be underpinned by ethical and legal considerations.

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