Conference:

‘Who Owns Your Body? – Beyond The Physical’

Tuesday 6 & Wednesday 7 November 2018

Academic Conference Room, 11/F, Cheng Yu Tung Tower,
The University of Hong Kong

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<td>9:00 - 9:30 am</td>
<td>Registration</td>
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<td>9:30 - 9:40 am</td>
<td><strong>Welcome Address</strong></td>
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<td>Mr Terry Kaan, Co-Director, Centre for Medical Ethics &amp; Law, the University of Hong Kong</td>
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<td>9:40 - 10:00 am</td>
<td><strong>PRESENTATION 1:</strong></td>
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<td><em>Handling Foetal Remains - A Hong Kong case study: obtaining a dignified and respectful internment for little Wally</em></td>
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<td>Associate Professor, Department of Pathology, the Li Ka Shing Faculty of Medicine, the University of Hong Kong</td>
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<td><em>WHO OWNS YOUR BODY – Please come and collect?</em></td>
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<td>10:20 - 10:50 am</td>
<td><strong>BREAK</strong></td>
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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 - 2:20 pm  **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 - 2:40 pm  **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

6:00pm

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
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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?
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.

Personalized medicine (PM) is often portrayed as the new paradigm 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.
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**
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.

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.
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.

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