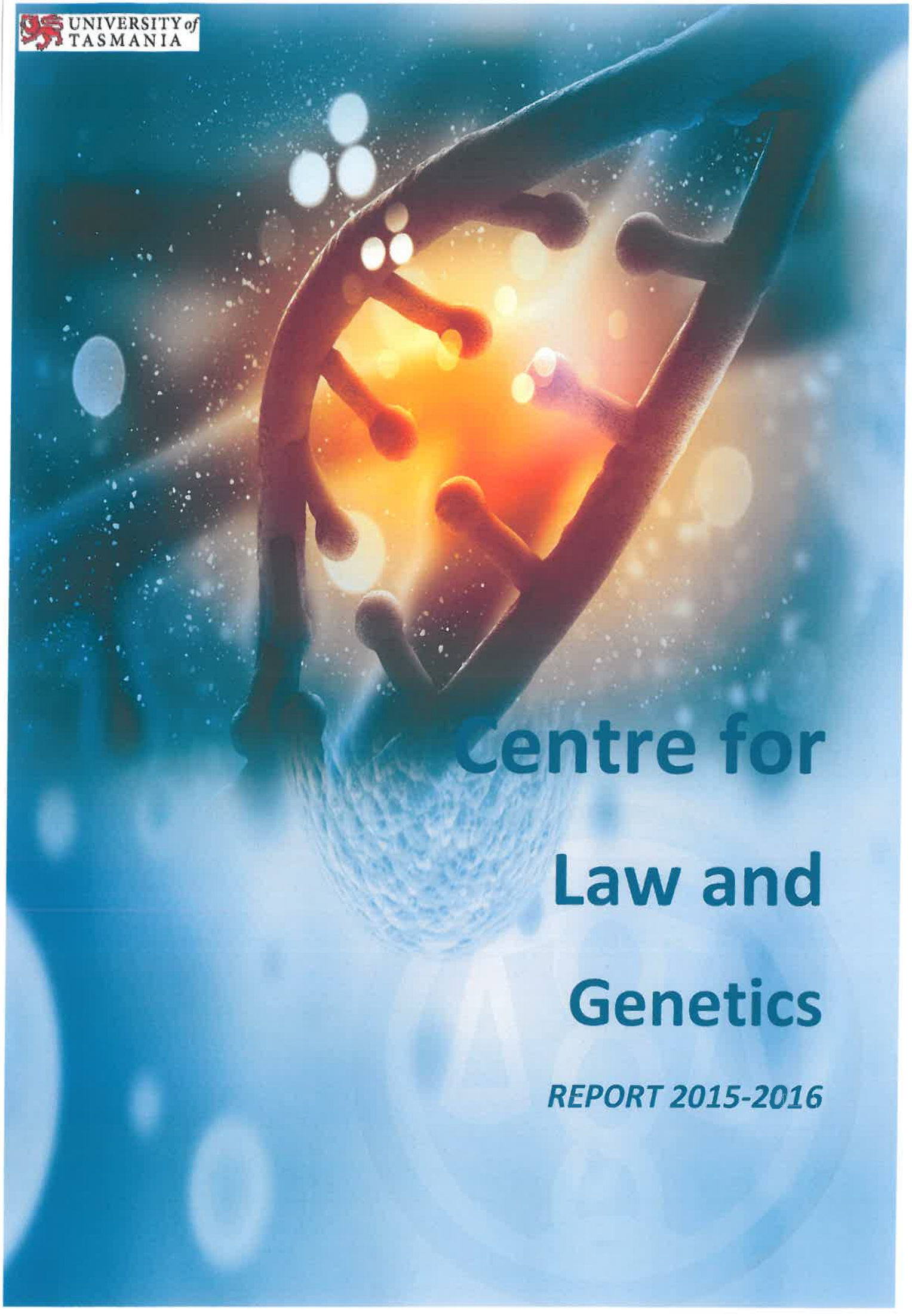
UNIVERSITY of TASMANIA
Centre for
Law and
Genetics
REPORT 2015-2016

Highlights

- CLG directors participated in a number of international bioethics and law workshops
- Jan Charbonneau presented to the US Federal Trade Commission
- CLG website launched with Researcher, Project and Research information available
- New PHD Candidates
- PhD Completion – Dr John Liddicoat – now a postdoctoral researcher at the University of Cambridge
- *D'Arcy v Myriad Genetics Inc* [2015] HCA 35 - Judgement on the BRCA Patents Delivered
- *Nature Biotechnology* Article – 'Gene Patent Storm Clouds Dissipating? A Global Snapshot' published
- ARC Personalized Medicine Project Completed

From the Director

I am delighted to be writing this, my first Director's annual report on the activities of the Centre for Law and Genetics (CLG). I took over this role from my friend, colleague and mentor, Distinguished Professor Don Chalmers in February 2015. I would like to take this opportunity to thank Don for the enormous contribution he has made to the CLG, and to my own career, for more than twenty years. 2015 was an auspicious year for the CLG, primarily because strategic funding from the Deputy Vice Chancellor – Research at the University of Tasmania allowed us to re-invest in the Centre's development. We were able to appoint Tess Whitton as our Projects Manager. Her contribution to the CLG has been invaluable. We have re-designed our website, solidified existing international collaborations and made contact with new colleagues in the field. 2015 marked the end of our personalised medicine project, generously funded by the Australian Research Council (ARC). Our ARC funded project on material transfer agreements in the life sciences continues. 2015 also marked the start of a series of new projects on a range of topics including regulation of big genomic data, regulatory and intellectual property issues in gene editing, and the intellectual property environment for 3D printing, with particular focus on bioprinting. This is an exciting time to be working in this field of law and genetics and I look forward to reporting again on our progress in 2016.

Professor Dianne Nicol

Expanding our Horizons

Direct to Consumer Genetic Testing – PhD Candidate Jan Charbonneau

Jan's research focuses on consumer protection in the context of direct to consumer genetic testing and in early 2015 she completed a large scale online survey of public attitudes towards direct to consumer genetic testing in the USA and Australia. The initial findings were presented at Oxford University, King's College London, Edinburgh University and at the European Society for Human Genetics meeting in Glasgow in mid-2015 where they were positively received. The UK's Wellcome Trust actively encouraged submission of a funding proposal for replication and extension of this research in the UK, in collaboration with a UK university. The CLG has used strategic funding to support collection of UK data in order to place it in a strong position to collaborate in a bid for future funding. A CLG collaboration with the Graduate School of Medicine, Osaka has also facilitated survey replication in Japan, with shared contributions.

In January 2016, Jan and a colleague from Oxford presented to the United States Federal Trade Commission on genetic privacy. The presentation, one of the 19 selected out of over 90 submissions, was live streamed and permanently archived in video and transcript form on the FTC's website, with links to the broader CLG research.

TasBioGRiD – CLG Collaboration

The CLG has been researching biobanks for over a decade and along with many other researchers have dreamed of having a Tasmanian Biobank. Over the last year in particular, Associate Professor Joanne Dickinson has been working with other members of the CLG on the Tasmanian Biorepository for Genetic Research in Disease (TASBIOGRiD) project, which if implemented will provide a facility where Tasmanian Researchers can access human tissue for research. Our consultation has been directed to creating a transparent, trustworthy governance framework and increase the benefits obtained form such a facility. Whilst this is some time away, the CLG has high hopes for the future of TasBioGRiD.

D'Arcy v Myriad Genetics, Inc [2015] HCA [35] (7 October 2015)

This case considered a patent claiming rights to isolated DNA sequences relating to a gene linked to increased susceptibility to breast and ovarian cancer. The court unanimously decided that the patent was invalid as it amounted to a claim to information. The case attracted a great deal of media attention. Professor Dianne Nicol was interviewed by the Conversation, the ABC, the Sydney Morning Herald, New Scientist and the Saturday Paper and has presented on this topic in various forums. CLG research assistant Will Bartlett also published a case note on the case in the *Journal of Law, Information and Science.*

International Connections and Outreach

High Impact Outputs

Members of the CLG have attended conferences and workshops across the globe, including in India, Singapore, Switzerland and France. Some are more notable in terms of their future impact. Professor Chalmers spoke on the *Ethical Challenges for Consent in Research* at a conference in Singapore, arranged by the Singapore Ministry of Health, held in November 2015. The conference was held to discuss 'Advancing Research Ethics in Singapore: Ethical and Legal Challenges in a New Regimen' specifically considering Human and Biomedical Research legislation that was to be introduced. Attendees included the Ministry of Health, senior hospital administrators, researchers and ethics committee members. Singapore has since taken a novel approach in their legislation as human tissue and data are treated essentially in the same manner. In Australia by way of comparison, protection for tissue is more limited as privacy only covers extracted data.

Professors Nicol and Chalmers teamed up with Professor Kaye from the Centre for Health, Law and Emerging Technologies at the University of Oxford to co-host a workshop on *Embedding Biobanks as Tools for Translational Research?* In June 2015. The key question discussed by the group of experts was whether the 'biobank bubble has burst' and how Biobanks should continue to operate when funding in many countries has been cut. This was the first time this question about continuation and future plans for biobanks was considered in a formal context. A paper was produced in response to this discussion to be published in BMC Medical Ethics later this year. It is hoped that this paper will prompt consideration at the academic and operational level about how to incorporate commercial funding into trustworthy biobanking models.

Research Updates and New Ventures

Legal Implications of 3D Printing and Bioprinting

The CLG has been researching the legal issues arising from the use of 3D printing technology, particularly those relating to intellectual property. Because 3D printing offers vast opportunities for replication and precision in manufacturing, it raises many issues in relation to intellectual property subsistence and infringement. Issues relating to the regulation of these new technologies are also at the forefront of research in the area. Jane Nielsen has presented two conference papers on the intellectual property/3D printing intersection (IP Academics Conference, Perth, February 2016), and on product safety in the 3D printing arena (ACES International Symposium on Electromaterials Science, University of Wollongong, February 2015). Several papers and book chapters are in the process of being published by Dr Nielsen and Dianne Nicol, including one forthcoming paper in the Australian Intellectual Property Journal. Dr Nielsen will attend a bioprinting workshop at the Brocher Foundation, Geneva in May 2016, which will be a precursor to seeking funding to extend the CLG's involvement in researching in the emerging area of 3D bioprinting.

A reason to reconsider gene editing - CRISPR Technology

Academics at the CLG have eagerly been following the development of CRISPR technology. CRISPR allows for the accurate cutting and splicing of genes and was recognised by *Science* as the Breakthrough of the Year. As this opens up potential use in somatic and germ line modifications, it triggers a re-investigation of the legal and ethical questions about when, if ever, is it appropriate to manipulate our genes, and how CRISPR can be used in light of this. A workshop will be held late 2016 to discuss this question with key international experts in the bioethics space.

ARC Funded Material Transfer Agreement Project

At the outset of our research on material transfers we sought ways to streamline legal processes to better facilitate innovation. Over the last two years on this project, it has become clear that although common, material transfers are variable in terms of both reasons for transfer and the attached obligations and responsibilities. As agreements are highly bespoke, our aim is becoming more challenging and similarly has more potential benefit. We are planning a workshop with a practical output for November 2016.

HDR Updates

Suzana Nashkova Suzana joined the CLG in late March 2016 to undertake her PhD under the supervision of Professor Nicol and Dr Nielsen. Her thesis is entitled *An Analysis of the Thorny Issues within the Process of Drafting Know-How Licence Agreements for University/Biotechnology Purpose.* She also has an LLM from the Université Nice Sophia Antipolis in the area of Public and Private Law.

James Scheibner commenced his PhD in January 2015 and successfully completed the confirmation process by the end of the year. He is supervised by Professor Nicol and Dr Nielsen. The title of James's thesis is *Open Source Licensing and the Genomic Research Commons*. He is focusing specifically on bioinformatics and will be examining the patent landscape and its impact on open source initiatives.

John Liddicoat John recently completed his PHD entitled *Boundaries of Patent Infringement Law (2012),* which was highly commended by its assessors. He took up a post-doctoral research associate position at the University of Cambridge, Centre for Law, Medicine and the Life Sciences where he continues to explore the legal relationships particularly between biobanking, synthetic biology and the law. John remains involved in the work of the CLG as an associate researcher.

Occasional paper series

Centre for Law and Genetics Occasional Paper Series – selected texts available from utas.edu.au/law-and-genetics or in print on request.

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