CMEL
The University of Hong Kong
Centre for Medical Ethics and Law

Conference Report:

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, The Faculty of Law, The University of Hong Kong

Theme 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
Principal, Vidler & Co., Solicitors, Hong Kong

When miscarriages occur, grieving parents have to confront the further trauma of the dignified disposal of the foetal remains. In Hong Kong, the current practice and the authority's interpretation of the relevant legislation/ regulations mean that grieving parents are allowed to dispose of their foetal remains if the miscarriage occurred at or over 24 weeks of pregnancy, by way of burial or cremation. But as the recent controversy over the case of Angela and Kevin (not their real names) in 2017 illustrates, disposal by way of proper burial/ cremation for foetuses of less than 24 weeks remains an uphill battle for parents of such foetuses in Hong Kong. The child of Angela and Kevin was miscarried at 15 weeks of gestation. The couple faced a situation where foetal remains of less than 24 weeks were to be presumptively treated as clinical waste to be disposed of in landfills or by incineration. This approach reflects poorly coordinated legislation and institutional practice. This case strongly urges for public policy changes to overcome insensitive government policy and bureaucratic apathy. The guidance laid down by the Human Tissue Authority in the UK may provide a model: it lays down guidance requiring that women be given an opportunity to discuss their options and make an informed choice regarding their foetal remains. Institutional practice needs to be reviewed, and healthcare staff should be trained to support grieving parents with

respect and sensitivity. Only this way can parents dispose of their foetal remains in a dignified and respectful manner, which is the least they are entitled to in coming to terms with their grief.

Presentation 2:
WHO OWNS YOUR BODY – Please come and collect?

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

The number of deaths in Hong Kong in 2017 was approximately 46,000, over 90% of which occurred in the public hospitals. While the bodies of most people who died in the public hospitals are collected by family members, some of the remaining bodies classified as 'unclaimed' are left in mortuary compartments for a significant period of time and in one current case for as long as 300 days. Dead bodies can be kept in good condition in the mortuary for extended periods only if they are frozen (most bodies retained at mortuaries for the short term are not frozen, but are chilled to and maintained at an appropriately low temperature). Unfortunately, at present only a tiny number of mortuary compartments are freezers and dead bodies which are kept in mortuary compartments other than these freezers will inevitably deteriorate over time. The Births and Deaths Registration Ordinance does not specify who has ownership of and responsibility for such 'unclaimed' dead bodies. The reason why such bodies are left in mortuary compartments for so long varies. In some cases, there is no one who shows up to arrange for the burial of, the cremation of or other appropriate after-death arrangements for the deceased. In some other cases, the relatives and next of kin of the deceased are contacted, but collection of the body for the funeral is delayed because the relatives and next of kin prefer to wait for the results of the probate or letters of administration applications. In other cases, the hospitals and mortuaries are unable to trace the relatives or next of kin of those who die in the public hospitals. If the death is a reportable one in which case the coroner may rely on the police to conduct investigation, the police may assist in locating the relatives and next-of-kin of the deceased. If, however, the death is not a reportable one, then in practice it is rather difficult to procure the assistance of the police in tracing the relatives and next of kin of the deceased. It is suggested that either more freezers be made available in the mortuaries in Hong Kong for the longer-term storage of bodies, or that regulations be introduced limiting the time that bodies may be kept in mortuaries, with provision for mandatory disposal by burial or cremation by the authorities if a body is not claimed within an appropriate time limit.

Presentation 3:
Building Trust: The role of the professional and the role of the general public

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

Ms Suzuki is responsible for research ethics consultation at the Center for iPS Cell Research and Application (CiRA) at Kyoto University, Japan. One of her main interests is improving research practices by fostering and strengthening mutual trust in the relationship between

researchers and the public. She spoke about the efforts of her institution to build a positive and supportive trust relationship between biomedical researchers and their research subjects by communicating science and ethics to the public, and by fostering professionalism on the part of stem cell researchers at her centre.

As an example of her centre's public communication outreach effort, she gave as an illustration a booklet project entitled 'What is stem cell research' which sets out to explain in plain and simple language (the booklet is currently available in Japanese only) the work of the centre, and the likely impact of stem cell research on the future of medical technology and potential future clinical applications. It offers accessible information on the science of stem cell research and explores the relevant ethical issues from different perspectives. Ms Suzuki invited members of the audience to access the booklet at http://www.cira.kyoto-u.ac.jp/uehiro-ethics/report/what-is-stemcell/. Her institution holds events both on and off the campus of Kyoto University to engage the public, including a series of Center for iPS Cell Research and Application lectures for the public.

As for fostering professionalism, a professionalism programme is offered to stem cell researchers. The programme consists of lectures, case studies, group work and assignments, and is intended at prompting researchers to think about what kind of guidelines they wish to see adopted for the ethical regulation of their projects now and in the future, and why.

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 or precision medicine (PM) is a fast-growing field in patient care worldwide, both in the private and public sector. It requires efficient interaction between biobanks and holders of clinical data. However, this poses challenges to biobank governance. Some claim that PM increases the complexity and interdependencies in the biobanking business because data across different biobanks need to be aggregated to collect sufficient data. Others have privacy concerns over Big Data, which is typically created by genotyping large cohorts, and the issue of loss of health data. There have been significant legislative developments in this arena, notably the European Union General Data Protection Regulation (GDPR) which came into force on 25 May 2018 under which new and more stringent rules relating to individual privacy and data custodians' responsibilities have been established, together with increased penalties for breaches of obligations for responsible data management under the GDPR. To build trust with stakeholders it is suggested that lay members be included in the boards of biobanks and that there be increased interaction and collaboration with patient interest organizations. Where possible and appropriate, individual research results should also be returned to donors. Together this will make for improved biobank governance in the age of PM.

Roundtable and Q&A
Chair: Ron Zimmern, Chairman
Board of Trustees, PHG Foundation, the University of Cambridge
Panel: *All speakers in this first session*

Michael Vidler mentioned that there is public concern over increased commercialization of biobanks, and over whether biodata held by the HK government or governmental institutions and agencies may be accessible by other jurisdictions. Philip Beh suggested that Hong Kong might consider how individual collections of biodata in the Special Administrative Region could be aggregated and built into a biobank and whether consent has to be obtained from the data subjects again for the purpose of building the biobank. Mika Suzuki said that more efforts should be made in communicating the relevant issues to the public if the research community is to maintain its vital relationship with members of the public, and with volunteer subjects. Morten Øien pointed out that biobanks are long-term ventures and recommended gradual development rather than a search for one big solution. He said that harmonization on a global level takes time, and recommended that regional governments give resources to regional hospitals to create biobanks. Ron Zimmern pointed out that precision medicine requires the sharing of information - the larger the size of the database that is available to work on, the greater our scientific knowledge which will enable the more precise targeting of therapies for individuals. Ron Zimmern noted, in this connection, that putting together huge population size databases is quite a challenge. He also noted that commercialization is inevitably an important driving force for medicine. It is necessary for biobanks to have a proper governance structure and transparency in their governance.

Theme 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

Ms Hall gave an overview of the implications and likely impact of the European Union General Data Protection Regulation (GDPR), which came into force in May 2018. The GDPR strengthens the rights of data subjects by giving them more control over their data. Data is often utilized using automated processing. The GDPR now requires greater transparency and meaningful explanation to data subjects about how their data is used. This means easily accessible information about data processing should be delivered in clear and plain language (Article 12). Genetic data that relates to an identified or identifiable individual comes within the scope of the GDPR. Data subjects also have the right not to be subject to a decision based solely on automated processing with legal effects 'significantly' affecting him or her (Article 22(1)), and are entitled to obtain human intervention, express his or her point of view and to challenge the decision (Article 22(3)). A voluntary code of conduct for data-driven health and care technology was recently published in the UK, and there are a number of proposed new regulatory strategies such as the use of open source software for more transparency.

Presentation 2:

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

Gerard Porter
Lecturer in Medical Law & Ethics, Director of Ethics & Integrity, Edinburgh Law School, the University of Edinburgh

The 1990 Supreme Court of California's landmark decision in *Moore v Regents of the University of California* 51 Cal. 3d 120 (1990) held that there was no conversion of property in relation to the excised cells extracted from the plaintiff during the course of a medical treatment. There is still much debate over the equitable distribution of profits derived from donated human tissues, such as the request made by the family of the late Henrietta Lacks for financial compensation arising from the commercialization of a cell line developed from her tissues. One way to compensate donors is through cryptocurrency, as is the case with Nebula Genomics, which puts the donors' genomes on a blockchain in return for 'Nebula tokens'. Customers can get insights into their own health and contribute to medical breakthroughs. Dr Porter discussed the case of a successful patent application over a gene involved in the disorder of pseudoxanthoma elasticum (PXE), where the goal was for the patent licence to be made cheaply and readily available to support further research to find a cure of this rare disease. In the English case of *Yearworth and others v North Bristol NHS Trust* [2010] QB 1, the sperm samples stored by a hospital for the benefit of a group of men who were due to undergo cancer treatment and might lose fertility as a result of the cancer treatment were destroyed and the English court recognized, for the purposes of the negligence claims, that the sperm samples were the claimants' property. Although this case slightly disturbed the *Moore* regime in the UK and might indicate a move towards recognition of the property rights of donors, it might be restricted to eggs, sperms and gametes.

Presentation 3:

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

Kathleen Liddell
Director, Centre for Law, Medicine and Life Sciences, the University of Cambridge
Mateo Aboy
Senior Research Scholar, Centre for Law, Medicine and Life Sciences, the University of Cambridge

There is increasing concern about the boundaries of patent eligibility over human body parts, DNA sequences and the body's responses to medicines. *Association for Molecular Pathology v Myriad Genetics, Inc.* 569 U.S. 576 (2013) is one of the most significant cases relating to the patenting of materials of human origin that has come before the US Supreme Court. In that case, the Supreme Court held that isolated naturally-occurring DNA segments are unpatentable and that an action must be new 'with markedly different characteristics from any found in nature' to be patent-eligible. Another leading US Supreme Court decision in *Mayo Collaborative Services v Prometheus Laboratories, Inc.* 566 U.S. 66 (2012) held that, because the patent claims in question recited laws of nature, which were not themselves patentable, and had no additional features that provided practical assurance that the processes were genuine applications of these laws of nature rather than drafting efforts designed to monopolize the correlations, the processes claimed were not patentable. Although these

decisions do not completely block patent-based property rights for inventions derived from the human body, they nonetheless narrow opportunities and provide a disincentive for research and development. *Mayo* also causes legal uncertainty.

Presentation 4:

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

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

The current legal framework on Intellectual Property (IP) protection for works and inventions generated by Artificial Intelligence (AI) is insufficient. The position as to whether an AI-generated invention complies with the technical criteria for patent eligibility is unclear, especially when many general software patents have been denied pursuant to the 'laws of nature' or 'abstract idea' rule as discussed in a 2014 US Supreme Court decision in *Alice v CLS Bank International* 573 U.S. 208. Moreover, where AI-generated works digest/ analyse thousands of works to create a new work, it is unclear whether the copyright fair use doctrine should apply.

Several proposals have been made in this respect. First, AI can be assigned with the legal status of 'electronic persons' with specific rights and obligations. Alternatively, AI-generated works can be treated as works-made-for-hire but there are different views as to the identity of the employer. Only with a robust IP system on AI protection in place can we create a legal environment conducive to cultural creativity and science and technology innovation.

Roundtable and Q&A

Chair: Ron Zimmern, Chairman
Board of Trustees, PHG Foundation, the University of Cambridge
Panel: *All speakers in this second session*

The emergence of AI as a disruptive force across industries has escalated the fear of displacement of human labour in today's age of automation. Gerard Porter pointed out our tendency to measure the value of human on the basis of economic productivity since the onset of the Industrial Revolution. Alison Hall suggested that we should embrace AI as an opportunity which enhances human capabilities by freeing up the workforce to focus on more intellectually demanding tasks. Meanwhile, the question arose as to who should be held liable in the event of injuries or harm resulting from the operation of AI. Mateo Aboy took the view that whether the AI is self-learning makes a significant difference in this respect, while Kathleen Liddell pointed out that we might wish to think about who we want to attribute liability to and to whom it is fair to attribute liability taking into account factors such as the control and resources different actors have. Kathleen Liddell added that we might wish to require professionals to take reasonable care. Ya-Hong Li noted that it is impractical to shift the blame to the machine itself.

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

Presentation 1:
Benefit Sharing in Medical/ Genomic Research

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

Where traditional knowledge is involved, fair and equitable sharing of benefits arising from the use of genetic resources should be extended to the indigenous and local communities. However, there is no legally binding international framework or regime governing access and benefit sharing (ABS) in relation to human DNA at present. There are 3 major challenges for genomic research: (1) how benefit can be shared appropriately; (2) how to share benefits without inhibiting research; and (3) how not to provide undue inducement.

Issues of exploitation have arisen, including the lack of informed consent and abounding instances of biopiracy. Challenges have been posed to long-term equitable research relationships, resulting in suspicious and critical attitudes of the indigenous people despite the exceptional value they hold for genomic researches. Indigenous peoples have gone to court to complain about the lack of consent and perceived abuse. A number of such cases were examined. The first crisis involved the Havasupai people from Arizona who challenged for their DNA materials to be returned arguing that the consent did not cover the research in question. The case was settled in 2010. The second crisis involved the Hagahai people from Papua New Guinea. Patent protection was sought for an invention developed from a blood sample from the Hagahai. The Hagahai felt that consent was not properly taken and that benefit was not shared. The patent was eventually withdrawn. The third crisis involved the Nuu-Cha-Nulth people from Vancouver Island, who in 2000 asked for the return of their samples originally collected for a research study on arthritis. Fourthly, a genetic discovery was sold by Sequana for 70 million dollars but the relevant indigenous people, the Tristan da Cunha islanders, received no benefit. Fifthly, a genetic study found that the Maori people were much more likely to carry a gene allegedly linked to alcohol/tobacco abuse, which was dubbed the ‘warrior gene’. The finding was regarded as deeply insulting by the Maori people and hence resulted in mistrust in this kind of research on the part of the Maori people and other indigenous peoples.

Dr Chennells emphasized the importance of being conscious about the value of the indigenous people as containing ancient knowledge, genes and cultural practices. How to deal with the indigenous people as a genomic researcher does carry challenges. For genomic research involving indigenous peoples, one should obtain permission from the collective and consent from the individuals. In 2010, a group of researchers conducted genomic research on the San People with consent from the individuals tape-recorded, but the publication of their research findings was objected to by the elders of the San people. The San eventually launched the San Code of Research Ethics in 2017. The Global Code of Conduct for Research in Resource-Poor Settings has been recently adopted by the European Commission for Horizon 2020 to counter ‘ethics dumping’, the practice of exporting unethical research practices to lower-income settings. The code is based on the four values of fairness, respect, care and honesty.

Resources available:
https://www.nature.com/articles/d41586-018-05616-w
https://link.springer.com/book/10.1007%2F978-3-319-64731-9
http://www.globalcodeofconduct.org/
http://www.globalcodeofconduct.org/affiliated-codes/
http://trust-project.eu/

Presentation 2:
Ethical and Regulatory Considerations on Biobanking in the Republic of Korea

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

In 2008, the Korean Biobank Project was launched to collect and manage human biospecimens. It has established various biobanks in Korea, which are connected by the Korean biobank network enabling them to share information and resources through the Biospecimen Information Management System. A number of ethical, legal and social issues in relation to the regulation of biobanks have arisen. First, a plan to integrate the data from biobanks with data from other sources is being considered for the purpose of enhancing precision medicine but, the prospect of re-identification by combining anonymized data with other data and the risk of privacy infringement in a 'big-data' environment are issues of concern. Second, as reflected by the results of a public awareness study, there is a pressing need to develop legal and institutional frameworks against discrimination on the basis of genetics and health data. Yet, considerable difficulty is anticipated in drawing a line between discrimination and reasonable use of genetic information. Third, the option of adopting a dynamic consent model, which might enhance individual autonomy, is considered. In light of these challenges, a more comprehensive and responsive governance network is required to secure public trust in biobanking policies.

Presentation 3:
Re-thinking Social Value in Access to and Benefit Sharing of Biological Materials and Related Data in Biomedical Research

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

The social value of biobanking, that is, the creation of generalizable knowledge, which should be applied in a way that is beneficial to humanity without creating undue harm to the individuals and stakeholders concerned, and the equitable and fair sharing of the benefits, should remain the primary consideration for issues of accessing and benefit sharing of genetic resources. When an avian influenza (H5N1) outbreak took place in 2006, there was a global shortage of the medications and vaccines as countries stockpiled them. At that time, Indonesia refused to share virus samples with the international community. A series of negotiations within the framework of the Convention on Biological Diversity and the Nagoya Protocol took place and eventually gave rise to the Pandemic Influenza Preparedness (PIP) Framework, which assured that a certain percentage of diagnostics and therapeutic

interventions would be provided to countries in exchange for their granting access to their samples. However, subsequent outbreaks did not see this kind of response. Such episodic and transactional response is inadequate.

In a national context, the Human Biomedical Research Act, which facilitates the sharing of materials and data and is premised on consent, was enacted in Singapore in 2015. In a global context, the World Health Organization has issued Guidance for Managing Ethical Issues in Infectious Disease Outbreaks in 2016 setting out principles on the long-term storage of biospecimens collected during an outbreak and is developing a blueprint material transfer agreement (MTA) tool. It is suggested that a more holistic governance framework should be established. Nonetheless, there are a number of challenges, including the disputed scope of existing international documents, the insufficient legal capability of certain nations to put in MTAs and other legal arrangements, weak global governance and a lack of robust monitoring and evaluation mechanisms.

Presentation 4:

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

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

The issue of ownership of body parts is explored by examining the management of the human induced pluripotent stem cells (hiPSCs) banks and the accessibility of the stored cells. First, the homozygous HLA-typed hiPS cells, which are managed at the Center for iPS Cell Research and Application (CiRA), are accessible to other researchers upon approval from CiRA's ethical committee and on the condition of the existence of research collaboration with CiRA. Besides, the 'producers' (researchers) are entitled to set conditions for access to and use of the cells for the disease-specific hiPSCs that they deposit at RIKEN BioResource Center.

However, challenges have been posed to the notion of public ownership. Despite the emphasis on national interests, the hiPSCs stored at these banks seem to belong to their 'producers'. Hence it is unlikely that their ownership can be transferred to the public domain. As a result, the possibility of public management of privately owned matters to ensure that they are used in the interest of the wider public is raised. Alternatively, encouraging the circulation and appropriation of hiPSCs and the knowledge acquired may be a way to keep them in public hands.

Roundtable and Q&A

Chair: Ron Zimmern, Chairman
Board of Trustees, PHG Foundation, the University of Cambridge
Panel: *All speakers in this third and final session*

There was further discussion on the issue of the ownership of genetic resources. Calvin Ho took the view that individuals arguably have a moral obligation to make donations for the benefit of future generations if they have benefited from the research done on the basis of

donations made by others in the past. He suggested that, in terms of whether individuals should share their DNA or pathogens for the purpose of research, because individuals are embedded in society and society has supported individuals in different ways, arguably individuals have some moral obligation to do something that would advance the interest of the collective whole. Roger Chennells also stressed the notion of collective ownership of traditional knowledge with reference to the Nagoya Protocol. In response to the current lack of legal framework for benefit sharing, he commented on the emerging concept of 'genetic sovereignty', which is the idea that the national governments of the day are in effect the sovereign managers and custodians of all genetic resources in their countries meaning that the national governments can negotiate and protect the genetic resources in their countries. Moreover, clarification has been sought as to whether the genetic material by itself or the information derived from the material is the subject matter concerned in the debate of ownership. Roger Chennells suggested that the people arguably have the right to give or withhold consent with regard to the DNA, which might be called ownership. Calvin Ho argued from an economic standpoint that ownership is also about who is most likely to make the best use of the resources and is a matter of social value and social negotiations.

The notes of the presentations and panel discussions set out above were prepared by CMEL staff: any errors or inaccuracies are solely the responsibility of CMEL, and are not to be attributed to the authors or presenters.