WHO OWNS YOUR BODY?

BEYOND THE PHYSICAL

A conference on the control, custody, management, ‘ownership’, sharing and dissemination of medical and genetic information derived from the human body

6-7 November 2018, Tuesday

Academic Conference Room, 11/F,
Cheng Yu Tung Tower,
The University of Hong Kong,
Centennial Campus, Pokfulam Road,
Hong Kong.

Organized by:

CMEL
Centre for Medical Ethics and Law

CONFERENCE OVERVIEW

This conference is the second in a planned series of international conferences centering on the themes of property rights in the human body, in tissue and in data derived therefrom, and on human organ transplantation.

The first conference in the series, entitled 'Who Owns Your Body?' was organized by the Centre for Medical Ethics & Law (CMEL) of the University of Hong Kong (HKU) and was held over two days (6-7 November 2017) at the Large Moot Court of the Faculty of Law, HKU, Hong Kong. This conference brought together 17 speakers drawn from 9 jurisdictions for a exploratory examination of how the law governs the physical custody and ownership of human bodies, of its parts, and of things derived from it, the underlying fundamental legal principles governing such claims. The conference sought to explore these fundamental questions from ethical, legal, medical, religious and social perspectives, and to offer insights to academics and professionals in both the medical and legal professions a survey of the current state of the common law governing property and other interests and rights in the human body, in organs (especially in relation to transplants), in human tissue and other human samples, in 'waste' tissue and products.

Information on the first conference in this series may be found at http://www.cmel.hku.hk/events/who-owns-your-body/

The focus of this second conference is on remoter interests beyond claims to the purely physical: how does the law currently deal with (or does not, as the case may be) claims to rights asserted in respect of the control, custody, management, 'ownership', sharing and dissemination of (for research or for clinical purposes) medical and genetic information derived from the human body? The conference will consider (again under the general scope of remoter interests) intellectual property rights and claims, particularly in relation to likely future developments in competing major jurisdictions in relation to the human body. A particular focus of this conference will be the relationship between clinicians and researchers on the one hand, and donors, research subjects and even entire communities on the other: what kind of ethical, legal and social rights might be claimed for or asserted by donors of physical samples (including genomic samples) and of the data pertaining to such donors, and what might be the impact of such claims on the conduct of research? Is there an obligation for the return of benefits by researchers to their research subjects, and if so, in what terms might this obligation be best articulated? Given that the cooperation and consent of research subjects and donors is indispensable in the conduct of research, how might a programme of public outreach and education be best implemented?

The first session (Theme: Physical Property in the Body II) connects the first and second conference with topics that develop and expand on some of the themes raised in the first conference. These include the obligation for the return of human tissue, organs and bodies after post-mortems (compulsory coronial or otherwise), and also vexed practical issue of property / custody / control of pathological specimens (especially simple histopath slide collections) held by hospitals, universities etc and research access to such collections the donors of which are likely to be either dead or untraceable. In this first session, we will examine approaches to best practices in the governance of biobanks, and to the maintenance of public trust in biomedical research.

In the second session (Theme: Beyond the Physical: Pure Information), presentations dealing with current developments relating to the acquisition, custody (and responsibilities in relation to) and use of pure information derived from the human body will be offered. The impact of the EU General Data Protection Regulation (GDPR) will also be examined, particularly on its likely influence on inter-jurisdictional projects and transfers outside of the EU (particularly if there is a likelihood that EU collaborators or EU-origin data will be involved). We consider current and future developments in the sphere of intellectual property claims derived from the human body, and consider also future developments in which 'ownership' of intellectual property rights may be claimed by non-human entities (including AI).

In the final session (Theme: The Gifts of the Body: Return, Education, Responsibility), we will focus on the themes of return, education and responsibility for the proper stewardship of gifts derived from the human body, and in particular, from patients, donors and communities who make possible such research and discoveries in the first place. In 2000, the Ethics Committee of the Human Genome Organization (HUGO) chaired by Professor Bartha Maria Knoppers released a landmark statement advocating for the return of benefits of research to all humanity. Presentations on this theme will include a presentation on a specific example of the return of benefits to a donor community, and on the fundamental obligation of maintaining societal or public trust and engagement in the conduct of biomedical research. Almost seven decades ago, Henrietta Lacks gave to science in her death the gift of her immortal cells. The controversy over whether she (or her heirs) should have any rights to the profits made since has not diminished, but to the contrary, has grown over the years. On this last theme, we conclude the conference with a presentation that looks to the future: the issue of private and public ownership of stem cells.

ABOUT CMEL

Established in 2012, The Centre for Medical Ethics and Law (CMEL) is a joint effort of two leading faculties, the Li Ka Shing Faculty of Medicine and the Faculty of Law at the University of Hong Kong. Our visions are: to become a focal point for international research excellence in the area of medical ethics and law; to co-ordinate and provide teaching and training to university students and professionals; and to promote and disseminate our expertise to the benefit of the public.

The Centre's objectives are respectively in research, teaching, knowledge exchange and training:

Research: To produce and disseminate high-quality and cutting edge research in medical ethics and law.

Teaching: To contribute to the interdisciplinary teaching and learning at the University by providing a forum for the discourse of medical ethics and law. Knowledge Exchange: To provide expert training and continuing education to the professionals of both disciplines and to help setting the ethical standard on related issues.

Training: To promote and disseminate knowledge of medical ethics and law to the public at large and enhance the community's awareness in this regard.

Aligning with the University's vision of 'Internationalisation, Innovation and Interdisciplinarity', the Centre collaborates with institutions, professional bodies and scholars in Hong Kong and internationally in order to pursue these objectives.

SPEAKERS AND PANELISTS

Michael Vidler	Vidler & Co., Solicitors, Hong Kong
Philip Beh	Department of Pathology, the University of Hong Kong
Mika Suzuki	Kyoto University, Japan
Morten Øien	The International Society for Biological and Environmental Repositories Governance Committee
Alison Hall	PHG Foundation, the University of Cambridge, the United Kingdom
Gerard Porter	University of Edinburgh, the United Kingdom
Kathy Liddell	Centre for Law, Medicine and Life Sciences, the University of Cambridge, the United Kingdom
Mateo Aboy	Centre for Law, Medicine and Life Sciences, the University of Cambridge, the United Kingdom
Ya-Hong Li	Faculty of Law, the University of Hong Kong
Roger Chennells	Consultant, Chennells Albertyn, Cape Town and Stellenbosch, South Africa
Sumin Kim	Yonsei University, South Korea
Calvin Ho	Centre for Biomedical Ethics, National University of Singapore, Singapore
Koichi Mikami	University of Tokyo, Japan
Ron Zimmern	PHG Foundation, the University of Cambridge, the United Kingdom

PROGRAMME

Tuesday 6 November 2018

9:00 - 9:30 am	Registration
9:30 - 9:40am	***Welcome Address*** Mr Terry Kaan, Co-Director, Centre for Medical Ethics & Law, the University of Hong Kong

Theme 1: Physical Property in the Body II

9:40 - 10:00am	***PRESENTATION 1:*** Michael Vidler Principal, Vidler & Co., Solicitors, Hong Kong *Handling Foetal Remains - A Hong Kong case study: obtaining a dignified and respectful internment for little Wally*
10:00 - 10:20am	***PRESENTATION 2:*** Philip Beh Associate Professor, Department of Pathology, the Li Ka Shing Faculty of Medicine; and Co-Director, Centre for Medical Ethics & Law, the University of Hong Kong *WHO OWNS YOUR BODY – Please come and collect?*
10:20 - 10:50am	**BREAK**
10:50 - 11:10 am	***PRESENTATION 3:*** Mika Suzuki Uehiro Research Fellow , Uehiro Research Division for iPS Cell Ethics, Center for iPS Cell Research and Application(CiRA), Kyoto University, Japan *Building the Trust: The role of the professional and the role of the general public*

11:10 - 11:30 am **PRESENTATION 4:**

Morten Øien

Legal Advisor/Member of the International Society for Biological and Environmental Repositories Governance Committee

Good Biobank Governance in the Age of Personalized Medicine: From theory to practice

11:30 am - 12:30 pm **ROUNDTABLE DISCUSSION AND Q & A**

Chair: Ron Zimmern, Chairman, Board of Trustees, PHG Foundation, the University of Cambridge, the United Kingdom

12:30 pm - 2:00 pm ***Lunch***

Theme 2: Beyond the Physical: Pure Information

2:00 - 2:20pm ***PRESENTATION 1:***

Alison Hall

Head of Humanities, PHG Foundation, the University of Cambridge, the United Kingdom

Genetic data, automated processing and the EU General Data Protection Regulation

2:20 - 2:40pm **PRESENTATION 2:**

Gerard Porter

Lecturer in Medical Law & Ethics, Director of Ethics & Integrity, Edinburgh Law School, the University of Edinburgh, the United Kingdom

Patenting Materials Derived from the Human Body: Does the law give adequate regard to the interests of donors?

2:40 - 3:00pm **PRESENTATION 3:**

Kathy Liddell

Director, Centre for Law, Medicine and Life Sciences, the University of Cambridge, the United Kingdom

and

Mateo Aboy

Senior Research Scholar, Centre for Law, Medicine and Life Sciences, the University of Cambridge, the United Kingdom

The Impact of the (In)famous Myriad and Mayo Decisions

3:00 - 3:30pm **BREAK**

3:30 - 3:50pm **PRESENTATION 4:**

Ya-Hong Li

Associate Professor and Director of the LLM Program in Intellectual Property (IP) and Information Technology, Faculty of Law, the University of Hong Kong

Issues in IP Protection for AI-generated works and inventions and implications to science and cultural development

3:50 - 4:50pm **ROUNDTABLE DISCUSSION AND Q & A**

Chair: Ron Zimmern, Chairman, Board of Trustees, PHG Foundation, the University of Cambridge, the United Kingdom

6:30pm ***Conference Dinner***

Speakers and Invited Guests

Wednesday 7 November 2018

9:00 - 9:30am Registration

Theme 3: The Gifts of the Body: Return, Education, Responsibility

9:30 - 9:50am ***PRESENTATION 1:***

Roger Chennells

Consultant, Chennells Albertyn, Cape Town and Stellenbosch, South Africa

Benefit Sharing in Medical/ Genomic Research

9:50 - 10:10am **PRESENTATION 2:**

Sumin Kim

Ph.D. Candidate of Medical Law and Ethics, Graduate School, Yonsei University, South Korea

Researcher, Asian Institute for Bioethics and Health Law, Yonsei University, South Korea

Ethical and Regulatory Considerations on Biobanking in the Republic of Korea

10:10 - 10:30am ***PRESENTATION 3:***

Calvin Ho

Assistant Professor, Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore

Re-thinking Social Value in Access to and Benefit Sharing of Biological Materials and Related Data in Biomedical Research

10:30 - 11:00am **BREAK**

11:00 - 11:20am ***PRESENTATION 4:***

Koichi Mikami

Project Assistant Professor, Science Interpreter Training Program, KOMEX, University of Tokyo, Japan

'Implicated' Ownership and the Boundary of Public and Private – the Case of Regenerative Medicine in Japan

11:20am - 12:20 pm **ROUNDTABLE DISCUSSION AND Q & A**

Chair: Ron Zimmern, Chairman, Board of Trustees, PHG Foundation, the University of Cambridge, the United Kingdom

Tuesday 6 November 2018

SESSION 1:
Physical Property in the Body II

PRESENTATION 1

HANDLING FOETAL REMAINS -A HONG KONG CASE STUDY: OBTAINING A DIGNIFIED AND RESPECTFUL INTERNMENT FOR LITTLE WALLY

Michael Vidler, Vidler & Co., Solicitors, Hong Kong

This is a case study of a grieving couple's battle to bury the foetal remains of their son little Wally after miscarriage at 16 gestational weeks, in the face of poorly drafted legislation, insensitive government policy and bureaucratic apathy.

This presentation invites recognition of the rights of grieving parents, if they so wish, to dispose of post miscarriage foetal remains of under 24 gestational weeks in a dignified and respectful manner and not be treated simply as clinical waste to be disposed of in landfill.

PRESENTATION 2

WHO OWNS YOUR BODY – PLEASE COME AND COLLECT?

Philip Beh, the Li Ka Shing Faculty of Medicine; and Co-Director, Centre for Medical Ethics & Law, the University of Hong Kong

Nearly 45,000 individuals die in Hong Kong each year. In the majority cases, they die in the public hospitals and the body will be collected by family members. Most bodies in Hong Kong are cremated. What should the hospital authorities do with "unclaimed" bodies? What legislation should they abide by? Is a legal practice acceptable?

PRESENTATION 3

BUILDING THE TRUST: THE ROLE OF THE PROFESSIONAL AND THE ROLE OF THE GENERAL PUBLIC

Mika Suzuki, Center for iPS Cell Research and Application(CiRA), Kyoto University

Human pluripotent stem cells (hPSCs) can give rise to all cells in the body, suggesting great potential not only in the fields of regenerative medicine and drug discovery, but also in the fields of disease study and developmental biology. Adding to the potential, in theory, hPSCs could also be used to grow full human beings if grown in human embryos or through the creation of gametes.

Currently, hPSCs are being stocked or deposited in stem cell banks, which will be responsible for distributing the cells to institutes conducting stem cell research and/or application. One key to successful management of these banks is the building of trust between the public. This trust depends on well informed consent from the donors, but individual consent is limited with regards to biobanks. In response, new governance for biobanks has been proposed.

In my presentation, I will introduce our challenges to building the trust in the stem cell research field in Japan.

PRESENTATION 4

GOOD BIOBANK GOVERNANCE IN THE AGE OF PERSONALIZED MEDICINE: FROM THEORY TO PRACTICE

Morten Øien, Legal Advisor/Member of the International Society for Biological and Environmental Repositories Governance Committee

Personalized medicine (PM) is often portrayed as the new paragdigm of modern medicine. It by no doubt represents a fast-growing field in patient care globally, both in the private and the public sector. Genomics and related ICT-based technologies are core to PM, meaning that it can also be said to be part of a digitalization mega-trend. Furthermore, the world of PM necessitates the efficient interaction between biobanks/biobankers and owners/holders of clinical, imaging and laboratory data. What challenges are these novel developments posing in relation to biobank governance? The speaker intends to engage the audience in an active dialogue around the likely practical impacts of identified challenges.

ROUNDTABLE SESSION

SESSION 2:

Beyond the Physical: Pure Information

PRESENTATION 1

GENETIC DATA, AUTOMATED PROCESSING AND THE EU GENERAL DATA PROTECTION REGULATION

Alison Hall, Head of Humanities, PHG Foundation, the University of Cambridge, the United Kingdom

When the EU General Data Protection Regulation (GDPR) came into force in May 2018, it significantly changed the landscape of data protection law in Europe, strengthening the rights of data subjects and creating stronger protections for some types of data and data processing. This presentation will explore the protections that the GDPR places on genetic and biometric data for both clinical care and medical research. It will go on to examine how these types of data might be utilised using automated processing and evaluate what the GDPR imposes by way of requiring greater transparency or explanation.

Through using a number of different existing and potential applications of automated processing (including imaging, screening and drug administration), I will interrogate what a 'meaningful explanation' and safeguarding a data subject rights, freedoms and legitimate interests might look like. The presentation will end by considering whether these applications create novel challenges for health professionals, and, if so, how some of these challenges might be mitigated.

PRESENTATION 2

PATENTING MATERIALS DERIVED FROM THE HUMAN BODY: DOES THE LAW GIVE ADEQUATE REGARD TO THE INTERESTS OF DONORS?

Gerard Porter, Edinburgh Law School, the University of Edinburgh

In 1990, the Supreme Court of California's landmark decision in Moore v Regents of the University of California established a particular way of conceptualising and resolving disputes over patented material derived from the human body. This entailed prioritising the interests of medical researchers - and in the majority of the justices' view, the public good of biomedical research itself - over the interests of human sources of biological material. The 'Moore v Regents' framework has been widely adopted in other jurisdictions around the world. Yet despite being significantly disempowered by the formal legal regimes, donors of biological material have still tried to use a number of different strategies to

exercise control over biomedical research and claim remuneration. This talk presents some of the key trends and offers some suggestions for the future.

PRESENTATION 3

THE IMPACT OF THE (IN)FAMOUS MYRIAD AND MAYO DECISIONS

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

Patent law is the legal basis for property in intangible inventive concepts. In some areas (e.g. manufacturing), property in the form of patent protection is a well-accepted area of economic policy. However, the extent to which patents can and should be granted in relation to human body parts, DNA sequences and the body's responses to medicines is highly contested.

Association for Molecular Pathology v. Myriad Genetics, Inc. (2013) and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (2012) are two of the most significant and controversial US Supreme Court cases on this topic. Both addressed the boundaries of patent eligibility.

- *Myriad* held that isolated, naturally-occurring DNA sequences are unpatentable. DNA molecules are typically valuable for the information they encode, and claims to human DNA sequences would need to be "markedly different from nature" to be patent-eligible. The unnaturalness of an isolated DNA molecule is an insufficient difference. Commentators' responses to *Myriad* were mixed, with some describing the nuance of the decision as "far from illuminating" (Burk 2015).
- *Mayo* involved a method for gathering information about a patient's thiopurine-metabolite levels to see whether the patient needed bigger or smaller doses of thiopurine drugs. Although there was a link with improved drug dosages, the Court held that the patent was ineligible because it was *directed at a Law of nature* (namely the natural principle that thiopurine drugs are metabolised by the body to produce thiopurine metabolites). The patented process therefore needed additional features which "provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself". The decision was met with great concern, with commentators fearing that it marked the demise of patent protection for a wide range of inventions in diagnostics and personalised medicine.

This presentation discusses the impact of *Myriad* and *Mayo* over the past 6 years with evidence from ground-breaking empirical research. The results show that neither *Mayo*

nor *Myriad* completely blocked patent-based property rights for inventions based on the human body or information gleaned from it. Nor did either case have the impact that was predicted by commentators. For instance, while the impact of *Myriad* was less radical than some commentators anticipated for gene patenting, the decision had an unexpectedly strong impact on nature-based products beyond DNA. *Mayo* resulted in remarkably strong and sustained legal uncertainty, substantially increasing the cost and time involved in patent prosecution; but not, it seems, blocking precision-medicine style medical treatments. The next six years look equally interesting with on-going case law developments and calls for Congress to amend patent eligibility for nature-based products and correlations.

PRESENTATION 4

ISSUES IN IP PROTECTION FOR AI-GENERATED WORKS AND INVENTIONS AND IMPLICATIONS TO SCIENCE AND CULTURAL DEVELOPMENT

Professor Ya-Hong Li, Faculty of Law, the University of Hong Kong

This presentation identifies key issues in IP protection for AI generated works and inventions including whether these works and inventions are entitled to IP protection or whether AI can be considered author/inventor, how technical criteria in copyright and patent laws can be applied to determine the originality and inventiveness of these works and inventions, and who are the IPR owners of these works and inventions. The presentation then discusses the impact of how we view these issues on science (including AI technology itself, medical and other technologies) and cultural development.

ROUNDTABLE SESSION

Wednesday 7 November 2018

SESSION 3:

The Gifts of the Body: Return, Education, Responsibility

PRESENTATION 1

BENEFIT SHARING IN MEDICAL/ GENOMIC RESEARCH

Roger Chennells, Consultant, Chennells Albertyn, Cape Town and Stellenbosch, South Africa

Whilst access to human biological resources has been and will remain essential for all forms of medical research, particular questions arise when human genetic samples such as DNA are sought from developing world communities. This presentation addresses the topic with a focus on one particular vulnerable community whose DNA has been much sought-after over the past decades, and which has attempted to address the issue in a practical manner. Questions such as equity, undue inducement, and current 'best practice' are touched upon whilst attempting to propose practical ways of engaging in research on vulnerable communities.

PRESENTATION 2

ETHICAL AND REGULATORY CONSIDERATIONS ON BIOBANKING IN THE REPUBLIC OF KOREA

Sumin Kim, Graduate School/ Asian Institute for Bioethics and Health Law, Yonsei University, South Korea

Since the enactment of the Bioethics and Safety Act in 2004, the Republic of Korea has developed a regulatory framework that reflects ethical principles. However, the existing regulation of biobanks has recently proven to be limited in responding to newer ethical and legal issues that have arisen. Therefore there is a pressing need for continuing and deeper deliberation in order to develop a more comprehensive and responsive governance framework.

PRESENTATION 3

RE-THINKING SOCIAL VALUE IN ACCESS TO AND BENEFIT SHARING OF BIOLOGICAL MATERIALS AND RELATED DATA IN BIOMEDICAL RESEARCH

Calvin Ho, Yong Loo Lin School of Medicine, the National University of Singapore

This presentation argues that social value must remain a central consideration for issues on accessing, and benefit sharing of, biological materials and related data in biomedical research (ABS). The argument is made in two contexts (local and global) but its central concern relates to the type of control that interested individuals and institutions should have, as well as why social value could matter more. In a local context, the presentation will discuss recent legislative and regulatory changes on the topic in Singapore, where considerable emphasis has been placed on informed consent. While such a focus may be consistent with legal principles and operationally important, it ultimately fails to enable the right to science (in international law conventions) unless the principle of social value is given equal or perhaps even greater emphasis. In a global context, the presentation will focus on the Pandemic Influenza Preparedness (PIP) framework, which was established to facilitate sharing of the H5N1 and other influenza viruses with human pandemic potential. As the legality and legitimacy of the PIP framework is premised on the International Health Regulation, it is limited in scope and is arguably too focused on control, thereby undermining equally important considerations of social value and related concerns with transparency and trust. This presentation seeks to explain – in both the local and global contexts – how the principle of social value could be conceptualized and applied for the purposes of ABS, and why it should matter.

PRESENTATION 4

'IMPLICATED' OWNERSHIP AND THE BOUNDARY OF PUBLIC AND PRIVATE – THE CASE OF REGENERATIVE MEDICINE IN JAPAN

Koichi Mikami, Science Interpreter Training Program, KOMEX, University of Tokyo, Japan

In this presentation, I approach the question about ownership of body parts using regenerative medicine in Japan as a case. Regenerative medicine became a national project in the country in 2007 when Shinya Yamanaka at Kyoto University applied his cell reprogramming technique to human somatic cells successfully and produced human induced pluripotent stem cells (hiPSCs). And as part of this project, hiPSC banks have been established. By attending the ways in which these stem cell banks are managed and also in

which stem cells stored there may be accessed, I explore what it takes to keep the cells derived from citizens in public hands.

ROUNDTABLE SESSION

SPEAKERS AND PANELISTS BIOGRAPHY

Mr Michael Vidler

Principal, Vidler & Co. Solicitors, Hong Kong

Michael Vidler is the proprietor of Vidler & Co. Solicitors, a Hong Kong law firm renowned for its work in the field of human rights through public interest litigation. He has litigated many of the leading cases in Hong Kong concerning gay and transgender rights (*Leung TC William Roy v. The Secretary for Justice*, *W v Registrar of Marriages, QT v Director of Immigration*); race, sex and disability discrimination (Singh Arjun v Secretary for Justice); domestic worker rights (*D v S & K, FD v Shek Kwok-Ngai* and *Waliyah v Yip Hoi Sun and Chan Man Hong*) and children's rights (*KC, HY, YY v Director of Social Welfare* and *CHC v Director of Social Welfare*)

Michael is a proactive member of the public discourse and has served on the boards of AIDS Concern, Amnesty International Hong Kong, Pink Alliance, Hong Kong Refugee Advice Centre, Hong Kong Unison and is on the Chief Executives Election Committee. He also teaches trial advocacy on the PCLL course at the University of Hong Kong and is on the Department of Justice working party on human trafficking. He is the recipient of Hong Kong Law Society's Pro Bono Gold Award and the HKLGFF 2015 Prism Award.

Dr. Philip Beh

Co-Director, CMEL,
Associate Professor, Department of Pathology, Li Ka Shing Faculty of Medicine, The University of Hong Kong

Currently Associate Professor in the Department of Pathology, Li Ka Shing Faculty of Medicine, HKU. He is a forensic pathologist and has been performing autopsies since 1982. He has written and published in areas covering autopsies, homicides, sexual violence and medical education.

Ms Mika Suzuki
Uehiro Research Fellow
Uehiro Research Division for iPS Cell Ethics Center for iPS Cell Research and Application (CiRA) Kyoto University, Japan

Mika SUZUKI graduated from Kyoto University's School of Public Health (Clinical Research Coordinator Course) and received her Master's degree (MPH) in 2008. After working as an administrator of the research ethics review committee at RIKEN, she was appointed as a Research Fellow in the Uehiro Research Division for iPS Cell of Ethics at Kyoto University's Center for iPS Cell Research and Application (CiRA) in 2013. Her research interest is empirical research regarding the construction of the implementation structure and educational system for conducting clinical research based on the trust between researchers and the general public.

Selected publications:

1) Suzuki M, Sato K. Some Suggestions for Improving the Research Ethics Review System in Japan, Based on a Study Involving Interviews with Committee Members and Investigators Regarding Clinical Research Conducted in FY 2008 at an Institution. Japanese Journal of Clinical Pharmacology and Therapeutics. 2010; 41(3):113-124.

2) Fujita M, Yashiro Y, Suzuki M. Throwing the baby out with the bathwater: a critique of Sparrow's inclusive definition of the term 'in vitro eugenics.' Journal of Medical Ethics. 2013; Aug. 28.

3) Kamisato A, Iwae S, Iijima Y, Aizawa K, Suzuki M, Muto K. Survey of "Research Ethics Support" for understanding current conditions and organizing the concept of support. Journal of Japan association for Bioethics. 2015; 25(1): 123-132.

4) Suzuki M, Sato K. Description and evaluation of the research ethics review process in Japan: Proposed measures for improvement. Journal of Empirical Research on Human Research Ethics. 2016; 11(3): 256-266.

5) Sato K, Suzuki M. What is a stem cell research? 2nd ed. 2016. (In Japanese)
http://www.cira.kyoto-u.ac.jp/uehiro-ethics/wp-content/uploads/2016/02/what-is-stemcell.pdf

SPEAKERS AND PANELISTS BIOGRAPHY

Dr Morten Øien

Legal Advisor/Member of the International Society for Biological and Environmental Repositories Governance Committee

Morten Øien is a Norwegian lawyer, with more than 30 years experience in providing legal advice both in the private and the public sector. His special competence areas are international contract law and IP law. Presently he shares his time equally between his two employers, Norges teknisk-naturvitenskapelige universitet (NTNU) and St. Olav's Hospital HF, both institutions with their main offices in the City of Trondheim. Furthermore, Mr. Øien has been working extensively with legal issues related to human biobanks since 1998. He inter alia worked part-time for 3 years as General Counsel for the biobank spin-out company Lifandis AS, a limited company/ CRO that he also provided much of the legal foundation for when established in 2007. Morten is presently the only Nordic Member of ISBER's Governance Committee.

Ms Alison Hall

Head of Humanities, PHG Foundation, The University of Cambridge

Alison Hall leads the Humanities work at the PHG Foundation, a health policy think tank which is part of University of Cambridge. Her research focuses on the regulation and governance of genomic data for clinical care and research and the challenges and opportunities associated with delivering personalised healthcare. Recent work has focused on the impact of EU Regulations on data protection and in vitro diagnostic devices on the implementation of automated processing and artificial intelligence in healthcare. She is Chair of the Ethics and Policy Committee of the British Society for Genetic Medicine, a member of METADAC (a UK Data Access Committee) and a member of an NHS research ethics committee. Alison has professional qualifications in law and nursing and a master's qualification in healthcare ethics.

Dr Gerard Porter

Lecturer in Medical Law & Ethics, Director of Ethics & Integrity, Edinburgh Law School, The University of Edinburgh

Gerard Porter is a lecturer in Medical Law and Ethics at Edinburgh Law School, UK. He is a graduate of Cardiff University (LL.B. Law and Japanese) and Kyushu University, Japan (LL.M. International Economic and Business Law). His research interests include medical law, patent law and the regulation of the life sciences. He speaks Japanese and also conducts comparative research in Japanese law within these subject areas. He has held visiting fellowships at the Centre for Studies in Ethics and Rights (Mumbai, India), the Centre for Biomedical Ethics, National University of Singapore and with the Program on Science, Technology and Society at the John F. Kennedy School of Government, Harvard University. He is currently serving as the Director of Ethics and Integrity at Edinburgh Law School.

Working with partners in the UK and India, Gerard is also the Principal Investigator on a project funded by the Economic & Social Research Council (ESRC) and the Government of India, Department of Biotechnology (DBT) entitled: 'Smart regulation of antibiotic use in India: Understanding, innovating and improving compliance'. The aims of this inter-disciplinary project are first, to better understand the various problems surrounding the regulation of antimicrobial resistance (AMR) containment in India, and second, to improve the situation by applying the concepts and methods of 'smart regulation'.

Dr Kathleen Liddell

Director, Centre for Law, Medicine and Life Sciences, The University of Cambridge, the United Kingdom

Dr Kathy Liddell is the Director of Cambridge Centre for Law, Medicine and Life Sciences (LML), and the Herschel Smith Senior Lecturer of Intellectual Property (IP) Law at Faculty of Law, University of Cambridge. Her research focuses on health, medicine and society, with the aim of understanding and improving the legal frameworks that govern and support improvements in this field. She is an expert in intellectual property in the field of life sciences and has been the principal investigator for several large projects on IPRs and bioinnovation, including in relation to genomics, precision medicine and repurposing pharmaceuticals. Dr Liddell has worked on policy reports for national health departments, national ethical advisory commissions, and the European Commission. She is the recipient of grants from (for example) the Wellcome Trust, the Philomathia Foundation, the Cambridge ESRC-Impact Acceleration Account, and the Novo Nordisk Foundation. Her expertise extends to other areas of life sciences including national and international regulation of clinical trials, professional negligence, biomaterials (including human tissue, cells, organs), biodata (including large biobanks), pharmaceuticals, diagnostics, and personalised and regenerative medicine. Dr Liddell uses a wide range of interdisciplinary methodologies in her research including interviews, surveys and patent mapping. She studied law and natural sciences at the University of Melbourne before undertaking a Masters of Bioethics at Monash University and her doctorate in law at the University of Oxford. In addition to academia, Dr Liddell has worked in private legal practice and in the civil service.

Professor Mateo Aboy

Senior Research Scholar, Centre for Law, Medicine and Life Sciences, University of Cambridge
Professor of Electrical Engineering, EERE, OIT, US
Affiliate Professor & Fellow, CeBIL, University of Copenhagen, DK

Professor Mateo Aboy's multidisciplinary background includes a combination of intellectual property, science & engineering, and management experience. He holds degrees in engineering and data science (BS, MS, MPhil, PhD), law (LLB), international management (MBA), as well as professional registrations as a Chartered Engineer (COIT), Certified Licensing Professional (CLP), and Licensed Patent Agent with Bar Admission to practice in patent cases before the United States Patent Office (USPTO) and the Patent Trials and Appeals Board (PTAB).

His professional experience includes work in both the private sector in various senior engineering roles and in academia as a tenured Professor of Engineering. As a Licensed Patent Practitioner, he has successfully prosecuted numerous cases before the USPTO, focusing primarily on medical device and computer-implemented inventions. He holds over 20 patents as an inventor and is the co-founder of four companies.

Professor Aboy has taught courses in engineering (computational data science; scientific & engineering computation; digital signal processing; electronics; programming; research methods & innovation), law (patent law for engineers & managers; business law), and management (strategy, innovation, and entrepreneurship; engineering management).

Professor Aboy pursues research at the interface between engineering, law, and management sciences. He is currently researching the status of information age inventions as patentable subject matter. A core component of this work is an in-depth quantitative analysis of trends in patenting activity and patent examination following key United States Supreme Court decisions affecting biomedical, biotech, computer and information process inventions (Myriad, Mayo, Alice), coupled with a comparative study of European patent law. This work sheds light on the implications of legal doctrine for prosecution strategies, licensing and innovation.

SPEAKERS AND PANELISTS BIOGRAPHY

Dr Yahong Li

Associate Professor and Director of the LLM Program in Intellectual Property (IP) and Information Technology, Faculty of Law, The University of Hong Kong

Yahong Li, JSD and JSM (Stanford), is an Associate Professor and Director for LLM Program in IP/IT at the Department of Law of the University of Hong Kong (HKU). She specializes in IP law with a focus on cross-disciplinary study of IP, culture and technological innovation. She is an author/editor of, inter alia, Patents and Innovation in Mainland China and Hong Kong: Two Systems in One Country Compared (Cambridge University Press, 2017), Copyright, Internet and the Balance of Rights (HKU Press, 2016), Imitation to Innovation in China: the Role of Patents in Biotech and Pharmaceutical Industries (Edward Elgar, 2010), as well as numerous peer-reviewed journal articles. Dr. Li is a frequent speaker at international and regional conferences, and visiting fellow/Professor at, inter alia, Harvard Law School, Cambridge University, Max Planck Institute for Innovation and Competition, Melbourne University Faculty of Law, among others. She is a member of ATRIP, a Council Member of China IP Law Association, and an Honorary Advisor of Hong Kong Institute of Patent Attorneys.

Dr Roger Chennells

Consultant, Chennells Albertyn, Cape Town and Stellenbosch, South Africa

Roger Chennells is an attorney, based in Stellenbosch, South Africa. He has practiced as a human rights attorney since 1980, specialising in labour, land, environmental and human rights law, with an overall emphasis on public interest law affecting rural communities, and indigenous communities in particular. Prior to 1990, his practice represented and protected those that opposed the apartheid state, largely by launching cases against the police and the state. During this period he became an active practitioner of alternative dispute resolution as a means of achieving fair outcomes to legal problems, which he applied to many situations where rural communities, land and the environment were involved.

Over the last two decades he began representing indigenous peoples, primarily the San of Southern Africa, acting for them firstly in land claims, and later in matters related to traditional knowledge and intellectual property. Whilst “benefit-sharing” in the fields of medicine based upon traditional knowledge became a mainstream practice subsequent to the Convention for Biological Diversity in 1992, the question of rights, duties and ethics of all parties involved in genomic research became a central focus of interest. His PhD in 2014 was entitled “Equitable Access to Human Biological Resources” with a focus on policy suggestions for research in developing countries. Over the past few years he has assisted the San develop a Code of Research Ethics aimed at guiding research, which was launched in 2017.

Sumin Kim, Ph.D. Candidate
Graduate School/ Asian Institute for Bioethics and Health Law, Yonsei University, South Korea

Sumin Kim is a Ph.D. Candidate of Medical Law and Ethics in Yonsei University Graduate School, and also a researcher of the Asian Institute for Bioethics and Health Law.

Her main research area is ethical, legal, and social implications of human genome research, especially interests in social aspect and social participation of human genomic research.

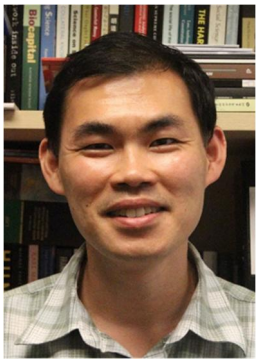
She participated in human genomic ELSI research in Korea, funded by the ministry of health and welfare since 2014. Most recently she participated in 'Research on Social and Ethical Basis for Precision Medicine' funded by Korea Centers for Disease Control and Prevention.

Currently, she is participating in ELSI Research on Human Genomics funded by Korea health industry development institute.

SPEAKERS AND PANELISTS BIOGRAPHY

Dr Calvin Wai-Loon Ho

Assistant Professor, National University of Singapore, Singapore



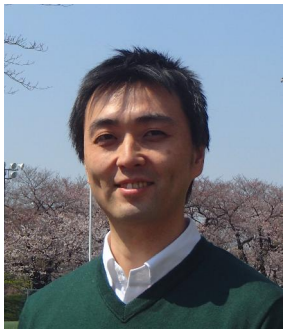
Calvin Ho is Assistant Professor at the NUS Centre for Biomedical Ethics, Co-Head of the WHO Collaborating Centre for Bioethics in Singapore, and Co-Head of the Accountability Policy Task Team of the Global Alliance for Genomics & Health. He is also the Editor-in-Chief of the journal Asian Bioethics Review (published by Springer Nature), and an Ethics Board member of Médecins Sans Frontières (Doctors Without Borders). Additionally, he serves as an Assistant Director with the Legal Aid Bureau of the Ministry of Law (Singapore), as well as on the Singapore Nursing Board and advisory committees for transplantation and for genetic testing of the Ministry of Health (Singapore). He has published on biomedical law and ethics, health policy and systems, and global health, and is the co-editor of Bioethics in Singapore: An Ethical Microcosm (2010, World Scientific) and Genetic Privacy (2013, Imperial College Press), the author of Juridification in Bioethics: Governance of Human Pluripotent Cell Research (2016, Imperial College Press), as well as an author of the WHO Guidelines on Ethical Issues in Public Health Surveillance (2017).

Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore

E-mail: medhwlc@nus.edu.sg; Tel: +65 6516 7201

Dr Koichi Mikami

Project Assistant Professor, Science Interpreter Training Program,



Dr. Koichi Mikami is project assistant professor of the Science Interpreter Training Program at the University of Tokyo (Japan). He completed his doctoral training in Management Studies at the University of Oxford (UK) in 2010, and has been working in an interdisciplinary field called Science and Technology Studies. His research explores development of social and technical platforms for modern biomedicine, including genomic medicine and regenerative medicine, and aims to understand how such platforms legitimize and materialize a certain kind of 'futures' while discrediting and dismissing others. From January 2014 to March 2017, he was research fellow of the medical humanities research project Making Genomic Medicine, led by a medical sociologist Professor Steve Sturdy, at the University of Edinburgh (UK). The project, funded by the Wellcome Trust, investigated entanglement of scientific, technological, social and political processes over the last half a century or so that produced the current state of medical genetics and is also shaping the future prospect(s) of genomic medicine, and he was responsible for one of its research strands examining the rise of rare diseases in domains of both medical science and public health policy. Prior to joining the project, he conducted social study on regenerative medicine research in Japan, which led to publication of a series of articles discussing the impact of the birth of human induced pluripotent stem cells in 2007 on the research field as well as the science and technology policy in the country.

Dr Ron Zimmern

Chairman, PHG Foundation, Cambridge; Honorary Professor of Public Health, The University of Hong Kong

Dr Ronald Leslie Zimmern is Chairman of the Foundation for Genomics and Population Health (the PHG Foundation), the successor to the Public Health Genetics Unit which he established in 1997 and which he directed until 2010. He graduated in 1971 following his medical training at Trinity College, Cambridge and the Middlesex Hospital, London. After specialising in neurology, he obtained a law degree and entered public health medicine in 1983. He was Director of Public Health for the Cambridge and Huntingdon Health Authority from 1991-1998. Dr Zimmern is known internationally as a founder of the field of public health genomics. He has an Honorary Professorship in Public Health at HKU and is a Fellow of Hughes Hall in Cambridge. He has written widely on medical ethics and law issues, such as on the ethical issues on revealing the results of whole-genome sequencing and predictive genetic testing.