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CENTRE FOR MEDICAL ETHICS AND LAW

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Personal Data Protection Regimes and the Sharing of Human Genetic Data for Research

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WEBINAR SUMMARY

The presentations were made by the presenters in their personal capacity. The opinions expressed are the presenter's own and do not necessarily reflect the views of the organisers, the Centre for Medical Ethics and Law and the PHG Foundation, or the views of the sponsoring organisation, WYNG Foundation.

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Personal Data Protection Regimes and the Sharing of Human Genetic Data for Research

On 22nd April 2022, the University of Hong Kong Centre for Medical Ethics and Law (CMEL) and the PHG Foundation co-organised a webinar exploring the impact of personal data protection laws on the sharing of genetic data for biomedical research. The panel discussed this topic across a number of jurisdictions: Hong Kong SAR, Mainland China, Canada, the European Union and the United Kingdom.

The 90 minute webinar began with introductory remarks from the Chair, followed by three speaker presentations and a Q&A session. Over 140 participants across Asia, Europe and America registered to attend, listen to the speaker's expert insights and participate in the discussion. Attendees included students, academics, researchers, healthcare professionals, legal practitioners and public sector representatives.

Summary of the key points:

- Human genomic research and innovation are dependent upon access to large quantities of data
- It is likely that in most instances genetic data qualifies as 'personal data' and is therefore subject to stricter data protection regulations
- There is some convergence in international approaches to data protection of genomic data in terms of definitions, principles and a range of similar obligations when processing personal data
- However, differences between the ethical, and policy frameworks and cultural norms limit the extent of actual convergence in the regulation of genomic data worldwide
- Although the model created by the EU GDPR has been well received, it is not up to one region to dictate normativity on a global scale. Law and policy must reflect ethical frameworks and cultural values if they are to be successful
- In the absence of a uniform, harmonised international framework, interoperability is an important objective to enable equitable and responsible data sharing

Speakers Presentations

Introduction and brief remarks on genome data sharing in Hong Kong SAR

Dr Calvin Ho, Associate Professor of Law & Co-Director of the Centre for Medical Ethics and Law, The University of Hong Kong, Hong Kong, China

To introduce the topic of this webinar, Dr Ho began by describing an open science initiative, and the particular importance of data sharing in the field of genomics. This provided the context for the other speakers' presentations on the different jurisdictional requirements for the collection and processing of personal data, and the challenges posed by the fact that they tend not to give specific regard to the varied research uses of personal data in genomics. With this in mind, Dr Ho then provided some insights into the regulatory landscape in Hong Kong SAR, drawing

attention to Personal Data (Privacy) Ordinance (PDPO) which is the key legislation governing the protection of personal data. The definition of 'personal data' contained in section 2 which applies to data that relates directly or indirectly to a living individual is remarkably similar to the definition in other international regulations, notably the European Union's General Data Protection Regulation (GDPR). However, the PDPO makes no specific mention of genetic data, whereas the GDPR explicitly refers to the 'processing of genetic data' in its Article 9 definition of 'sensitive personal data'. This does not mean that genetic data are excluded from the PDPO though, since as Dr Ho highlighted, in a statement in 2017 the Privacy Commissioner implied that genetic data could constitute personal data, indicating that genetic companies are required to notify the individuals concerned upon collection of genetic data from them, not to use the collected data for a new purpose, and not to retain the data longer than is necessary to fulfil the purpose for which it was collected. The PDPO contains further provisions relating to statistics and research (Section 62) and cross border data transfers (Section 33- although this is not yet in operation) which, alongside important guidance from the Privacy Commissioner on international data transfers and genetic data as sensitive biometric data, build a significant regulatory framework for the processing of personal genetic data.

An ethical perspective on the implications of the Personal Information Protection Law for human genomic research in China

Dr Haihong Zhang, Office Director of Peking University Human Research Protection Programme, Health Science Center, Peking University, China

Dr Zhang outlined the regulatory framework for personal data protection in China, describing the legal requirements for the processing of personal information under the recent Personal Information Protection Law, and placing these requirements in the context of the ethical and governance framework for genomic research. Her presentation highlighted some of the key challenges that are faced by researchers and Institutional Review Boards during the ethics review process for human genetic research, including conducting risk benefit assessments (which involves deciding upon an acceptable risk control measurement, and increasingly, evaluating the social value of such research), and the myriad different requirements for the different kinds of consent necessary for primary research, international sharing, and secondary uses.

Dr Zhang described the challenges raised by the lack of operational guidelines, even in the case of more established regulations such as the Regulations on the Management of Human Genetic Resources, and the knock on effect this has on researchers and investigators, leading to time consuming administrative procedures.

However, more detailed regulations and ethical guidelines are being developed to streamline and increase the efficiency of ethics review and national level administration processes of human genetic research. There is also a need for capacity building at an institutional level to support investigators so that they can be informed of the ethical and regulatory requirements.

The impact of the UK and EU General Data Protection Regulation (GDPR) on international genomic data sharing for research

Dr Colin Mitchell, Head of Humanities, PHG Foundation, University of Cambridge, UK

Dr Mitchell's presentation discussed the challenges for international genomic data sharing raised by the EU GDPR and the UK's closely aligned version of the same regulation. These include those stemming from uncertainty and disagreement around fundamental aspects of the Regulation and how they should be applied in this context, in particular which data fall within the scope of the GDPR, the appropriate legal bases for processing and safeguards that may be applied. Other challenges arise as a consequence of the specific rules contained in Chapter V on the GDPR governing transfers of personal data from the EU/EEA to 'third countries'. Notably, the overarching requirement to ensure essentially equivalent protection to that provided in the EU is very difficult for data 'exporters' to fulfil.

However, a range of different mitigations or solutions were also discussed: In terms of uncertainty, this is being progressively improved through guidance and developing consensus; in terms of the international transfer mechanisms, there is the potential for improvement in terms of codes of conduct (or, in the UK perhaps, alternative research specific mechanisms) and finally; bilateral agreements such as those between EU-US hold the promise of smoothing some international data flows.

Canadian Genome Data Sharing: Lessons learned from the experience of the CanCOGeN Network

Prof Yann Joly, Research Director, Centre of Genomics and Policy (CGP) and Professor, Department of Human Genetics, Faculty of Medicine McGill University, Canada

Professor Joly's presentation raised current challenges in sharing genomic data, within Canada and between Canada and other countries. He used a case study approach, based on his experience of the past two years as Chair of the CanCOGeN data sharing Committee, to illustrate the various hurdles to data sharing encountered in Canada. At the start of the pandemic, in April 2020, CanCOGeN was launched to coordinate a pan-Canadian, cross-agency network for large-scale SARS-CoV-2 and human host genome sequencing and sharing, with plans to oversee the sequencing of genomes of up to 150,000 viral samples and 10,000 patients. The open sharing of minimal privacy risk viral sequences and their associated contextual data information is crucial for understanding key factors surrounding COVID-19. However, they encountered challenges in doing so at a sufficiently rapid pace due to the privacy and data governance concerns from public health authorities that publicly releasing such data triggers. Other barriers included the federated-provincial division of powers in Canada, lack of capacity, and perceived lack of incentives.

In responding to these challenges, CanCOGeN assembled a Data Sharing Workgroup, invested in capacity building in the Canadian Public Health Laboratory Network and provincial labs, created the Canadian VirusSeq Data Portal to securely facilitate data sharing in a manner that is accessible, and developed a data sharing roadmap. The initiative also identified avenues for legal reform for more sensitive data types, such as amending data protection legislation to

stipulate that personal information can be collected and disclosed for public health purposes in combination with appropriate anonymization and good information stewardship practices.

Key themes from the discussion

Identifiability and anonymised data

The audience questioned the extent to which some genomic data, for example derived from tumours, would be considered personal data within the legal frameworks. This led to discussion of the difficulty in determining that data are not identifying in contexts where other information may be used to help single out or identify an individual (such as associated clinical data) and the need for ongoing consideration of whether new technologies or techniques have rendered previously unidentifiable data 'personal data'.

Convergence of regulatory approaches across jurisdictions

There was discussion around the extent to which there is convergence, or alternatively divergence, in international approaches to data protection impacting the genomic context. Speakers noted that whilst there is some convergence in the regulation in terms of the formal definitions of personal data and many of the general principles or requirements for processing, this must be caveated by acknowledging the gaps in alignment between the ethical, and policy frameworks and cultural norms in different counties.

Interoperability

It was agreed that complete harmonisation between countries was unlikely in the near future, and that therefore developing interoperability around governance is an important objective to enable international data flows. The work of the Global Alliance for Genomics and Health was highlighted as particularly important in this regard for genomic research collaborations.

The future of data sharing and the impact on researchers

There was discussion around whether increasing bureaucracy around data sharing arrangements may result in a regulatory structure which is complex and time consuming for researchers.

Part of the solution identified by the panel is data federation, which allows integration and analysis of large datasets from various sites without moving the data from locally controlled databases and computing environments. This allows researchers access to larger sample sizes, facilitating large-scale data comparison without compromising security. Overall, the panel noted that the edifice of successful data sharing ultimately rests on the trust of individuals and that it is crucial that those involved in data-sharing demonstrate their trustworthiness through transparent policies and careful deliberation of the appropriate approach with patients, participants and public involvement.