



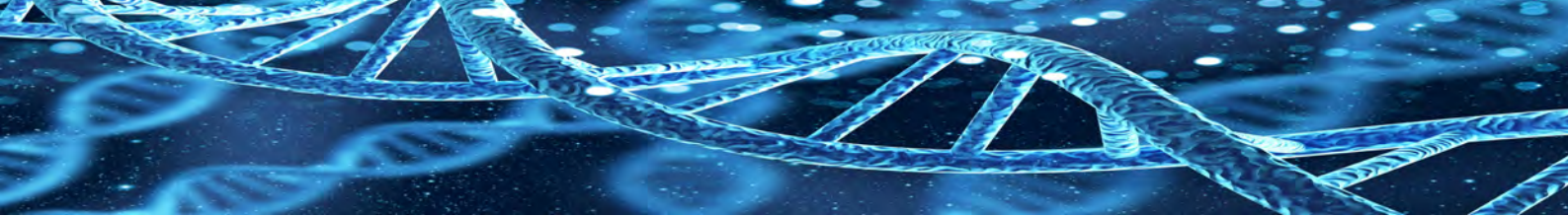
UNIVERSITY of  
TASMANIA



# Centre for Law and Genetics

## Annual Report 2021-2022





## From the Director

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2021-2022 have been productive years for the Centre for Law and Genetics (CLG). We progressed work on research grants, secured new research funding and continued to publish our research in high impact journals. Our community activities continued through a range of new external appointments and we also built on our collaborative networks.

During the earlier months of 2021 with the opening of the border here in Tasmania, we experienced greater exposure to Covid-19 after having been cocooned for a long time from the impacts of the pandemic. Fortunately, with high vaccination rates, our Tasmanian community has generally managed well.

At the end of 2021, Distinguished Professor Dianne Nicol stepped down from her position at the Law School and her role as CLG Director and was made Emeritus Professor. I took over from Di as Director of the CLG in January 2022 and Jane has stepped in to replace my role as Deputy Director.

## Highlights

- 8 Continuing grants
- 4 new grants
- 2 submissions
- 1 workshop
- 18 presentations
- 13 appointments
- 4 HDR completions
- 1 new enrolment
- Continued publication in high-ranking journals

A major piece of work by the CLG team in collaboration with the University of Melbourne HeLEX group which came to completion in 2021 was a consultancy with the Commonwealth Department of Health to undertake an assessment of the regulatory environment for health related genetic information. With the Department's permission, this Report was published in 2021 in our Occasional paper Series - '*Essentially Ours.*'

In addition to progressing the two continuing ARC Discovery Projects - *Genomic Data Sharing* and *The Regulatory Environment for Innovative Health Technologies*, we were excited to secure new grant funding. This has principally been in the form of Genomics Health Future Mission grants, funded by the Medical Research Future Fund highlighting how beneficial it is to have dedicated funding for genomics related research, including into ELSI.

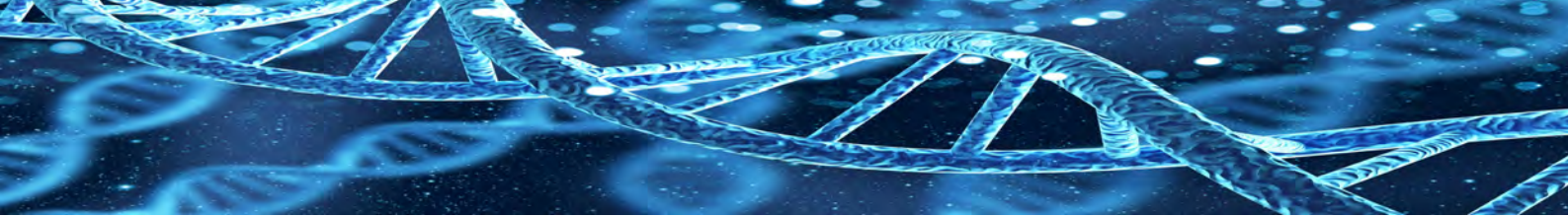
A highlight for this reporting period was the bringing together of many of our Australian and international collaborators in November 2022 for a Workshop for the *Genomic Data Sharing* project which was scheduled to run before the 2022 Australasian Association of Bioethics and Health Law Conference which CLG members Dr Rebekah McWhirter and Dr Lisa Eckstein convened. After an extended period of the Australian borders being closed, it was a delight to be able to welcome international visitors back to Tasmania.

Over the course of 2021-2022 CLG staff presented at numerous conferences and workshops (mostly within Australia due to border closures for some of this period and quite a few by Zoom.) Two of our PhD students graduated in this period - Olumayowa Adesanja and Asma Bint Shafiq and two others completed- Pratap Devarapalli and Robin Banks. We are also very pleased to have recently have welcomed Andrew Rankine as a new PhD candidate.

Sincere thanks to Di for leading the CLG so well from 2015-2021 and we look forward to our ongoing collaborations with you - luckily for us, the usual concept of retirement is alien to Di and she and continues to be as productive as ever!

Professor Margaret Otlowski





## Project Updates

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### Genomic Data Sharing (GDS)

In 2021-2022, the CLG GDS team continued our research into the legal, ethical and social implications of genomic data sharing as part of our Australian Research Council Discovery Grant. CLG members have been working on issues associated with privacy, research ethics, consent, intellectual property rights and formalised transfers of data and materials in the context of genomic data flows between laboratories, regions, countries and sectors. This analysis is guided by a set of representative data sharing scenarios, and their associated issues, which are based on interviews with a number of practitioners involved in genomic data sharing across a range of areas. We also created a dataset of international genomic data sharing consortia and are using this dataset to examine governance arrangements, with particular focus on access.

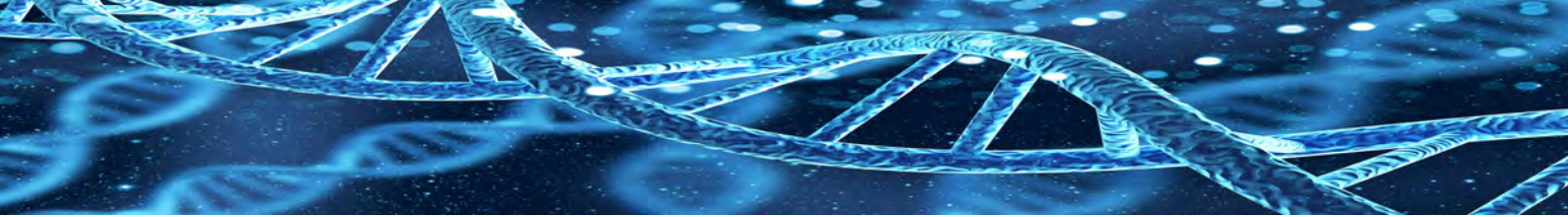
### Innovative Health Technologies (IHT)

In 2021-2022, the CLG IHT team continued to investigate the regulation of innovative health technologies in a project funded by an Australian Research Council Discovery Grant. The project involved a deep examination of the regulatory landscape. Interviews with researchers, clinicians and industry personnel supplemented the regulatory landscape mapping. These data are contributing to an overarching analysis of the regulatory landscape that has formed the basis for an interactive online map, designed to assist product manufacturers and suppliers, researchers, patients and government personnel in understanding this complex area. During 2021-2022, we continued to publish our findings, carry out interviews and refine the interactive map.

### Assessment of Legislation and Regulations Applying to the Collection and Use of Health-Related Genomic Information

In 2021-2022, the whole of the CLG team, along with collaborators Professor Jane Kaye, Associate Professor Mark Taylor and Dr Megan Pictor from the University of Melbourne continued our work assessing the legislation and regulations applying to the collection and use of health-related genomic information in Australia, under contract from the Federal Department of Health, Government of Australia. This research was informed by our Genomic Data Sharing project. The final product was published in our Occasional Paper series. We called the final report *Essentially Ours* to reflect the technological and ethical, legal and social changes that have emerged since the Australian Law Reform Commission and Australian Health Ethics Committee published their report on the protection of genetic information, *Essentially Yours*, in 2003.





## **Genome Editing: Formulating an Australian Community Response**

In 2021-2022, Nicol, along with collaborators Professors Simon Niemeyer, John Dryzek and Nicole Curato from the University of Canberra, and Sonya Pemberton from Genepool Productions continued our work on the Australian Citizens' Jury on Genome Editing project, funded by the Genomics Health Futures Mission of the Medical Research Futures Fund. The citizens' jury was held at the Museum for Australian Democracy in Canberra. The project also included interviews and surveys with members of the Australian public and interviews, surveys and workshops with international experts. Analysis of these inputs led to the development of five themes for policy development, which have been reported to key national and international policy makers. The final report was published in our Occasional Paper series.

## **Towards a Trusted Genomic Repository: Tackling Commercialisation Fears**

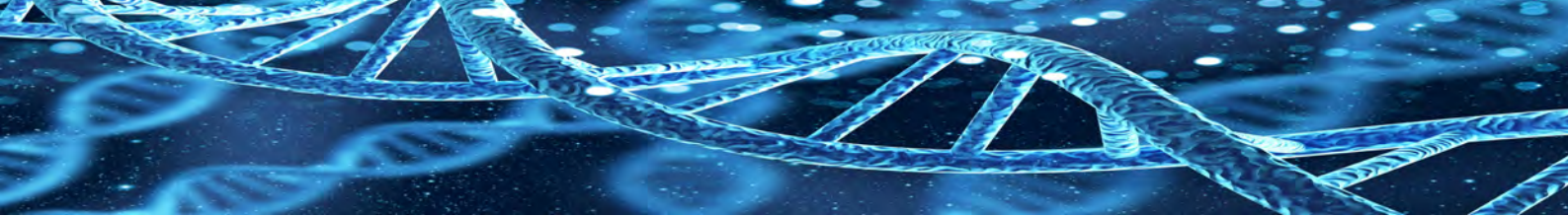
In 2021-2022 Nicol, with collaborators Dr Brad Elphinstone and Jarrod Walshe from Swinburne University and Associate Professor Mark Taylor from the University of Melbourne continued our work examining public attitudes towards deposit of genomic data in repositories, with particular focus on how attitudes changed with commercial involvement. The research is funded by the Genomics Health Futures Mission of the Medical Research Futures Fund. This research has included an examination of the legal landscape, surveys and interviews with members of the Australian public. The aim is to provide the Australian Genomics Health Futures Mission with the empirical and doctrinal evidence needed to reduce tension between public trust and industry involvement.

## **Developing an Evidence Based Model for Building Trust in Australian Stem Cell Research and Therapies**

In late 2021, Nicol, with collaborators Professor Rachel Ankeny from the University of Adelaide, Professor Joan Leach from the ANU and Professor Christine Wells from the University of Melbourne received funding from the Medical Research Futures Fund Stem Cell Therapies Mission to examine models for building trust in Australian stem cell research and therapies. We are particularly focusing on models for ensuring that stem cell lines are made widely available for research purposes. Commons based models have been a major theme so far, but we are also examining adaptive governance and other open forms of governance. The research includes historical, legal, bioethical and sociological research methods.







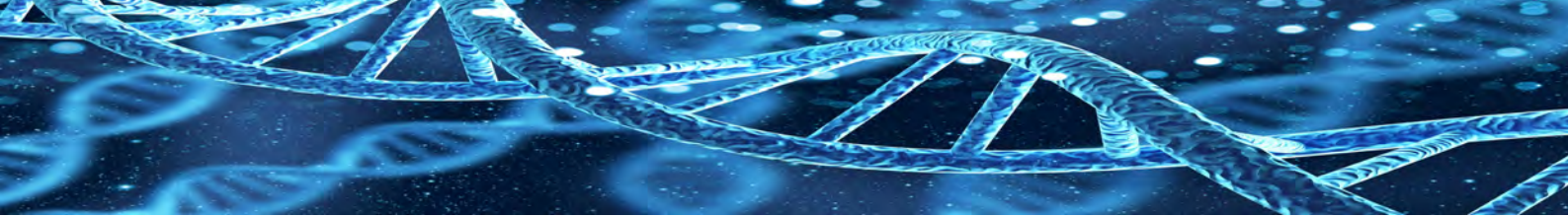
## **Returning Raw Genomic Data; Patient Autonomy or Legal Minefield?**

This project led by Nielsen with Otlowski and McWhirter as CIs along with other Australian collaborators focusses on the return of raw genomic sequence data to patients and research participants and considers legal and ethical obligations to do so. Sydney Children's Hospital Network HREC granted ethics approval in June 2021 and subsequently Nielsen and Johnston have conducted interviews with scientists, clinicians, patients, policy and advocacy groups, exploring their views on 'ownership' of genomic data, the utility of such information and processes to support a return of raw genomic data. Significant work has been undertaken on legal analysis with key papers published / accepted for publication. In 2023 work will continue with analysis of qualitative data, content analysis of Third-Party Interpretative websites, development of protocol/ guidance and a dissemination workshop.

## **Australian Genetics and Life Insurance Moratorium: Monitoring the Effectiveness and Response (A-GLIMMER)**

This interdisciplinary project focusses on genetic discrimination. Otlowski is one of the CIs on this project led by Associate Professor Lacaze from Monash University, with collaborators Professor Louise Keogh from the University of Melbourne, Associate Professor Kris Barlow-Stewart from the University of Sydney, Dr Aideen McNerney-Leo from the University of Queensland and clinical leads – Professors Martin Delatycki and Ingrid Winship. The project aims to monitor the life insurance moratorium on use of genetic test results and to make recommendations to government as to the adequacy of existing regulation. In 2021-2022 work progressed on the various aspects of the project which has involved surveys and interviews of genetics health professionals, patients and consumers, genetics researchers and financial advisers. This has entailed significant engagement and collaboration with project partners and stakeholders, including a number of specific consumer advocacy and support groups. Findings from each study within the project have been published as results become available. In 2022, an interim Stakeholder report was also published.





## New Projects

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### **Addressing Emerging Ethical, Legal and Social Issues in the Governance of Clinical and Genomic Datasets, to Improve Human Health**

Centre for Law and Genetics researchers Otlowski, Nielsen, Nicol, Eckstein and McWhirter are CIs in the LINEAGE consortium project which has been awarded almost \$5 million by the Medical Research Future Fund, through the Genomics Health Future Mission funding to examine the ethical governance for clinical and genomic data.

The LINEAGE consortium is led by Professor Ainsley Newson from the University of Sydney and together with researchers from around the country, this 5-year inter-disciplinary research project will address pressing ethical, legal and social issues in the development and use of genomic datasets. The project will develop, implement and evaluate solutions to deliver a national governance framework for these data, facilitating the successful integration of genomic information in Australian health care. The University of Tasmania will receive over \$430,000 in funds from the project.

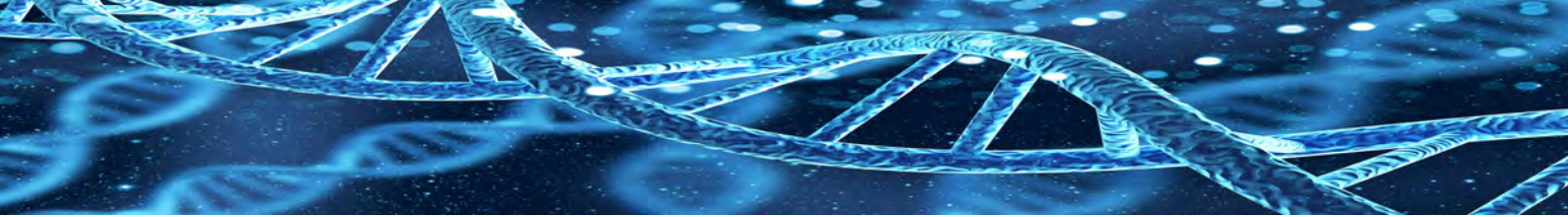
### **genomics4newborns**

Otlowski is CI on an inter-disciplinary research project with researchers from across Australia examining ethical, legal and equity aspects of genomic newborn screening. The project led by Associate Professor Sarah Norris from the University of Sydney, with a team of collaborators has received \$2.1 million from the Medical Research Future Fund, through the Genomics Health Future Mission funding. This 'genomics4newborns' project will research the views of the general population, people living with genetic conditions, patient advocates, clinicians, health service providers, and policy makers to co-develop health technology assessment tools for policy makers that integrate the 4 'Es' of ethics, equity, effectiveness and economics.

### **Pathways to Benefit for Indigenous Australians in Genomic Medicine**

McWhirter is part of a large team of investigators led by Prof Alex Brown (ANU) awarded a Genomics Health Future Mission grant of \$5 million over five years from the Medical Research Future. This project establishes a National Indigenous Genomics Network that synergistically builds and extends Indigenous leadership in genomic science, research, precision health care, data sciences, and ethics to increase participation in genomics, deliver benefit from its application, and ultimately reduce inequity among Australia's First Peoples.





## Ethics in the Interim: Learning From the COVID-19 Pandemic to Develop Ethical Guidance for Data Safety and Monitoring Committees Overseeing Clinical Trials

Eckstein is part of a team on a project funded by the Greenwall Foundation for review of ethical guidance for data and safety monitoring committees overseeing clinical trials, taking account of learnings from the COVID-19 pandemic. The lead researcher is Associate Professor Seema Shah from the Lurie Children's Hospital, with international collaborators from Canada and Kenya. Funding of US \$219,685 was awarded for a two year project, commencing in 2021.

## Submissions

- Eckstein, Nicol, Otlowski together with Professor Newson prepared a submission to the Australian Government Attorney General's Department Review of the *Privacy Act 1988 (Cth)* (2021).
- Otlowski, Tiller together with Associate Professor Lacaze, on behalf of the AGLIMMER Project, prepared a submission to the Financial Services Council Review of the Moratorium on the Use of Genetics Tests in Life Insurance (2022).

## Workshops

### Genomic Data Sharing Workshop

In November 2022 the CLG organised a workshop which brought together a group of 34 participants to debate genomic data sharing using funding from our Australian Research Council Discovery Grant. Four themes were discussed: what are the most significant regulatory and policy backdrops to genomic data sharing globally; how should community attitudes towards genomic data sharing influence policy development; what types of governance arrangements exist for genomic data sharing in consortia; and are human research ethics committees well enough equipped to deal with genomic data sharing? One or more journal articles are flagged for publication in 2023-2024.







# Conferences

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## Australasian Association of Bioethics and Health Law

The Australasian Association of Bioethics and Health Law (AABHL) was held in Hobart held between 17-19 November 2022 at the Hobart Function and Conference Centre. McWhirter and Eckstein convened the conference, originally slated for 2020 but postponed twice during the pandemic.

In addition to the organising team, the CLG was well represented at AABHL 2022 Conference amongst presenters and attendees. There were 200 delegates, including 159 onsite and 41 online, from Australia, New Zealand, Singapore, the UK, Hong Kong and elsewhere. CLG members and postgraduate students presented work relating to a range of CLG projects. Abutting the CLG Genomic Data Sharing Workshop, this conference was an excellent opportunity to showcase CLG research, establish new collaborative connections and maintain existing connections.

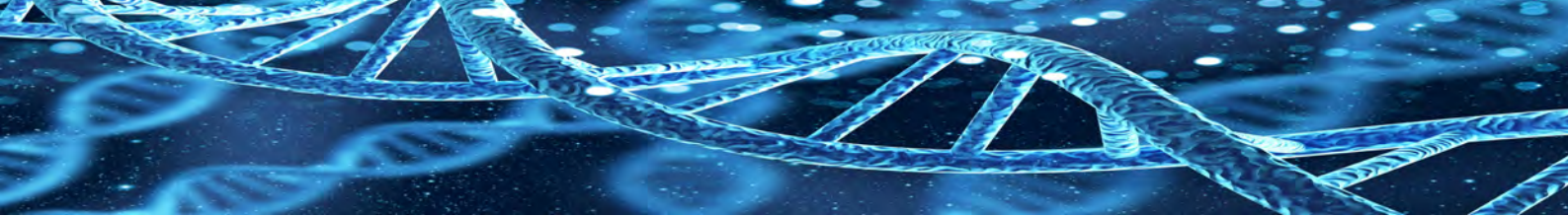
## CLG Presentations

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- Nicol presented on the 'Legal Aspects of Gene Editing', Precision Medicine in ART, Sydney (23 May 2021)
- Nicol presented on 'Law, Regulation and Policy on Human Genome Editing' Centre for Law and Genetics and Centre for Deliberative Democracy, Australian Citizens' Jury on Genome Editing, Canberra (18 June 2021)
- Nicol, Niemeyer and Pemberton presented on 'Briefing to the World Health Organisation Expert Group on Genome Editing' (14 July 2021) (by zoom)
- Nicol presented on the 'Legal ethical and social aspects of human genome editing' John Curtin School of Medicine, Australian National University (6 August 2021) (by zoom)
- Nicol presented on 'Genome editing and the vulnerabilities of future generations', International Seminar on Biolaw (9 September 2021) (by zoom)
- Nielsen and Devarapalli presented on 'The Intellectual Property Landscape in Bioprinting' presentation at Biofab 2021, The International Conference on Biofabrication, Wollongong, (September 2021) (online)
- Otlowski presented on 'Genetic Discrimination in Australia: Monitoring the Moratorium on Use of Genetic test Results in Life Insurance' for the Science and Society Network, Healthy Futures, Deakin University (19 October 2021) (by zoom)
- McWhirter presented on 'Legal Scrutiny of Vaccination Laws' at the Australasian Association of Bioethics and Health Law Conference 2021 (online) (20 November 2021)
- Nielsen and Johnston presented on 'Do Research Participants in Australia have a Right to Receive their Raw Genomic Data?' at the Australasian Association of Bioethics and Health Law Conference 2021 (online) (November 2021)







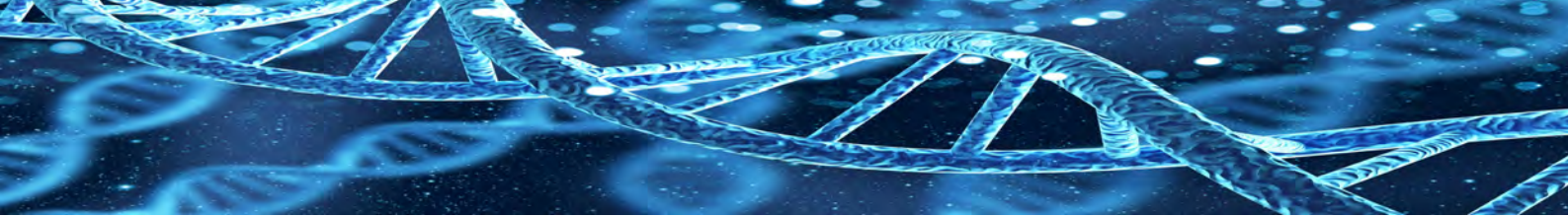
- McWhirter presented on 'Vaccination Laws in Australia, 1853-present' ANZSHM 2021 (3 December 2021)
- Nicol presented on 'A Role for Citizens' Juries in Understanding Community Attitudes towards Innovative Technologies: A Case Study in Human Genome Editing', 9th National Institutional Biosafety Committee Forum, Canberra (12 May 2022)
- McWhirter was invited to speak at the Australian ELSI Genomics Network Launch (30 May 2022)
- Nicol presented on 'Genome Editing in Australia' University of Queensland Annual Philip Walker Lecture on Medical Ethics, Brisbane (13 September 2022)
- Nicol presented on 'Genomic Data Sharing Workshop Introduction', Centre for Law and Genetics Genomic Data Sharing Workshop, Hobart (15 November 2022)
- Nielson and Nicol presented on 'Are there unifying factors in the establishment and operation of data sharing consortia?' Centre for Law and Genetics, Genomic Data Sharing Workshop (16 November 2022)
- Nicol presented on 'Australian Citizens' Jury on Genome Editing', Australasian Association of Bioethics and Health Law Conference, Hobart (17 November 2022)

## CLG External Appointments

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- McWhirter was appointed as a Member of the Community Advisory Group for the Undiagnosed Diseases Network Australia 2021.
- McWhirter was appointed as a Member of the Aboriginal and Torres Strait Islander Steering Committee, Australian Pharmacogenomic Diversity Panel 2021.
- McWhirter was appointed as a MRFF Genomics Health Futures Mission Grant Assessment Panel Member 2021.
- Nicol was appointed Chair, National Health and Medical Research Council, Embryo Research Licensing Committee (2021-2024).
- Otłowski was appointed as Commissioner of the Tasmanian Voluntary Assisted Dying Commission (2021-2025).
- Otłowski was reappointed as a member of the Australian Research Integrity Committee (2021-2024).
- Eckstein was appointed as CT:IQ Director and Bellberry Programme Manager in March 2022 (leading to a reduction in her academic role to 0.1FTE).
- McWhirter was appointed as a Member of the Scientific Program Committee of HGSA 2022.
- McWhirter was appointed as an External international reviewer for UK Medical Research Council Scientific Review of Health Data Research UK 2022
- Nicol was appointed as Co-lead, Regulatory Ethics Work Stream, Global Alliance for Genomics and Health (2022-ongoing).
- Otłowski was appointed to the *Frontiers in Genetics*, Editorial Board as Review Editor (2022-ongoing).
- Otłowski was appointed as a Member of the Genomic Screening Consortium for Australian Newborns (GenScan) Ethical, Legal and Social Implications (ELSI) Working Group (2022-ongoing).
- McWhirter was appointed as a Member of the Education, Ethics and Social Issues Committee of the Human Genetics Society of Australasia 2022.





## Teaching

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- Eckstein was the unit coordinator for LAW252 Foundations of Private Law and LAW296 Law and Ethics of Health Care (2021).
- Nicol was the unit coordinator for LAW364 Intellectual Property Law (2021).
- Nielson was the unit coordinator for LAW256 Torts (2021-2022) and 262 Private Law Obligations and Remedies (2022).
- Otowski was the unit coordinator for LAW181 - Ethics, Social Responsibility and the Law (2021-2022).

## HDR Updates

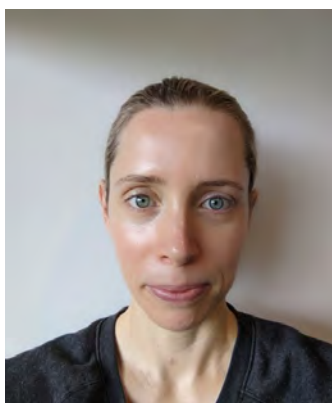
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### Vanessa Warren

Vanessa's thesis, *'Translating Public Trust to Law Reform in Genomic Data Sharing'*, examines the intersection of public trust in genomic data sharing and the regulatory context governing data sharing practices in Australia. Her research is interdisciplinary, involving both empirical social methodologies, and normative and doctrinal legal analyses. Her supervisors are Nicol, Eckstein, McWhirter and Dr Emily Hansen (Sociology).



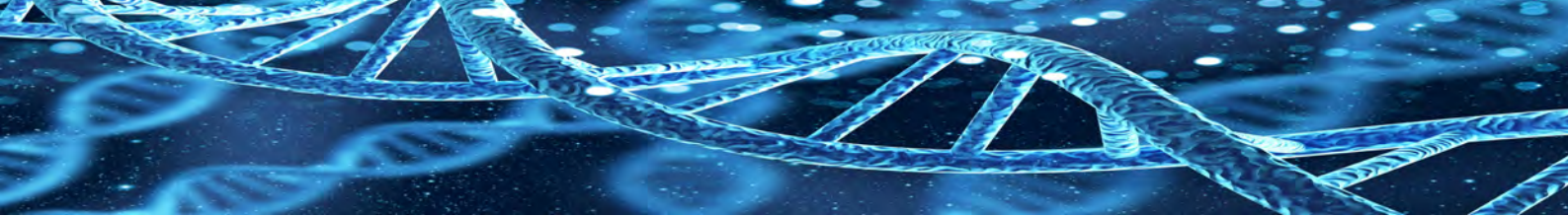
### Stephanie Green



Stephanie started her thesis in February 2019, under the supervision of Eckstein, Nicol and Nielsen. Her thesis, titled *'Waiving, Not Drowning": Using Solidarity to Address Consent Issues in Genomic Data Sharing'*, aims to examine the ethical issues raised by HRECs and DACs in their assessment of research proposals for genomic data sharing to determine whether consent concerns are one of the primary reasons why these committees delay or reject these proposals. She will argue that an increased focus on including solidarity as one of the criteria against which these proposals are assessed may assist in addressing the concerns these committees have in relation to consent, specifically in terms of their willingness to use 'waiver of consent'.







## Pratap Devarapalli

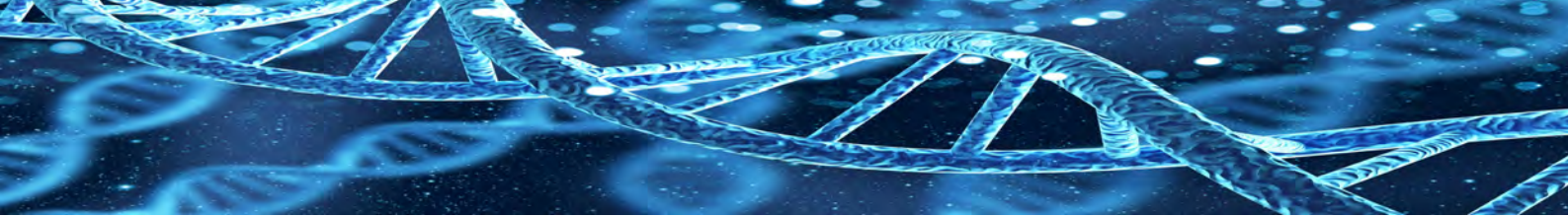
Pratap Devarapalli commenced his PhD with the CLG in February 2019, under the supervision of Nicol and Nielsen. His research titled '*Patenting Aspects of 3D Bioprinted Tissues and Bioink*' project examines the capacity of the traditional patent system to adapt to such challenges by assessing whether specific subject matter related to 3D bioprinted tissues and bioinks falls within the scope of patentable subject matter and can be considered patentable. The first phase of his research analysed patentable subject matter requirements and relevant patent jurisprudence in Australia, US and Europe in light of 3D bioprinted tissues and bioinks. In the second phase, his research project evaluated the patent prosecution history of granted and rejected patent applications to identify the present practice of patent offices on how patent examiners are assessing subject matter requirements to claims directed towards bioprinted tissues and bioinks. Pratap was finalising his thesis in late 2022 for planned submission early 2023.



## Olumayowa Adesanja

Olumayowa Adesanya commenced her PhD candidature with the CLG in November 2016. Her research was conducted under the supervision of Nicol and Nielsen. In her thesis titled '*Patenting Bioprinting: An Ethical Dilemma in the Provision of Accessible Health Technologies*', Mayowa examined the patentability of bioprinted constructs and related bioprinting processes across three jurisdictions with divergent approaches to the matter of patentability, namely: Australia, the European Patent Convention system, and the United States of America. Noting that the differences in legislative provisions appear to have limited impact on patentability, and in light of evidence that patents have been granted for bioprinted constructs across all three jurisdictions, Mayowa recommends the use of a number of tools in ensuring access to bioprinting. These are TRIPS flexibilities, limitation of the scope of patents and industry-driven initiatives. Overall, Mayowa recommends a cautious approach to patenting bioprinting given the absence of evidence to suggest that existing patents are being exploited in a manner that is detrimental to the growth of the bioprinting industry. Mayowa holds an LLB (Hons) from Babcock University and an LLM (Intellectual Property Law) from Queen Mary University of London. Mayowa successfully completed her thesis in 2021 and graduated in 2022.





## Robin Banks

Robin started her PhD in February 2018, under the supervision of Otlowski and Winnifred Louis (Psychology Professor from the University of Queensland). Her thesis, titled '*An Exploration of the Capacity of Psychology, Stigma, Prejudice and Discrimination to Enhance Discrimination Law*' considers the potential to improve the effectiveness of discrimination law through incorporating understandings of prejudice, stigma and discrimination from social psychological research into the substantive provisions of discrimination law and the related legal processes.



Drawing on both qualitative and quantitative research data, the thesis seeks to expose and address gaps and failings in discrimination law that reflect the current absence of consideration of the psychology of prejudice and discrimination. The effectiveness of discrimination law in Australia is investigated using both qualitative and quantitative methods. Robin submitted in August 2022 and the PhD thesis has since been conferred.



## Asma Bint Shafiq

Asma started her PhD in November 2017, under the supervision of Otlowski, Dr Susan Bartie and Anja Hilkemeijer. Her thesis titled '*Human Rights Protections in Bangladesh: The Life of Salma Sobhan*' is a life history of Salma Sobhan, a lawyer, academic, and human rights activist who played a pioneering role in human rights protection in Bangladesh between the late 1970s and 1990s. Asma's thesis examines Sobhan's work and surroundings to provide a stronger understanding of her

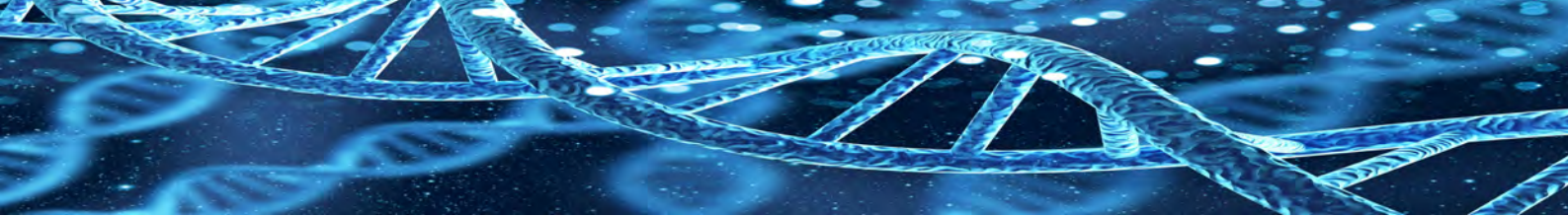
contributions and to gain a greater appreciation of who she was. Her life history provides a deeper and richer analysis of human rights protection at a national level comprehending law, culture, and politics of Bangladesh. The thesis argues that the lesson offered by Sobhan's life and work might provoke new ways of thinking about meeting the current challenges of human rights protections in a poor society. Asma submitted her thesis early 2022 and it was conferred later that year.

## Arpita Verma

Arpita began her PhD in September 2020, under the supervision of Nielsen and Professor Gino Dal Pont. Her thesis is entitled '*The Intersection between Privacy and Trade Secret Rights In Video Game Industry*' and will address the issue in the video game industry of opposing rights and control exercised by the video game companies and individual gamers over the same personal data of the gamer. She hopes to explore conflict and develop a way to balance it in a just, fair, and equitable manner.







## Jürgen Gnoinski



Jürgen Gnoinski joined the CLG in the early July 2016 to undertake a PhD under the supervision of Nicol and Nielsen. The title of this thesis is '*Australian Designs Law and Virtual Designs*'. His research is an in-depth analysis of the designs law and copyright, patent and trademark approaches to virtual designs such as Graphical User Interfaces (GUIs) in Europe and the U.S. and their relevance to the Australian approach. Jürgen has BCom (law), LLB, MBA, MSc degrees and recently completed a Masters' degree in Intellectual Property Law at the University of Technology Sydney.

## Andrew Rankine

Andrew commenced his PhD in 2021 under the supervision of Nicol and Jane Nielsen. His project, titled '*The Regulation of Claim Scope Under Contemporary Australian Patent Law: A Comparative Perspective*', focuses on the use of doctrinal tools to regulate the breadth of protection afforded to patented inventions under Australian law. Andrew's research has a particular focus on the requirement for disclosure in contemporary patent jurisprudence, examined from a comparative law perspective. His doctoral thesis will investigate the relationship between these doctrinal issues and innovation policy in the Australian context. Andrew has a particular interest in the application of patent doctrine and innovation policy to the life sciences sector, reflecting his background in medicine and the biological sciences. Concurrently with his doctoral research, Andrew is engaged in private legal practice, specialising in IP disputes.





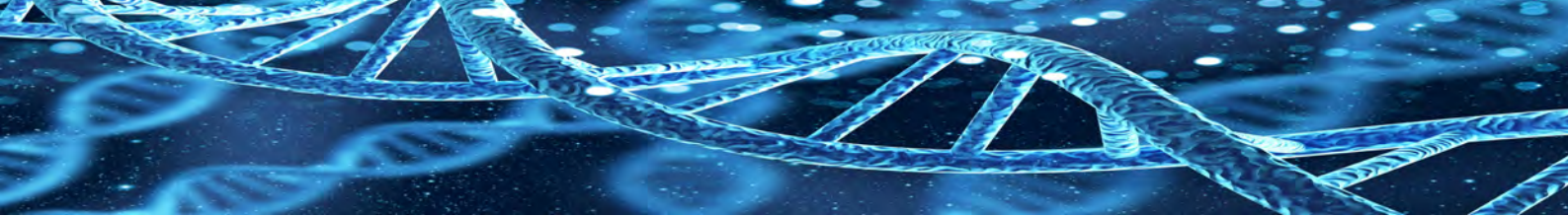
## Publications from CLG Members

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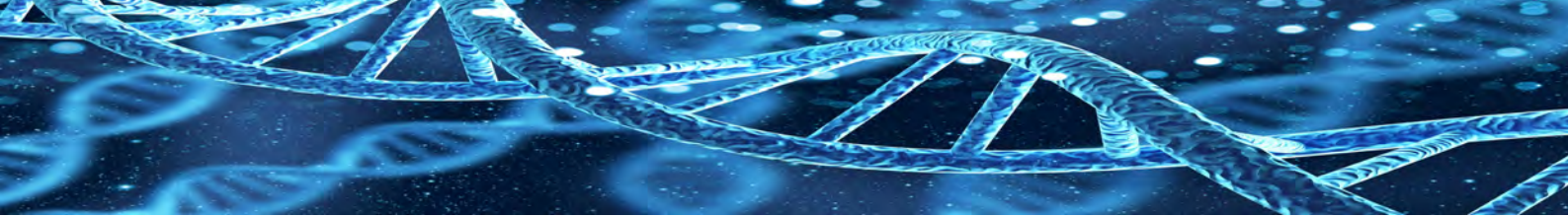






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