



Centre for Law and Genetics Annual Report 2017–2018



From the Director



Highlights

- Received ARC Discovery Grant for *'The Regulatory Environment for Innovative Health Technologies: Identifying Overreach and Filling Gaps'*
- Received ARC Discovery Grant for *'Genomic Data Sharing: Issues in Law, Research, Ethics and Society'*
- Resolution of the *'IP Australia'* Project and the *'MTA Project'*
- Prof Dianne Nicol appointed as Chair of the NHMRC Embryo Licensing Committee
- 1 new PhD candidate enrolled

2017–2018 was a prolific period for the Centre for Law and Genetics (CLG). In this time, we added high-impact research to our publication record and expanded our staff, PhD cohort, collaborative networks and external appointments.

Of particular excitement was the award of two Australian Research Council (ARC) grants in the 2018 discovery project round. These grants fund new projects addressing issues in genomic data sharing and the regulation of innovative health technologies. Both projects build upon research themes in recently completed projects such as: *'Intellectual Property and Diagnostic Testing'* and *'Material Transfer Agreements and the Genomic Research Commons'*. In addition to these grants, I would like to thank the University of Tasmania for providing strategic funding to promote the CLG's development during 2017.

In 2017–2018, CLG staff presented at conferences and workshops in Geneva, Hong Kong, Singapore, California, Sydney, Brisbane, Adelaide, Hobart, Canberra and Townsville. We further developed links with our international collaborators, and maintained relationships with former CLG members appointed to positions overseas. While this period saw the departure of several CLG members to pursue careers in academia and legal practice, our team has also expanded. Dr Rebekah McWhirter has been appointed as a senior research fellow, and Jenny Kaldor as a postdoctoral researcher. I am also pleased to report the enrolment of Vanessa Warren as a PhD student.

I look forward to reporting in 2019 on the results of our ongoing projects and the CLG's continued success.

Professor Dianne Nicol

Australian Research Council Grants

Genomic Data Sharing: Issues in Law, Research Ethics and Society

Genomic data sharing is becoming an essential component of clinical and research practice. Globally, legal and quasi-legal requirements may constrain free and open genomic data sharing. However, these requirements might also provide the assurances necessary to protect donors, encourage research and innovation, and promote ongoing public trust in genomic data sharing activities. In late 2017, the CLG was notified that we had been awarded an ARC Discovery Grant in order to focus on these issues for the next four years, commencing in January 2018.

In 2018, the project team conducted interviews with key stakeholders involved in the collection, storage, sharing and use of genomic information. From these interviews, the team has developed representative scenarios. These scenarios focus on relevant issues such as: data collecting; constraints on data sharing; originators' control over subsequent sharing; originators' knowledge of how and where data is stored, used and developed; and data destruction. In 2019, after conducting a thematic analysis, the team will validate these scenarios with key stakeholders and international collaborators. Following this, a representative sample of Australians will be surveyed on their reactions to these scenarios.

Reforming the Regulatory Environment for Innovative Health Technologies

Procedures such as genome editing, medicines such as biologics targeted to individual patients, and devices such as 3D printed biological structures, to name a few, are enhancing our capacity to identify and correct individual bodily defects. Given the pace of scientific discovery, clinical transition is not occurring as rapidly as might be expected. While insufficient oversight can impede patient safety, resulting in unnecessary morbidity and mortality, an undue regulatory burden can impede innovation and associated health and economic benefits.

In late 2017, the CLG was notified that we had been awarded an ARC Discovery Grant to investigate these issues. This project commenced in July 2018. The project aims to provide recommendations about best regulatory practice by mapping the landscape of regulatory requirements governing the clinical transition of innovative medical technologies in Australia. While this study focuses on a limited number of case studies, it uses a methodology that allows comparison across technology areas and across regulatory pressure points to account for multiple and diverse perspectives. The project's initial findings will be published early in 2019.



<http://www.utas.edu.au/law-and-genetics>



Outcomes and Projects Coming to a Close

Intellectual Property and Diagnostic Testing

The genetic diagnostic testing project was commissioned in 2016 by Intellectual Property Australia in response to the High Court's 2015 decision in *D'Arcy v Myriad Genetics*. This case concerned the patentability of BRCA DNA sequences in Australia, but has broader implications for patentability in the genetic diagnostic testing area. The aim of the project was to analyse whether the decision in *D'Arcy* has had a discernible impact on the cost of genetic diagnostic testing. The methodology for the project involves an analysis of relevant case law, literature reviews and interviews with stakeholders in the genetic diagnostic testing sector.

The project concluded that there are a number of factors that have impacted on the cost of genetic diagnostic testing over the previous decade, and that it is very difficult to attribute any reduction in cost to one particular factor, including the *D'Arcy* decision. The outcomes of the project have been published as Occasional Paper #9 in the CLG's Occasional Paper series and have been accepted for publication in the *European Intellectual Property Review* in 2019.

Material Transfer Agreements and the Genomic Research Commons

The Material Transfer Agreement (MTA) project aimed to examine the history, development, use and impact of MTAs by Australian universities, research institutes, companies and scientists. This included a doctrinal analysis of relevant issues in contract law and intellectual law, including an investigation into the feasibility of a nationwide standard for model MTAs.

The project resolved in late 2018. The results have been published as Occasional Paper #10 in the CLG's Occasional Paper series, as well as a number of journal articles and book chapters.

CLG Collaborations

- **Professor Cameron Stewart** from the University of Sydney is a Chief Investigator on the 'Reforming the Regulatory Environment for Innovative Health Technologies' project.
- During 2017 and 2018, the CLG continued its collaboration with **Professor Jane Kaye**. Professor Kaye is one of the experts on the Genomic Data Sharing advisory panel. The team have also been collaborating with Professor Kaye on adaptive governance for the Innovative Health Technologies project. In 2018, Professor Kaye, Professor Otlowski and Professor Nicol co-convened the Brocher Foundation Conference on Applying Adaptive Governance to Emerging Technologies in Health.
- **Associate Professor Mark Taylor** and **Dr Jessica Bell** from the HeLEX team at the University of Melbourne visited the CLG in 2018, and hosted a seminar called 'Second-Hand Data: What does healthy governance look like?'
- **Dr Michael Morrison**, from the University of Oxford's HeLEX group, is an advisor on the Innovative Health Technologies project and visited the CLG in October 2018. Professor Nicol is on the advisory panel of Dr Morrison's Biomodifying Technologies project, and travelled to Oxford in March to collaborate with the HeLEX group.
- **Dr Ruth Stirton** came to the University of Tasmania in 2018 as a visiting scholar. She presented a seminar to staff called "'I felt I had failed forever at breastfeeding"; Why mothers' voice need to be heard in legal and policy developments around infant feeding.'
- In 2017, **Professor Rochelle Dreyfuss** was a visiting scholar at the UTAS Faculty of Law. Following her visitation period, Professor Nicol, Dr Jane Nielsen and Professor Dreyfuss published 'Patenting Nature – A Comparative Perspective' in the *Journal of Law and the Biosciences*.
- In 2018, former CLG member **Dr John Liddicoat** came to UTAS Faculty of Law as a visiting scholar. Dr Liddicoat and Professor Nicol wrote a paper that has been approved for publication in the *European Journal of Human Genetics*. While at the Faculty of Law, Dr Liddicoat presented a seminar to staff.
- **Associate Professor Clara Gaff** visited the CLG in 2018, and presented a seminar to staff called 'Putting law and ethics into practice: implementing a large scale genomic data system'. Associate Professor Gaff also assisted the CLG with its Genomic Data Sharing project.
- In 2017, Professor Nicol and Distinguished Professor Don Chalmers published 'The Path to reducing duplication of Human Research Ethics Review in Australia' with

Amber Johns, who works at the Garvan Institute. Ms. Johns visited the team in 2018.

- The CLG collaborated with **Dr Ian Freckelton**, contributing to his book *Disputes and Dilemmas in Health Law*. In 2018, Dr Freckelton came to Hobart to discuss recent developments in health law with the CLG.
- **James Scheibner** has just submitted his PhD under the supervision of Professor Nicol and Dr Nielsen. He is currently working with Professor Effy Vayena's team at the Health, Ethics and Policy laboratory at ETH Zurich.
- Following his appointment at the Auckland University of Technology in 2017, the CLG has continued to keep in touch with **Dr Moshood Abdussalam** about the development of intellectual property law.
- Professor Otlowski, Dr Lisa Eckstein and Dr Rebekah McWhirter continued working with the **Genetic Counselling team** at the Royal Hobart Hospital over 2017–2018.

CLG Presentations

- In 2018, Professor Nicol was invited to present on regulation of genome editing in Australia at the Second International Summit on Genome Editing in Hong Kong.
- In 2018, Professor Nicol co-convened a workshop at the AABHL Conference with collaborators Professor Taylor, Professor Kaye and Dr Bell, titled 'Exploring the Implications of Collapsing Boundaries in Health Law and Ethics'. The workshop addressed privacy and anonymity, the research/ clinical divide, return of research results, the public/private divide and public trust.
- Dr McWhirter also hosted a workshop at the 2018 AABHL Conference. With the help of Professor Stacy Carter, Assistant Professor Tamra Lysaght and Professor Vikki Entwistle, Dr McWhirter addressed standards in empirical ethics research.
- In 2018 Professor Otlowski was an invited speaker at the Queensland Genomics Health Alliance ELSI Public Lecture at the Queensland University of Technology titled 'Genetic Discrimination in Australia: A Timely Reappraisal.'
- Professor Otlowski also acted as Session Chair and Panel Member at the ATSE NSW Health Symposium on Big Data and Genomics 2018.
- In 2018, Professor Otlowski and Professor Nicol co-convened the Brocher Foundation Workshop, Applying Adaptive Governance to Emerging Technologies in Health. At the workshop, they chaired sessions and led discussions. Professor Nicol presented on the regulatory challenges in genome editing.
- In 2018 Professor Nicol presented with Professor Rochelle Dreyfuss at Professor Hank Greely's Bio Lawpalooza Conference at Stanford Law School. Their

presentation addressed issues raised in their paper: 'Patenting Nature – A Comparative Perspective'.

- In 2018, Professor Otlowski and Dr McWhirter presented at the Big Data Symposium in Singapore.
- In 2017 Professor Otlowski was a Panel Member at the Introductory Short Course in Genomics and Molecular Pathology at the Royal College of Pathologists of Australia.
- In 2017 Professor Otlowski was a Panel Member at the Gene Editing Symposium held at the Menzies Research Institute.
- In 2018 Professor Otlowski was a speaker for the RANZCO Translation of Genetic Eye Research symposium.
- In 2017, Dr McWhirter co-convened a workshop in Sydney titled 'The Elephant in the Room'.
- In 2017, Professor Nicol presented on various intellectual property and regulatory issues in Sydney, Brisbane, Canberra and Hobart.

External Appointments

- In 2018, Professor Nicol was appointed Chair of the National Health and Medical Research Council Embryo Research Licensing Committee, after being a member since 2015.
- In 2018, Professor Nicol was appointed as a member of the Steering Committee for the Federal Government's Genomics Health Futures Mission and Chair of the Committee's Ethical, Legal and Social Implications Working Group. Professor Otlowski was also appointed as a member of the Working Group
- In 2018, Professor Dianne Nicol concluded her membership with the Gene Technology Ethics and Community Consultative Committee of the Office of the Gene Technology Regulator and the National Health and Medical Research Council Australian Health Ethics Committee. She also concluded her position as Chair of the National Health and Medical Research Council Australian Health Ethics Committee/Embryo Research Licensing Committee Emerging Technology Sub-group.
- In 2017 and 2018 Dr Eckstein continued as Deputy Chair of the Tasmanian Health and Medical Research Human Research Ethics Committee. Dr McWhirter is also a member of the Committee.

- In 2017, Professor Dianne Nicol concluded her membership to the Ethics Review Equivalency Task Team of the Global Alliance for Genomics and Health Regulatory and Ethics Working Group.
- In 2017 and 2018, Distinguished Professor Chalmers continued his work as member of the Governance Board of the National Centre for Indigenous Genomics.
- In 2017 and 2018, Distinguished Professor Chalmers continued his work as the chair of the Data Access Committee of the International Cancer Genome Consortium.
- In 2017 and 2018, Dr McWhirter was appointed co-leader of the Empirical Ethics stream in the Australasian Association of Bioethics and Health Law.
- In 2017 Professor Otlowski was appointed as a member of the Australian Research Integrity Commission.
- In 2017, Professor Otlowski was appointed as Chair of the Australian Genetic Non-Discrimination Working Group.

Teaching

- Dr Nielsen and Dr McWhirter were part of the teaching team for 'Complementary Medicines in Contemporary Society' (XBR120). This multidisciplinary course aims to give students the opportunity to analyse the use and place of complementary medicines in the modern health care system.
- In 2017, Dr Eckstein taught 'Law and Ethics of Health Care' (LAW695), which examines the relationship between law and ethics, and the delivery of health care and research.
- Professor Nicol and Distinguished Professor Chalmers taught 'Biotechnology Law' (LAW619) in the Summer of 2017. This unit teaches students about the major legal issues encountered by participants in the biotechnology industry.
- Dr Eckstein formulated and began teaching 'Ethical and Legal Aspects of Dementia Care' (CAD206). This unit examines the ethical theories, principles, and decision-making models that underpin dementia care.
- Dr McWhirter and Dr Eckstein guest lectured at the Queensland University of Technology as part of its new program in the Masters of Diagnostic Genomics. Dr McWhirter lectured on genetic research with indigenous communities, while Dr Eckstein lectured on ethical and psychosocial issues related to genetic research.
- The team have continued to teach into the first and second year of the Bachelor of Medicine.

New Arrivals

Jenny Kaldor

Jenny began work as a postdoctoral research fellow on the 'Reforming the Regulatory Environment for Innovative Health Technologies' project in mid-2018. She is currently focusing on the regulatory dimensions of the project: what is regulation? What regulation currently exist in this arena, and what would "fit-for-purpose" regulation look like? What problems do we encounter at the intersection of regulation and innovative health technologies?



Jenny is a graduate of Sydney Law School and was admitted to practice in 2007. Before coming to academia, she worked as a lawyer at AAR (as it then was) in Sydney, and in-house in the pharmaceutical sector in Cambridge, UK. Jenny has a Masters of Food Policy from City University London, and is in the final months of her PhD through Sydney Law School. Her doctoral research has focused on innovative regulatory instruments for the prevention of diet-related disease. Jenny has been involved in a number of high-profile public health law projects, including as the Rapporteur for a WHO consultation on obesity, overweight, diabetes and law in the Western Pacific Region, and as an author of a forthcoming Lancet commission on global health and the law, due to be published in April 2019.

Vanessa Warren

Vanessa Warren commenced her PhD with the CLG in 2018. Vanessa's PhD is an interdisciplinary, mixed-methods project investigating the social construction of public trust in genomic data sharing (GDS). Vanessa will consider how trust is developed, understood, and expressed by and through social norms, beliefs and assumptions, and the implications this has for effective GDS regulation. She takes a broad socio-legal approach, integrating empirical data collected from the Australian public and doctrinal and normative analyses of GDS regulatory processes and practices to identify opportunities for empirically supported law reform. Dr Lisa Eckstein, Professor Di Nicol, Professor Christine Critchley and Dr Emily Hansen are supervising Vanessa's PhD. Before coming to the CLG, Vanessa obtained a Bachelor of Arts (Sociology) from the University of Queensland and a Graduate Diploma in Information Management from the University of Tasmania.



Rachel Hay and Adam Irwin

Rachel Hay and Adam Irwin joined the CLG in 2018 as Research Assistants. Their positions are provided for by the Australian Research Council. Rachel is assisting the team on the ARC Genomic Data Sharing Grant, while Adam is working on the ARC Innovative Health Technologies Project.



Farewells

In 2017, Tess Whitton left the CLG to begin her PhD on the Adaptive Governance of Emerging Health Technologies at the University of Melbourne. During her time at the CLG, Tess worked as a Research Assistant and Project Manager, coordinating many of the CLG's projects. We wish her the best of luck with all of her future endeavours, and look forward to continuing our association with her.

In 2017, James Scheibner completed his PhD with the CLG and was subsequently appointed at the Department of Health, Sciences and Technology at ETH Zurich. We wish James the best of luck in his exciting new position.

In 2018, Ruthie Jeanneret left the CLG to go into practice. In her time with the CLG, Ruthie was a Research Assistant on the ARC Genomic Data Sharing project.



Publications from CLG members 2017–2018

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Tania Bubela, Yael Mansour and **Dianne Nicol**, 'The ethics of genome editing in the clinic: a dose of realism for healthcare leaders' (2017) 30(3) *Healthcare Management Forum* 159–163.

Ainsley J Newson, Jane Tiller, Louise Keogh, **Margaret Otlowski** and Paul Lacaze, 'Genetics and insurance in Australia: concerns around a self-regulated industry' (2017) 20(4) *Public Health Genomics* 247–257.

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