UNIVERSITY of TASMANIA

MENZIES
Institute for Medical Research

Celebrating 25 years of Research

into the Ethical, Legal and Social Implications of Genetics, Genomics and Related Technologies at the Centre for Law and Genetics

Introduction

In 1994, Don Chalmers, Margaret Otlowski and I, together with our collaborator Loane Skene, began to discuss the need to investigate the ethical, legal and social implications (ELSI) of health and genetic technologies, from a distinctly Australian perspective. At the time, Chalmers was Dean of the Faculty of Law at the University of Tasmania in Hobart, Australia. He subsequently was given the title of Distinguished Professor in 2010. Otlowski was a senior lecturer in Law, and soon became a full professor. She was Dean of Law from 2010 to 2017, and later the University of Tasmania's Pro Vice-Chancellor, Culture and Wellbeing. Skene had just returned to academic life at the Law School at the University of Melbourne, following a period working with the Victorian Law Reform Commission. Before retiring in 2016, Skene had a long and distinguished career as Professor of Law at Melbourne Law School and served as Chair of Melbourne University's Academic Board.

I was a humble undergraduate student in law back in 1994, but brought my postdoctoral experience in cell biology to the group. By 2000, after a stint in legal practice, I rejoined the Centre for Law and Genetics (CLG) team as a lecturer in law. I have now been a professor of law for ten years and served as Chair of the University of Tasmania's Academic Senate from 2013 to 2018 and acting Provost during 2017 and 2018. My academic success is due in no small measure to the excellent mentoring I received from Chalmers and Otlowski.

At the time we were starting our research program, the global Human Genome Project (HGP) was already underway and major funders in the US and Europe committed 3-5% of all HGP funding to ELSI research. The HGP brought a clear international focus to our CLG work. Although Australia made no matching ELSI funding commitment, in 1995 the CLG successfully obtained research project funding from the Australian Research Council (ARC) to examine Australian perspectives on the legal and ethical implications of human genetic research. By 1997, we were formally recognised by the University of Tasmania as the CLG.

Advances in genetic technologies have continued apace. As we moved into the genomics era, the post-genomics era and now the precision medicine era, concerns about core ELSI have followed. The CLG has been fortunate in maintaining almost constant funding from the ARC to continue our Australian ELSI research. We have had an overall success rate of 73 percent through the ARC's Discovery Grant Scheme (11 out of 15 applications). Our grants and other sources of funding are listed on page 16.

Over time, our focus has shifted with the tides of technology. The overriding aim of our research is to promote effective governance of genetic and other new technologies in healthcare delivery and biomedical research, and to facilitate equitable distribution of benefits, all with a distinctive Australian focus, informed by international developments. The mission of the CLG is to promote safe, ethical, prudent and socially acceptable governance of genetic, genomic and related technologies to support healthcare delivery and biomedical research. We provide short summaries of overarching CLG research themes in the next few pages of this report, and follow this with accounts of some of the most significant current ELSI research topics to which CLG members are contributing. We include some of our key outputs in each area.

Over the past 25 years, the CLG members have developed and maintained our mission of high quality, evidence-based ELSI research locally, nationally and internationally. The CLG has grown significantly since 1994, and currently comprises 21 members, including 10 core staff, adjuncts and research fellows, and 11 PhD candidates. Over the years we have been able to enlist a number of passionate and committed undergraduate students as research assistants and honours students. We also have an extensive network of colleagues from across the globe. We list our current and past staff, research fellows, postgraduates, research assistants and some of our key collaborators on pages 25 and 26.

Our opportunities for collaboration have been enhanced by the generosity of our colleagues in providing funding to assist us to travel to conferences, symposia and workshops across the globe. We have also been fortunate in being able to use our research funding to bring colleagues to Hobart for workshops and conferences, and to co-convene workshops and conferences elsewhere. Our CLG workshops and conferences are listed on page 19.

The CLG has had a major commitment to national policy debates, including well-cited submissions to public inquiries. The CLG has contributed to Australia's national research ethics guidelines through contributions to the National Statement on Ethical Conduct in Human Research (National Statement), and to legislative reform (particularly relating to intellectual property). CLG members have been consultants to the Australian Law Reform Commission (ALRC) and have been appointed to National Health and Medical Research Council (NHMRC) principal committees, as well as other national and state bodies.

Internationally, in addition to research collaborations with leading scholars in the field, we have made contributions to policy development with international agencies such as the Organisation for Economic Cooperation and Development (OECD), the World Health Organisation and UNESCO. Chalmers, the founding director of the CLG, has provided significant inputs into policy debates around ELSI research and practice, including membership of the International Cancer Genome Consortium Ethics and Policy Committee and the Regulatory and Ethics workstream of the Global Alliance for Genomics and Health. He was also one of the founders of the international ELSI 2.0. Some of our key national and international appointments and contributions are listed on pages 20 and 21.

Our CLG team has produced around 250 peer-reviewed articles, books and book chapters. Our early career researchers and postgraduates have written some 40 percent of these outputs, collaboratively or as sole authors. Our CLG work has been published in high impact science journals, including Nature Biotechnology, Science and Nature and in highly ranked Australian law journals including New South Wales Law Journal, Federal Law Review, Melbourne University Law Review, Monash Law Review and Sydney Law Review. We list 15 of our key publications over the time since the inception of the CLG research program on page 17, to illustrate the breadth of our contributions. We have also established an Occasional Paper series, to publish workshop papers, results of our empirical studies and policy statements. A full list of our Occasional Papers is provided on page 18.

I am delighted to mark this—our 25th year of ELSI research—with this summary of our activities over that time. I draw particular attention to the recent news that Chalmers, the foundation Director of the CLG was made an Officer of the Order of Australia on 26 January 2019, for his distinguished service to education, particularly to health law and medical research ethics, and to legal reform.

Professor Dianne Nicol
Director, Centre for Law and Genetics

Contents

Research Themes

Genetic Discrimination

The concept of 'genetic discrimination' was an early topic to emerge amongst the ELSI of genetics. This concept featured in the first research project for the CLG funded by the ARC, 'Legal and Ethical Implications of Human Genetic Research: Australian Perspectives' (Chalmers, Otlowski and Skene, with Nicol as research associate) in 1995-1998. Amongst other things, this led to the first two of a series of CLG Occasional Papers reporting on a national consultation process that canvassed the issues of genetic discrimination in the Australian life insurance and employment contexts authored by Otlowski. This issue of genetic discrimination was subsequently further explored in a dedicated empirical interdisciplinary cross-institutional research project (2002-2004) led by Otlowski in collaboration with Dr Sandra Taylor from University of Queensland and Associate Professor Kristine Barlow-Stewart from the Centre of Genetics Education in Sydney.

CLG members (Chalmers, Otlowski and Skene) were involved with the Australian Law Reform Commission (ALRC) Inquiry into the Protection of Human Genetic Information, a key focus of which was to examine the issue of genetic discrimination in life insurance and employment (Chalmers as consultant and member of the Advisory Committee and Otlowski and Skene as consultants). CLG members also made submissions to the inquiry that were extensively cited in the Discussion Paper (2002) and Final Report, *Essentially Yours* (2003). Further opportunities to influence policy in this area came through membership of the NHMRC Human Genetics Advisory Committee (HGAC - Chalmers and Otlowski).

The CLG has continued active engagement in this area. Otlowski has been invited to give a range of public talks on this issue and is Chair of the Australian Genetic Non-Discrimination Working Group formed in 2016 - an interdisciplinary group which has been advocating for policy reform. In particular, the group contributed to the Joint Parliamentary Inquiry into the Life Insurance Industry, which subsequently recommended that a moratorium be imposed on the use of genetic test information by Australian life insurers. The peak body for the life insurance industry, the Financial Services Council, has since announced its intention to introduce a moratorium on the use of genetic test information for risk-rated life insurance products.

The relevance of this issue has been highlighted through the recognition by key bodies of the potential for genetic discrimination to be a barrier to the mainstreaming of genetics/genomics into healthcare and also a deterrent to public participation in genetic research: Australian National Health Genomics Policy Framework 2018-2021 and also the Australian Council of Learned Academies (ACOLA) Report, *The Future of Precision Medicine in Australia* 2018. More recently, the issue of genetic discrimination and its implications for genomics in Australia was canvassed by the Genomics Health Future Mission in 2018; Nicol was on the Steering Group and chaired the ELSI Working Group of which Otlowski was also a member.

Key Outputs

Margaret Otlowski, Kristine Barlow-Stewart, Sandra Taylor, **Mark Stranger** and Sue Treloar, 'Investigating Genetic Discrimination in The Australian Life Insurance Sector: Use Of Genetic Test Results In Underwriting 1999-2003' (2007) 14 *Journal of Law and Medicine* 367–395.

Margaret Otlowski, Sandra Taylor, Kristine Barlow-Stewart, **Mark Stranger** and Sue Treloar, 'The Use of Legal Remedies in Australia for Pursuing Allegations of Genetic Discrimination: Findings from an Empirical Study' (2007) 9 *International Journal of Discrimination and the Law* 3–35.

Margaret Otlowski, **Mark Stranger,** Sandra Taylor, Kristine Barlow-Stewart and Sue Treloar, 'Practices and Attitudes of Australian Employers in Relation to the Use of Genetic Information: Report on a National Study' (2010) 31 *Comparative Labor Law and Policy Journal* 637–691.

Genetic Privacy

Privacy, and in particular the emergence of 'genetic privacy', has also been a topic raising ELSI that the CLG has been engaged with from its inception. Due to the integral and pervasive nature of privacy as an issue, it has continued to be a feature of most subsequent CLG large project grants. Genetic privacy was also a central issue in the ALRC inquiry into the Protection of Human Genetic Information, and was the subject of numerous submissions made by CLG members to this inquiry as well as other national and state inquiries into health privacy reform. The CLG was involved with the ALRC's subsequent Inquiry into Australian Privacy Law and Practice through Otlowski's involvement on the Health Advisory Sub-Committee.

CLG members have influenced national privacy policy through involvement on national committees – including the HGAC (Chalmers and Otlowski) and the Australian Health Ethics Committee (AHEC - Chalmers, Otlowski and Nicol). In addition, Otlowski was a member of the Federal Privacy Commissioner's Health Leaders' Forum 2004-2010. She was also involved in the development of guidelines on the use and disclosure of genetic information to a patient's genetic relatives under section 95AA of the *Privacy Act 1988* and has published on this topic.

Privacy has also formed part of consultancy work commissioned by the NHMRC with which CLG members have been engaged - Otlowski and Nicol with CLG research fellow Dr Mark Stranger on the Biobank Information Paper (2010) and Otlowski on the Medical Genetic Testing Information Paper for Health Professionals (2010). Nicol and Otlowski were invited contributors to the ACOLA Report, *The Future of Precision Medicine in Australia* 2018 which included coverage of privacy. This was also a key topic for consideration by the Genomics Health Future Mission ELSI Working Group.

The issue of privacy/genetic privacy remains foundational to the CLG's current work on the ARC-funded project on genomic data sharing. One key issue in this project is the changing nature of genetic/genomic privacy in the era of whole genome sequencing, which generates massive quantities of genetic information.

Key Outputs

Sergio Romeo-Malanda, **Dianne Nicol** and **Margaret Otlowski**, 'Genetic Testing and Protection of Genetic Privacy: A Comparative Legal Analysis in Europe and Australia' in Soraj Hongladarom (ed), *Genomics and Bioethics: Interdisciplinary Perspectives* (IGI Global, 2011) 235–255.

Margaret Otlowski and **Dianne Nicol**, 'The Regulatory Framework for Protection of Genetic Privacy in Australia' in Terry Sheung-Hung Kaan and Calvin Wai-Loon Ho (eds), *Genetic Privacy: an Evaluation of the Ethical and Legal Landscape* (Imperial College Press; 2013) 283–321.

Margaret Otlowski and **Lisa Eckstein**, 'Genetic Privacy' in Ian Freckleton and Kerry Peterson (eds), *Tensions and Traumas in Health Law* (Federation Press; 2017) 283–296.

Biobanking

The CLG became interested in biobanking in the mid-2000s, when it became clear that the next phase of genomic research would require access to large collections of human tissue from which genomic information could be extracted. This genomic information, linked with health, genealogical and other information, was seen as a vital tool in understanding the genetic basis of human disease. Internationally, large-scale population-wide collections started being funded, both publicly and privately. The privately-funded Icelandic DeCode database was an early entrant. The publicly funded UK Biobank, Canadian CARTaGENE and others followed. The value of these collections, or biobanks (which became the accepted terminology, in around 2006) was largely as a resource for future research projects. The prospective nature of this research, and the linkage of genomic and other information, immediately raised concerns relating to consent, privacy, public trust, commercialisation and a host of other issues.

A CLG team (Chalmers, Nicol, Otlowski and Skene) received funding from the ARC for a five-year project (2005-2009) to explore facilitation and regulation of research and development involving human genetic databanks (as they were then called). The project resulted in close to 100 outputs (including books, book chapters, refereed and non-refereed journal articles and conference proceedings) as well as presentations and submissions to public inquiries, particularly in relation to privacy (to the ALRC) and biobank governance (to the OECD). The project also marked the start of ongoing collaborations with our current Adjunct Professors, Christine Critchley from Swinburne University (on public attitudes towards biobanking) and Joanne Dickinson from the University of Tasmania's Menzies Institute for Medical Research (on the development and governance of a Tasmanian biobank). The NHMRC Information Paper on Biobanking, drafted by Otlowski, Nicol and Stranger, was a significant development in the field in Australia.

The CLG has continued engagement in biobanking. Of particular note, in 2014, the CLG hosted a Deliberative Democracy event, inviting 25 diverse members of the Tasmanian community to debate their concerns and hopes relating to the creation of a biobank in Tasmania over a two-weekend period. CLG collaborator Professor Michael Burgess from the University of British Columbia facilitated the event. CLG members Nicol, Chalmers, Otlowski, Critchley, Dickinson and Dr Rebekah McWhirter participated. This event also marked the start of a five-year contribution to the CLG by Tess Whitton, first as a research assistant and later as a research fellow, before moving to the University of Melbourne to undertake her PhD. Outputs included three refereed articles. The event also informed further research.

Although ELSI issues arising from biobanking have been canvassed for close to 15 years, new developments in genomics continue to push technological boundaries. Privacy, consent, return of research results, data security, custodianship, commercial involvement and intellectual property protection remain live issues. The CLG remains committed to exploring these matters through our doctrinal, policy-oriented and empirical research.

Key Outputs

Margaret Otlowski, **Dianne Nicol** and **Mark Stranger**, 'Biobanks Information Paper 2010' (2010) 20 *Journal of Law, Information and Science* 87–203, reproduced with permission from NHMRC, *Biobanks Information Paper* (2010).

Rebekah E McWhirter, **Christine Critchley**, **Dianne Nicol**, **Don Chalmers**, **Tess Whitton**, **Margaret Otlowski**, Mike Burgess and **Joanne L Dickinson**, 'Community Engagement for Big Epidemiology: Deliberative Democracy as a Tool' (2014) 4 *Journal of Personalised Medicine* 457–474.

Don Chalmers, **Dianne Nicol**, Jane Kaye, Jessica Bell, Alastair V Campbell, Calvin W L Ho, Kazuto Kato, Jusaku Minari, Chih-hsing Ho, Colin Mitchell, Fruzsina Molnár-Gábor, **Margaret Otlowski**, Daniel Thiel, Stephanie M Fullerton and **Tess Whitton**, 'Has the Biobank Bubble Burst? Withstanding the Challenges for Sustainable Biobanking in the Digital Era' (2016) 17 *BMC Medical Ethics* 39–53.

Patents and Licensing

The completion of the HGP brought with it concerns around commercialisation, particularly around the patenting of gene sequences. Patents provide a right to exploit an invention, and patent owners may exercise this right themselves or license a patent to another party to do so. In biomedicine, patents have implications in research, product development and access to healthcare. During the 1990s, a 'gene patent rush' resulted in a huge number of applications for patent protection being filed in major western jurisdictions, including Australia. While many of these applications lapsed, a number of patents considered to be potentially problematic were granted. The implications of this have been felt particularly strongly in the diagnostic testing arena and culminated in the ongoing Myriad-BRCA gene patent litigation which resolved only recently.

Issues associated with patent protection over biotechnological inventions have been at the forefront of CLG research since its inception. Nicol has followed and provided expert commentary on the Myriad-BRCA gene patent debate since the mid-1990s. With colleagues Dr Jane Nielsen, John Liddicoat and Whitton, Nicol conducted empirical analysis of the implications of patents for the provision of genetic testing. Liddicoat joined the team as a research assistant in 2010 and went on to complete his PhD and continue his work with us as a research fellow, before moving to Cambridge University. Most recently, Nicol and Nielsen were contracted by IP Australia to investigate whether the Myriad litigation in Australia has had any discernible effect on the cost of genetic testing. These issues centred primarily around the question of whether patents can be granted on biotechnological inventions.

CLG members have also conducted a considerable amount of work on the manner in which patented inventions are used. In 2003, Nicol and Nielsen co-authored an Occasional Paper investigating the impacts of patents and licensing practices on biotechnological research in Australia. This study was cited extensively by the ALRC in its Report No 99: *Genes and Ingenuity* (2004) and has been influential since this time. A further two Occasional Papers followed, both of which examined the impacts of patent licensing practices on the biotechnology research environment in Australia, and the potential for patent pooling arrangements in biotechnology. CLG members have been successful in obtaining ARC funding to explore these issues through discovery project grants DP0557608 (to Nicol, in collaboration with Dr Janet Hope and Distinguished Professor John Braithwaite from ANU) and DP0985077 (to Nicol, Nielsen and Critchley in collaboration with Professor Reiko Aoki from Hitotsubashi University in Japan).

During this period CLG members made many submissions to public inquiries, most of which investigated the prevalence, and the use and misuse of patents in genetic research. Patent law has undergone significant amendment, and the CLG has been engaged in this process for its duration. CLG work in this area continues, with focus shifting recently to the impact of patents in genomics research. Our current ARC-funded project investigating the need to reform the regulatory environment for innovative health technologies includes consideration of the role of patents as a regulatory tool, encompassing deeper philosophical consideration of the role of patents in shaping research environments.

Key Outputs

Dianne Nicol and **Jane Nielsen**, Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry (Centre for Law and Genetics Occasional Paper No 6; 2003).

Dianne Nicol, **Jane Nielsen**, **Christine Critchley**, **John Liddicoat** and **Tess Whitton**, The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation (Centre for Law and Genetics Occasional Paper No 8; 2014).

Dianne Nicol, **Jane Nielsen** and **Verity Dawkins**, *D'Arcy v Myriad Genetics: The Impact of the High Court's Decision on the Cost of Genetic Testing in Australia* (Centre for Law and Genetics Occasional Paper No 9; 2018).

Genomic Data Sharing

Rapid innovation in genomic technology, combined with the dramatic decline in the cost of sequencing data, has resulted in the generation of massive amounts of genomic data. Genomic data sharing (GDS) is becoming an essential component of clinical and research practice. Internationally, legal and quasi-legal requirements may constrain free and open GDS. However, these requirements might also provide the assurances necessary to protect donors, encourage research and innovation, and promote ongoing public trust in GDS activities.

CLG members have been working on key issues associated with GDS for a number of years. The well-traversed issues associated with privacy, research ethics, consent, intellectual property rights and formalised transfers of data and materials are all relevant, but must be situated in the specific contexts of genomic data flows between laboratories, regions, countries and sectors. In 2018, the regulation of GDS became one of the CLG's major research projects, following receipt of funding from the ARC to undertake this research over the next four years. All CLG staff are involved in the project and CLG adjunct Dickinson is our scientific advisor. The grant funds a research fellowship for McWhirter and two PhD scholarships which have been awarded to Vanessa Warren and Stephanie Green.

Despite the large literature on GDS, there are few examples of systematic analysis based on *real-world* data sharing challenges. This project takes a different approach. We have already interviewed a number of practitioners involved in genomic data sharing across a range of areas. From these interviews, we created a number of data sharing scenarios, which we will use to guide our legal, ethical and social analysis. The scenarios will be validated by experts in the field and from this combination of methods a list of emerging issues will be identified which will guide our legal, ethical and social analyses.

Key Outputs

Don Chalmers, **Dianne Nicol** and **Margaret Otlowski**, 'To Share or Not to Share is the Question' (2014) 3 *Journal of Applied and Translational Genomics* 116–119.

Amber L Johns, **Dianne Nicol**, Nik Zeps and **Don Chalmers**, 'The Path to Reducing Duplication of Human Research Ethics Review in Australia' (2017) 36 *Medicine and Law* 7–24.

Lisa Eckstein, **Don Chalmers**, **Christine Critchley**, **Ruthie Jeanneret**, **Rebekah E McWhirter**, **Jane Nielsen**, **Margaret Otlowski** and **Dianne Nicol**, 'Australia: Regulating Genomic Data Sharing To Promote Public Trust' (2018) 137 *Human Genetics* 583–591.

Public Trust and Commercialisation

There is widespread academic and policy agreement that commercial involvement in translational genomic research is an inevitability. Product development is considered too risky and expensive for the public purse, and therefore depends on industry investment. However, industry will only be involved if there is adequate return on investment. This presents problems for determining research priorities and equitable access to the products of translation. There are also implications for public confidence and support, with an extensive body of research suggesting that commercial involvement can erode trust in researchers, regulators and organisations. If a large proportion of the public is less willing to participate in genomic research and provide permission to share their genomic information because of commercialisation concerns, this will have inevitable consequences on research efforts. A significant question, therefore, is how to balance the need for industry involvement with the need to maintain significant goodwill from the public and patients.

Commercialisation and the legal status of intellectual property rights have been key pillars in the CLG's research on the ELSI of genomics and related technologies since 1994. Nicol examined the patentability of human genetic technologies for her Master of Law thesis, awarded in 1997. The ARC funded the first CLG project focusing specifically on commercialisation in 1999 and a number of other ARC-funded commercialisation projects have flowed from this. Members started to focus particularly on issues associated with public trust and commercialisation in the early 2000s. The 2004 article by Chalmers and Nicol, Commercialisation of Biotechnology: Public Trust and Research, was a key milestone, and marked the start of Critchley's involvement with the CLG. Since then, our research has attempted to examine the relationship between commercialisation and public trust by first, examining the specific aspects of commercialisation that generate most unease, and second, considering mechanisms for alleviating concern.

While much more research is needed, preliminary findings suggest that the place where the research is conducted (in the public or private sector) is a more potent determinant of trust than industry providing funding to researchers employed in public research organisations. The concept of public research organisations sharing their data with private organisations also erodes trust but may be alleviated if research participants are assured that their privacy will be protected, that there will be ethical oversight in how the information is used and if private organisations are obliged to share any benefits of the research with research participants and those in need. Finally, our research has also shown that general concerns about commercialisation may be alleviated with independent governance mechanisms that incorporate public representation, and an increased awareness of the need for industry involvement.

Key Outputs

Don Chalmers and **Dianne Nicol**, 'Commercialisation of Biotechnology: Public Trust and Research' (2004) 6 *International Journal of Biotechnology* 116–133.

Christine Critchley, **Dianne Nicol** and **Margaret Otlowski**, 'The Impact of Commercialisation and Genetic Data Sharing Arrangements on Public Trust and Intention to Participate in Biobank Research' (2015) 18 *Public Health Genomics* 160–172.

Dianne Nicol, **Christine Critchley**, **Rebekah McWhirter** and **Tess Whitton**, 'Understanding Public Reactions to Commercialization of Biobanks and Use of Biobank Resources' (2016) 162 *Social Science and Medicine* 79–87.

Innovative Health Technologies

Innovative, personalised health technologies are being heralded as solutions to intractable health conditions. 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. The law should play a key role in ensuring that the clinical translation of these technologies is regulated in ways that are responsive to societal values and needs, ensuring safety, effectiveness, access, affordability, allocative efficiency and fairness. While insufficient oversight can impede patient safety, resulting in unnecessary morbidity and mortality, an undue regulatory burden can impede the development of innovative health products and associated heath and economic benefits.

For many years, the CLG has tracked the issues associated with translation of genomic and related research into the clinic. This became a major research project for CLG members Nicol, Nielsen and Dr Lisa Eckstein and our collaborator Professor Cameron Stewart from Sydney University in 2018, with the award of an ARC Discovery Grant to investigate these issues. The grant funds a postdoctoral fellowship for Jenny Kaldor and two PhD scholarships: one at the University of Tasmania and one at Sydney University. The Tasmanian scholarship has been awarded to Pratap Devarapalli.

The innovative heath technologies project commenced in July 2018. The project aims are to:

1. comprehensively map current regulatory requirements applicable to the translation into the clinic for genome editing, 3D bioprinting and personalised biologics in Australia and other jurisdictions;
2. review and analyse these regulatory provisions for each of these three case studies, to provide a comparative analysis of the regulatory environment in Australia as compared with other jurisdictions;
3. compile an evidence base to assess compliance with regulatory requirements, and the conduciveness of these existing regulatory instruments to innovative technology translation for each case study;
4. identify areas of over and under regulation and innovation pathways and blockages for each case study; and
5. develop interactive maps for regulatory frameworks for each of the selected case studies, establishing guiding principles transferable to other innovative, personalised health technologies.

Key Outputs

Tania Bubela, Yael Mansour and **Dianne Nicol**, ‘The Ethics of Genome Editing in the Clinic: A Dose of Realism for Healthcare Leaders’ (2017) 30 *Healthcare Management Forum* 159–163.

Dianne Nicol, **Lisa Eckstein**, Michael Morrison, Jacob S Sherkow, **Margaret Otlowski**, **Tess Whitton**, Tania Bubela, Kathryn P Burdon, **Don Chalmers**, Sarah Chan, Jac Charlesworth, **Christine Critchley**, Merlin Crossley, Sheryl de Lacey, **Joanne L Dickinson**, Alex W Hewitt, Joanne Kamens, Kazuto Kato, Erika Kleiderman, Satoshi Kodama, **John Liddicoat**, David A Mackey, Ainsley Newson, **Jane Nielsen**, Jennifer K Wagner, **Rebekah E McWhirter**, ‘Key Challenges in Bringing CRISPR-Mediated Somatic Cell Therapy into the Clinic’ (2017) 9 *Genome Medicine* 85–88.

Dianne Nicol and **Jane Nielsen**, ‘The Role of Biotechnology Patents in Regulating Innovative Health Research and Development’ in Edward Dove and Graeme Laurie (eds), *Cambridge Handbook of Health Research Regulation* (in press).

A Sample of Our Current Research Interests

Stem Cells and Cloning

The CLG's focus on the national and international policy, regulation and governance of human genetics extends to stem cell science. Interest in stem cell technology accelerated with the report of the isolation of pluripotent stem cells from human embryos in 1998. The CLG tracked stem cell technology and the explosion of international reports following this scientific announcement (for example, Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings*; House of Commons Science and Technology Committee, *The Cloning of Animals from Adult Cells*; and, National Bioethics Advisory Commission, *Cloning Human Beings*: Report and Recommendations). Research standards for clinical applications were also developed at around this time in the form of the *International Society for Stem Cell Research Guidelines*.

Significantly, the CLG was involved in the corresponding Australian debates, public consultations and submissions, legislative initiatives and the resulting NHMRC Embryo Research Licensing Committee system. Chalmers and Nicol, together with our research assistant and PhD candidate Brendan Gogarty, took responsibility for this area, tracking scientific and legal developments. They published on international and national regulatory developments, public trust and the role of regulation in these areas.

The CLG continues to undertake research on the Australian dual regulatory model of the *Prohibition of Human Cloning for Reproduction Act* the *Research Involving Human Embryos Act*. Chalmers and Nicol were sequentially appointed to the NHMRC Embryo Research Licensing Committee, which administers both Acts and is responsible for the licensing regime created by the *Research Involving Human Embryos Act*. This approach to licensing of embryos for research purposes is largely replicated in the UK, Finland, Greece, The Netherlands, Sweden, Singapore, South Korea, and China and in two states in the United States of America; California and New Jersey. Outright research bans apply in Germany, Austria, Ireland, Canada and the Philippines. New genome editing techniques have reopened debates about the adequacy and appropriateness of these regulatory approaches.

Key Outputs

Dianne Nicol, **Don Chalmers** and **Brendan Gogarty,** 'Regulating Biomedical Advances: Embryonic Stem Cell Research' (2002) 2 *Macquarie Law Journal* 31–59.

Don Chalmers and **Dianne Nicol**, 'Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic Values?' (Part 1) (2003) 18 *Law and Human Genome Review* 43–53 and Part 2 (2003) 19 *Law and Human Genome Review* 91–108.

Don Chalmers, Peter Rathjen, Joy Rathjen and **Dianne Nicol,** 'Stem Cells and Regenerative Medicine: From Research Regulation To Clinical Applications' (2013) 20 *Journal of Law and Medicine* 831–844.

Material Transfer Agreements

The CLG became particularly interested in the legal issues associated with the transfer of research material between laboratories in 2013. A range of biological materials are routinely transferred for genomic research, including but not limited to whole living organisms, human and other tissue, reagents, cell lines, plasmids and vectors. The tradition of sharing these research tools is not new: customarily, biological materials were freely exchanged between researchers, frequently without any type of legal documentation. Material transfer agreements (MTAs) began to enter the picture as universities increasingly moved towards capturing the commercial potential of innovation. Scholars became concerned that MTAs could interfere with progress in genomics, particularly if they involve protracted negotiations and include the following types of terms: grant-back provisions providing for an option to license patent rights to subsequent discoveries; prohibitions on researchers from sharing with other institutions; and pre-publication review of research results.

In 2014 Nicol, Chalmers and Nielsen (as senior research fellow) received funding from the ARC to research this topic from an Australian perspective. The study included an empirical component which involved interviews with technology transfer officers and scientists in universities and research institutes, a survey of scientists involved in transferring materials, and detailed review and comparison of the terms of a number of standard MTAs.

We found that MTAs are an important tool to track provenance of biological materials, and to facilitate collaboration. In a vast majority of cases they need do little more than this. From this perspective, formalisation is a positive development in the materials transfer environment. However, MTA practices remain inefficient and unwieldy and are in need of reform. Unrealistic expectations of commercialisation opportunities and unnecessary risk aversion can also increase duration and complexity of MTA negotiations. Even where standard-form MTAs are used, there can be an irresistible urge to 'tinker' with them. While a standard-form Australian MTA would not be universally acceptable, there is significant scope for alignment in key MTA terms.

The project culminated in 2016, with a workshop in Hobart which brought together experts from around the globe. Discussions at the workshop corroborated the veracity of empirical findings from our ARC-funded study, and highlighted the difficulty of introducing standard MTAs into a research environment dominated by risk averse public institutions.

Key Outputs

Jane Nielsen and **Dianne Nicol,** 'The Legal Vacuum Surrounding Access to Gene-Based Materials and Data' (2016) 24 *Journal of Law and Medicine* 72–88.

Jane Nielsen, Tania Bubela, **Don Chalmers,** Amber Johns, Linda Kahl, Joanne Kamens, Charles Lawson, **John Liddicoat, Rebekah McWhirter**, Ann Monotti, **James Scheibner, Tess Whitton,** and **Dianne Nicol,** 'Provenance and Risk in Transfer of Biological Materials' (2018) *PLOS Biology* doi.org/10.1371/journal.pbio.2006031

Jane Nielsen, Dianne Nicol, Tess Whitton and **Don Chalmers**, *My Way or the MTA: The Use of Material Transfer Agreements in Publicly Funded Research in Australia* (Centre for Law and Genetics Occasional Paper No. 10; 2018).

3D Printing

The CLG has invested significant research time since 2013 considering the legal implications brought about by 3D printing technologies. 3D printing is a transformative technology which is revolutionising the way we design and manufacture goods. It facilitates precision and complexity in manufacturing, and its great benefit lies in the fact that designs may be customised. 3D printing is currently being used for a range of applications by a range of users, and its uptake by various industries and the public has been nothing short of phenomenal.

In 2013, Nielsen secured funding from the University of Tasmania to research this area. Along with the promise 3D printing brings, the potential for legal issues has loomed large. 3D printing makes it easier to 'copy' and produce similar, functioning objects, so infringement of intellectual property rights has been highlighted as a risk of the technology. Many websites offer downloadable files from which objects may be printed, and 3D scanners provide the opportunity to scan objects from which printable files may be derived.

There has also been significant concern about the safety of products produced using 3D printing and the capacity of existing product safety laws to protect consumers against 3D printed goods that are either faulty, or not fit for purpose. For example, consumers may use unsafe 3D printed products in their home or car, or consume food from 3D printed plates that are not food-safe. It is not difficult to envisage a situation where a product is printed and passed on without adequate warnings as to its safety.

Finally, 3D printing is yet another way in which personal data may be generated and aggregated. Already whole-body scanners are being used to produce body measurement data for various purposes, including for fashion and the production of miniature 3D 'selfies'. The storage and sale of this data raises concerns, as there is no guarantee of compliance with privacy principles.

The study conducted by Nielsen (with assistance from Liddicoat) involved interviews with those involved in producing 3D printed goods for profit. It resulted in a number of outputs, and transitioned into researching the legal and ethical implications of bioprinting. This burgeoning area is progressing rapidly, and brings with it many questions of a regulatory nature. These questions are being addressed in our most recent ARC-funded project on the regulation of innovative health technologies.

Key Outputs

Jane Nielsen and Lynden Griggs, 'Allocating Risk and Liability for Defective 3D Printed Products: Product Safety, Negligence or Something New?' (2017) 42 *Monash University Law Review* 712–739.

Jane Nielsen and John E Liddicoat, 'The Multiple Dimensions of Intellectual Property Infringement in the 3D Printing Era' (2017) 27 *Australian Intellectual Property Review* 184–208.

Dinusha Mendis, **Jane Nielsen**, **Dianne Nicol** and Phoebe Li, 'The Co-existence of Copyright and Patent Laws to Protect Innovation: Case Study of 3D Printing in UK and Australian Law' in Roger Brownsword, Elaine Scotford and Karen Yeung (eds), *The Oxford Handbook of Law, Regulation and Technology* (Oxford University Press; 2017) 451–476.

Germline Genome Editing

One of the most exciting developments in biomedicine over the past few years is the vast improvement in the ability to directly alter the genetic sequence of mammalian cells, particularly through the adaptation of Clustered Regularly Interspersed Short Tandem Repeat (CRISPR) and CRISPR associated (Cas) systems. This technology is positioned to become as transformative in the laboratory as the polymerase chain reaction, which facilitated rapid multiplication of DNA strands in the 1980s. Although still very much a research tool, CRISPR-Cas has been touted as having potential clinical application in the treatment of cancer and a range of other diseases. These technological advances in genome editing have reignited debates about the potential for therapeutic germline gene therapy, which is currently prohibited in many jurisdictions, and deeper philosophical discussions around the manipulation of human embryos.

In 2015, CLG members recognised that ELSI of genome editing required special attention. This is particularly the case in Australia, in light of the prohibitory approach to regulation of germline therapy, the prescriptive approach to regulation of embryo research and uncertainty about the regulation of somatic cell genome editing. The University of Tasmania provided funding in 2016 to initiate this research, allowing the CLG to appoint a short-term research fellow and to host a workshop. The workshop involved a group of scholars with deep interest in the ethical, legal and social implications of genome editing. The workshop allowed the group to dissect the ethical, legal and social environment within which gene editing is situated, and to debate how this technology might be safely and ethically translated into the clinic and unacceptable practices, whether of a legal, moral or social nature, curtailed.

Nicol has been particularly active in this area, with two book chapters on the regulatory environment for germline genome editing and embryo research, and a paper reporting the results of a survey of Australian public attitudes towards genomic editing (with Critchley and other colleagues). Her work on the NHMRC *Embryo Research Licensing Committee* is informed by this research. In November 2018 she was asked to present on the Australian regulatory environment at the Second International Summit on Genome Editing in Hong Kong. The announcement of the alleged birth of first two genome-edited babies was a key topic for discussion at the summit, illustrating the urgent need for research in this area.

Key Outputs

Tess Whitton, **Dianne Nicol** and **Don Chalmers**, 'Human Embryos, Genome Editing and Future Directions' in Ian Freckleton and Kerry Petersen (eds), *Tensions and Traumas in Health Law* (Federation Press; 2017) 384–400.

Christine Critchley, **Dianne Nicol**, Gordana Bruce, Jarrod Walshe, Tamara Treleaven and Bernard Tuch, 'Predicting Public Attitudes Towards Gene Editing of Germlines: The Impact of Moral and Hereditary Concern in Human and Animal Applications' (2019) 9 *Frontiers in Genetics* article 704.

Dianne Nicol, 'The Regulation of Human Germline Genome Modification in Australia' in Andrea Boggio, Caesare Romano and Jessica Almqvist (eds), *Human Germline Modification and the Right to Science: A Comparative Study of National Laws and Policies*. In press.

Return of Research Results

Over the past decade, there has been a growing discussion about the ELSI involved in returning research results, especially in the context of genetic and genomic research. Many agree that researchers have an ethical obligation to return at least some results to participants, but satisfying this precept raises overarching questions about what data researchers should generate, the degree of verification and analysis to which it should be subject, and the degree of clinical or other value that warrants an obligation of disclosure. As genomic information becomes ever more available, these questions become increasingly acute.

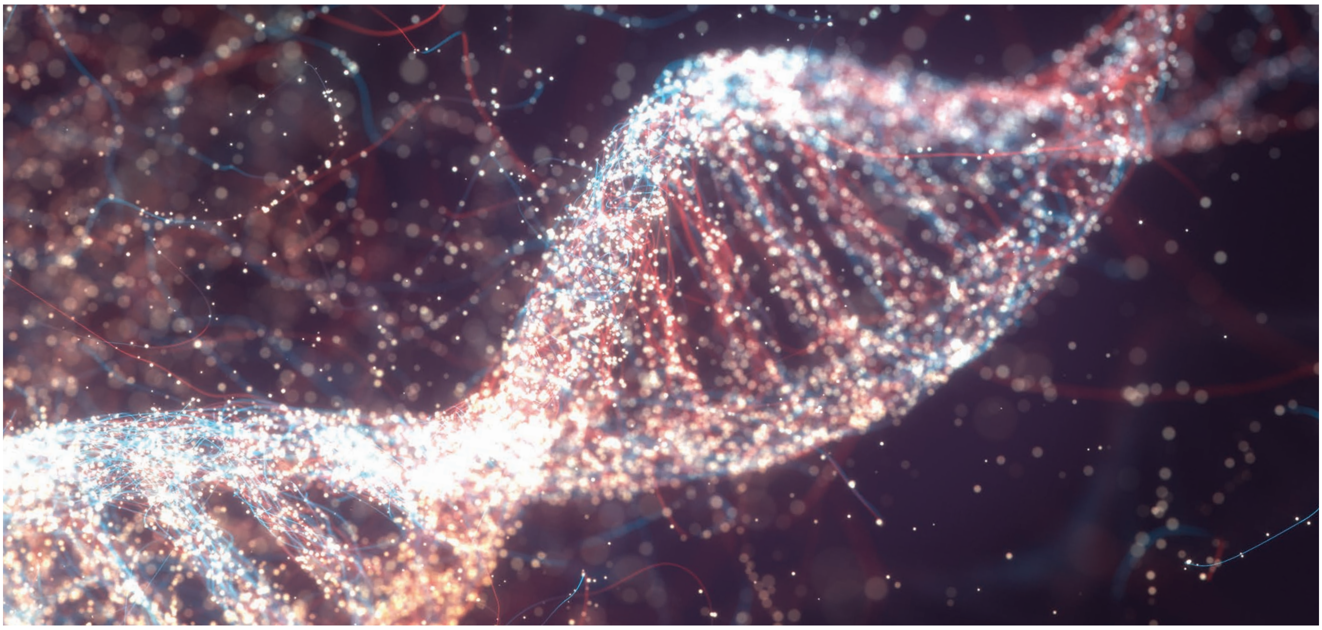
Members of the CLG have been influential in addressing the frameworks for disclosure of genomic research results in Australia and more broadly. Most notably, Otlowski chaired the initial working group (2015 to mid-2016) responsible for revising Chapter 3.5 of the NHMRC *National Statement on Ethical Conduct in Human Research*, which deals with human genetic and genomic research. The revised chapter includes a new section on the communication of research findings or results to participants including a decision tree for the management of findings in genomic research and clinical care.

Scholarly engagement on this issue by CLG researchers (Otlowski and Eckstein) include peer-reviewed journal articles, book chapters, and conference, workshop and panel presentations. Otlowski, Eckstein and McWhirter regularly engage with genetic counsellors and other professionals in the area to discuss legal and ethical challenges they encounter with regard to return of results. CLG members are involved with the NHMRC Centre for Research Excellence on Translation of Genetic Eye Research (TOGER) led by Professor David Mackey (Otlowski as CI and Nicol on the Advisory Board); one of the key ELSI issues encompassed in this program is the return of results to research participants, including incidental findings. The CLG will continue to explore return of finding decisions through the genomic data sharing project.

Key Outputs

Lisa Eckstein, Jeremy Garrett and Benjamin Berkman, 'A Framework for Analyzing the Ethics of Disclosing Genetic Research Findings' (2014) 42 *Journal of Law and Medical Ethics* 190–207.

Lisa Eckstein and **Margaret Otlowski**, 'Strategies To Guide the Return of Genomic Research Findings: an Australian Perspective' (2018) 15 *Journal of Bioethical Inquiry* 403–415.



Genetic and Genomic Research with Aboriginal and Torres Strait Islander People

A key ethical issue for Australian genomics researchers is ensuring that Aboriginal and Torres Strait Islander people are included in the benefits of precision medicine and genomics. The CLG has actively engaged with this issue by identifying and assessing the impact on Indigenous Australians as an important part of our wider projects in genomics. In 2014, we undertook a Deliberative Democracy event, which highlighted the significance of this issue for mainstream genomics and facilitated the inclusion of Indigenous voices in developing a trustworthy biobank governance framework. Similarly, our 2016 workshop on MTAs included examination of the potential effect of standardised MTAs on Indigenous communities.

The CLG's work in this area has resulted in a number of peer-reviewed publications, conference presentations and submissions to the NHMRC regarding revisions of the National Statement. As part of an NHMRC Project Grant investigating genetic risk factors for vulvar cancer in Indigenous women resident in Arnhem Land, CLG members Dickinson and McWhirter, together with Professor John Condon, Djapirri Mununggirritj and Dipililnga Marika, developed practical strategies for undertaking ethical genetic and genomic research with Indigenous communities. Building on this, later work by CLG members identified potential harms to Indigenous Australians in the regulation of non-consensual genetic testing of deceased individuals and in the exclusion of Indigenous participants from genomic health research, as well as making recommendations for preventing these in practice.

Chalmers sits on the governance board of the National Centre for Indigenous Genomics (NCIG), an Indigenous-led initiative to promote ethical inclusion of Indigenous Australians in genomics. The NCIG acts as custodian of genomic samples and data relevant to Indigenous Australians. In the course of his appointment, Chalmers has contributed to the management of Indigenous genomic resources in accordance with principles of respect, consultation, consent and trust.

Our current project on genomic data sharing will expand upon our work to date by investigating the impact of data sharing practices on Indigenous Australians, with the aim of accelerating equitable access to the benefits of precision medicine and genomics.

Key Outputs

Rebekah E McWhirter, Djapirri Mununggirritj, Dipililnga Marika, **Joanne L Dickinson** and John R Condon, 'Ethical Genetic Research in Indigenous Communities: Challenges and Successful Approaches' (2012) 18 *Trends in Molecular Medicine*, 702–708.

Rebekah E McWhirter, **Dianne Nicol** and Julian Savulescu, 'Genomics in Research and Health Care with Aboriginal and Torres Strait Islander Peoples' (2015) 33 *Monash Bioethics Review* 203–209.

The CLG's Grants

- 'Legal and Ethical Implications of Human Genetic Research: Australian Perspectives', ARC Discovery Grant 1995–1997, $79,005 (Chalmers, Otlowski and Skene).
- 'Legal Standards in the Commercialisation of Human Genetic Technology', ARC Discovery Grant 1999–2001, $115,000 (Chalmers, Otlowski and Skene).
- 'Legal and Ethical Regulation of the Use and Commercialisation of Human Biological Material', ARC Discovery Grant DP0208258 2002–2004, $364,323 (Chalmers, Nicol, Skene and Otlowski).
- 'Biotechnology Patent Licensing in Australia: A Preliminary Study', UTAS Institutional Research Grant 2002–2003, $20,000 (Nicol and Nielsen).
- 'Facilitation and Regulation of Research and Development Involving Human Genetic Databanks', ARC Discovery Grant DP0559760, 2005–2009, $602,594 (Chalmers, Nicol, Otlowski and Skene).
- 'Co-operative Intellectual Property Management and Technology Transfer for the Australian Biotechnology Industry', ARC Discovery Grant DP0557608, 2005–2007, $331,586 (Hope, Nicol and Braithwaite).
- 'Expand the capacity of an international multidisciplinary research network focussed on the ethical, legal and social implications of emerging biotechnologies', ARC International Linkage Grant 2006–2007, $20,000 (Chalmers, Nicol, Otlowski, Skene, Stranger, Professors Bartha Knoppers, Andrew Webster and Jeong-Ro Yoon).
- 'The Innovation Pool in Australian Biotechnology: Assessing Strategies for Fostering Innovation through Patenting and Patent Pooling', ARC Discovery Grant DP0985077, 2009–2013, $412,000 (Nicol, Nielsen, Critchley and Aoki).
- 'The Age of Personalised Medicine: Regulatory Challenges for Australia', ARC Discovery Grant DP110100694, 2011–2014, $281,000 (Nicol, Chalmers, Otlowski and Critchley).
- 'Ensuring the Utility and Sustainability of Tissue Banks: Supporting Translational Research in Australia through Informed Regulation and Community Engagement', NHMRC Project Grant, administered through the University of Sydney, 2012–2015, $437,215 (Professor Ian Kerridge, Stewart, Otlowski, Nicol and Critchley).
- 'Delivering on the Promise of 3D Printing: Identifying Legal Barriers' UTAS Research Enhancement Granted Scheme, 2013, $10,000 (Nielsen)
- 'Material Transfer Agreements and Open Science in the Genome Era', ARC Discovery Grant DP140100301, 2014–2016, $294,776 (Nicol and Chalmers).
- 'Expanding the Centre for Law and Genetics to Achieve Local, National and International Recognition for Research Excellence', UTAS Strategic Research Funding, 2015–2016, $235,000 (Nicol, Chalmers and Otlowski), with renewal of $87,000 in 2017.
- 'Reforming the Regulatory Environment for Innovative Health Technologies', ARC Discovery Grant DP180101262, 2018–2021, $628,576 (Nicol, Nielsen, Eckstein and Stewart).
- 'Genomic Data Sharing: Issues in Law, Research Ethics and Society', ARC Discovery Grant DP180100269, 2018–2021, $614,454 (Nicol, Otlowski, Critchley, Eckstein, Chalmers and Nielsen).

A Sample of Core CLG Team Publications

1. Don Chalmers, Margaret Otlowski, Dianne Nicol and Loane Skene, ‘Legal and Ethical Implications of Human Genetic Research: Australian Perspectives’ (1995) 3 *Law and the Human Genome Review* 211–220.
2. Dianne Nicol and Jane Nielsen, ‘The Australian Medical Biotechnology Industry and Access To Intellectual Property: Issues for Patent Law Development’ (2001) 23 *Sydney Law Review* 347–374.
3. Dianne Nicol, Don Chalmers and Brendan Gogarty, ‘Regulating Biomedical Advances: Embryonic Stem Cell Research’ (2002) 2 *Macquarie Law Journal* 31–59.
4. Don Chalmers and Dianne Nicol, ‘Commercialisation of Biotechnology: Public Trust and Research’ (2004) 6 *International Journal of Biotechnology* 116–133.
5. Margaret Otlowski, ‘Exploring the Concept of Genetic Discrimination’ (2005) 2 *Journal of Bioethical Inquiry* 165–176.
6. Don Chalmers and Dianne Nicol, ‘Human Genetic Research Databases and Biobanks: Towards Uniform Technology and Australian Best Practice’ (2008) 15 *Journal of Law and Medicine* 538–555.
7. Christine Critchley, Dianne Nicol, Margaret Otlowski and Mark Stranger, ‘Predicting Intention To Biobank: a National Survey’ (2010) 22 *European Journal of Public Health* 139–144.
8. Margaret Otlowski and Dianne Nicol, ‘The Regulatory Framework for Protection of Genetic Privacy in Australia’ in Terry Sheung-Hung Kaan and Calvin Wai-Loon Ho (eds), *Genetic Privacy: An Evaluation of the Ethical and Legal Landscape* (Imperial College Press; 2013) 283–321.
9. Don Chalmers, Dianne Nicol, Margaret Otlowski and Christine Critchley, ‘Personalised Medicine in the Genome Era’ (2013) 20 *Journal of Law and Medicine* 577–594.
10. Rebekah E McWhirter, Christine Critchley, Dianne Nicol, Don Chalmers, Tess Whitton, Margaret Otlowski, Michael Burgess and Joanne L Dickinson, ‘Community Engagement for Big Epidemiology: Deliberative Democracy as A Tool’ (2014) 4 *Journal of Personalized Medicine* 459–474.
11. Christine Critchley, Dianne Nicol, Margaret Otlowski and Don Chalmers, ‘Public Reaction To Direct-To-Consumer Online Genetic Tests: Comparing Attitudes, Trust and Intentions across Commercial and Conventional Providers’ (2015) 24 *Public Understanding of Science* 731–750.
12. John Liddicoat, Tess Whitton and Dianne Nicol, ‘Are the Gene Patent Storm Clouds Dissipating? A Global Snapshot’ (2015) 33 *Nature Biotechnology* 347–352.
13. Dianne Nicol, Christine Critchley, Rebekah E McWhirter and Tess Whitton, ‘Understanding Public Reactions To Commercialisation of Biobanks and Use of Biobank Resources’ (2016) 162 *Social Science and Medicine* 79–87.
14. Jane Nielsen and Dianne Nicol, ‘The Legal Vacuum Surrounding Access To Gene-Based Material and Data’ (2016) 24 *Journal of Law and Medicine* 72–88.
15. Lisa Eckstein, Don Chalmers, Christine Critchley, Ruthie Jeanneret, Rebekah E McWhirter, Jane Nielsen, Margaret Otlowski and Dianne Nicol, ‘Australia: Regulating Genomic Data Sharing To Promote Public Trust’ (2018) 137 *Human Genetics* 583–591.

Our Occasional Papers

Margaret Otlowski, *Implications of Genetic Testing for Australian Insurance Law and Practice* (Centre for Law and Genetics Occasional Paper No 1; 2001).

Margaret Otlowski, *Implications of Genetic Testing for Australian Employment Law and Practice* (Centre for Law and Genetics Occasional Paper No 2; 2001).

Imogen Goold (ed) *Regulating Human Genetics* (Centre for Law and Genetics Occasional Paper No 3; 2001).

Jane Nielsen (ed), *Regulating the New Frontiers: Legal Issues in Biotechnology* (Centre for Law and Genetics Occasional Paper No 4; 2001).

Brendan Gogarty (ed), *Breaking the Code* (Centre for Law and Genetics Occasional Paper No 5; 2003).

Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (Centre for Law and Genetics Occasional Paper No 6; 2003).

Dianne Nicol, *Patent Licensing in Medical Biotechnology in Australia: A Role for Collaborative Licensing Strategies* (Centre for Law and Genetics Occasional Paper No 7; 2010).

Dianne Nicol, Jane Nielsen, Christine Critchley, John Liddicoat and Tess Whitton, *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* (Centre for Law and Genetics Occasional Paper No 8; 2014).

Dianne Nicol, Jane Nielsen and Verity Dawkins, *D'Arcy v Myriad Genetics: The Impact of the High Court's Decision on the Cost of Genetic Testing in Australia* (Centre for Law and Genetics Occasional Paper No 9; 2018).

Jane Nielsen, Dianne Nicol, Tess Whitton and Don Chalmers, *My Way or the MTA: The Use of Material Transfer Agreements in Publicly Funded Research in Australia* (Centre for Law and Genetics Occasional Paper No 10; 2018).

Our Workshops

Regulating Human Genetics Symposium, Centre for Law and Genetics, University of Tasmania November 2000.

Key output: Imogen Goold (ed), *Regulating Human Genetics* (Centre for Law and Genetics Occasional Paper No 3; 2001).

***Regulating the New Frontiers: Legal Issues in Biotechnology Symposium*, Centre for Law and Genetics, University of Tasmania 10 December 2001.**

Key output: Jane Nielsen (ed), *Regulating the New Frontiers: Legal Issues in Biotechnology* (Centre for Law and Genetics Occasional Paper No 4; 2001).

***Breaking the Code Symposium*, Centre for Law and Genetics, University of Tasmania, hosted at Murdoch Children's Research Institute and Walter and Eliza Hall Institute Melbourne 28 and 29 November 2002.**

Key output: Brendan Gogarty (ed), *Breaking the Code* (Centre for Law and Genetics Occasional Paper No 5; 2003)

***The Stem Cell Debate in Australia and the United States: Legal, Ethical and Policy Considerations Symposium*, Centre for Law and Genetics, University of Tasmania, Hobart, 16 November 2004.**

***Human Biotechnology and Public Trust: Trends Perceptions and Regulation Symposium*, ACETS, Swinburne University, and Centre for Law and Genetics, University of Tasmania, hosted at Swinburne University, 23 November 2006.**

Key output: Mark Stranger (ed), *Human Biotechnology and Public Trust: Trends Perceptions and Regulation* (Centre for Law and Genetics; 2007).

***Governing Biobanks – What Are the Challenges Symposium?* Ethox Centre, Oxford University; Centre for Law and Genetics, University of Tasmania, hosted at Oxford University, 24–26 June 2008.**

Key output: Jane Kaye and Mark Stranger (eds), *Principles and Practice in Biobank Governance* (Ashgate; 2009).

***The Innovation Pool Expert Workshop*, Centre for Law and Genetics, University of Tasmania, Hobart, 14–16 December 2011.**

Key output: Dianne Nicol, Jane Nielsen, Christine Critchley, John Liddicoat and Tess Whitton, *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* (Centre for Law and Genetics Occasional Paper No 8; 2014).

***Personalised Medicine Workshop*, Centre for Law and Genetics, University of Tasmania, Hobart, 11–12 July 2014.**

Key output: Dianne Nicol, Tania Bubela, Don Chalmers, Jan Charbonneau, Christine Critchley, Joanne L Dickinson, Jennifer Fleming, Alex W Hewitt, Jane Kaye, Johnathon Liddicoat, Rebekah E McWhirter, Margaret Otlowski, Nola M Ries, Cameron Stewart, Jennifer Wagner, Nik Zeps, 'Precision Medicine: Drowning in a Regulatory Soup?' (2016) 3 *Journal of Law and the Biosciences* 281–303.

***MTA Workshop*, Centre for Law and Genetics, University of Tasmania, Hobart, 8–9 November 2016.**

Key output: Jane Nielsen, Tania Bubela, Don Chalmers, Amber Johns, Linda Kahl, Joanne Kamens, Charles Lawson, John Liddicoat, Rebekah McWhirter, Ann Monotti, James Scheibner, Tess Whitton, Dianne Nicol, 'Provenance and Risk in Transfer of Biological Materials' (2018) 16 *PLOS Biology* 1–7.

***Genome Editing Workshop*, Centre for Law and Genetics, University of Tasmania, Hobart, 12–14 November 2016**

Key output: Dianne Nicol, Lisa Eckstein, Michael Morrison, Jacob S Sherkow, Margaret Otlowski, Tess Whitton, Tania Bubela, Kathryn P Burdon, Don Chalmers, Sarah Chan, Jac Charlesworth, Christine Critchley, Merlin Crossley, Sheryl de Lacey, Joanne L Dickinson, Alex W Hewitt, Joanne Kamens, Kazuto Kato, Erika Kleiderman, Satoshi Kodama, John Liddicoat, David A Mackey, Ainsley Newson, Jane Nielsen, Jennifer K Wagner, Rebekah E McWhirter, 'Key Challenges in Bringing CRISPR-Mediated Somatic Cell Therapy into the Clinic' (2017) 9 *Genome Medicine* 85–88.

Our CLG-Related External Appointments and Other Contributions to Law and Policy Reform

International

CLG members have contributed to the work of international organisations dedicated to furthering progress on ELSI concerns relating to genomics. For example, Chalmers was Co-Chair from 2011 to 2016, and a member from 2009 to 2011, of the Data Access Committee of the International Cancer Genome Consortium. He was also Deputy Chair of the Ethics Committee of the Human Genome Organisation between 2007 and 2015, and member of Genome Canada's International Scientific Review Panels from 2004 to 2009. Both Chalmers and Nicol have contributed to the Global Alliance for Genomics and Health, Chalmers as a member of the Regulatory and Ethics Working Group since 2014 and Nicol as a member of the Ethics Review Equivalency Task Team from 2014 to 2017.

Other notable contributions include Chalmers' work on the US National Bioethics Advisory Commission report on *Ethical and Policy issues in Research involving Humans* in 2001, the CLG team's submission to the OECD relating to the development of *Guidelines for Human Biobanks and Genetic Research Databases* in 2008, and work conducted by Nicol with the OECD on collaborative licensing of intellectual property and genome editing. Chalmers, Nicol and Otlowski also contributed to UNESCO's Declaration on Bioethics and Human Rights and Declaration on the Human Genome.

National

NHMRC

Since the CLG's inception, members have consistently contributed to the work of the NHMRC. Chalmers was chair of the committee which reviewed the role and function of institutional ethics committee system from 1995 to 1996 and scientific, ethical and regulatory considerations relevant to cloning of human beings in 1999. He was a member of the National Biobanking Strategy Committee from 1996-1999 and, during the same period, played a significant role in the development of the National Statement.

Otlowski, Nicol and Chalmers have all been members of AHEC; Otlowski and Nicol were members from 2009 to 2015 and 2015 to 2018 respectively, whilst Chalmers served as Chair from 1993 to 2000. During her time on AHEC, Otlowski was actively involved in AHEC working groups (including as chair), particularly those tasked with reviewing various chapters of the National Statement.

Chalmers was Deputy Chair of the NHMRC Embryo Research Licensing Committee from 2003 to 2012 and Nicol was a member from 2015 to 2018 and was appointed as Chair in 2018. Both Chalmers and Otlowski were members of the Human Genetics Advisory Committee, the former from 2006 to 2009 and the latter from 2009 to 2015.

Collectively, the CLG has also made comprehensive submissions to the NHMRC during the course of reviews of the National Statement.

Gene Technology Committees

Both Nicol and Chalmers sat on the Gene Technology Ethics and Community Consultative Committee, with Chalmers serving as Chair from 2002 to 2012 and Nicol as a member from 2017 to 2018.

Law Reform Agencies

As already noted, members of the CLG have made significant contributions to law reform. From 2000 to 2003, Chalmers and Otlowski were consultants to the ALRC/AHEC reference on the protection of genetic information and Chalmers was a member of the advisory group. Otlowski was a member of the Health Privacy Subcommittee for the ALRC privacy reference from 2006 to 2008. Similarly, Nicol was a consultant and member of the advisory group to the ALRC reference on gene patenting and human health between 2003 and 2004. The CLG made detailed and lengthy submissions to each of these inquiries. Nicol and Nielsen have also made extensive written and oral submissions to IP Australia, the Australian Senate and Australian Productivity Commission inquiries into patent law reform, with specific focus on gene patents. Members of the CLG have been involved in a number of other submissions to public inquiries.

Continues on next page.

Health and Related Topics

CLG members have given their time to diverse topics in health. Nicol was a member of the Expert Panel of the Federal Government Review of Pharmaceutical Patents between 2012 and 2013, and a member of the Federal Government Genomics Health Futures Mission Steering Group in 2018. She was chair of the Mission Steering Group's Ethical, Legal and Social Implications Working Group. Otlowski was also a member of this working group.

Chalmers was a member in the CSIRO Health Sector Advisory Council from 2002 to 2009 and the Advisory Council of the Organ and Tissue Authority between 2008 and 2012. He also was a board member of the National Breast and Ovarian Cancer Council between 2008 and 2011 and the National Centre for Indigenous Genomics at ANU since 2014.

Otlowski was a member of the Stem Cell Ethics Australia Committee in 2004, the Federal Privacy Commissioner's Health Leaders' Forum from 2004 to 2010 and of the Independent Advisory Committee of the Western Australian Genetic Epidemiology Resource (WAGER) and WA DNA Bank (WADB) between 2006 and 2008. She has also been a member of the Advisory Board of the Melbourne Genomics Health Alliance in 2016, the Australian Twin Registry since 2005 and the Working Group on Archiving Data between 2006 and 2007. Between 2009 and 2014, Otlowski was a member of the Management Committee of the National Breast Cancer Foundation Collaborative Breast Cancer Research Program: BreastScreen Cohort Demonstration Project, 'Lifepool'.

Tasmania

Members of the CLG have also shown a commitment to ELSI concerns on a state level. Otlowski was chair of the University of Tasmania Social Sciences Human Research Ethics Committee for over a decade from 2002. Dianne Nicol was a member of this committee from 2001 to 2007 and was chair of the University of Tasmania's Animal Ethics Committee from 2007 to 2013. Currently, Dickinson is chair, Eckstein is deputy chair and McWhirter is a member of the Tasmanian Health and Medical Research Human Research Ethics Committee. Nielsen is a current member of the University of Tasmania Social Sciences Human Research Ethics Committee.

Prizes, Awards and Fellowships

Chalmers, Otlowski and Nicol are Fellows of the Australian Academy of Law.

Chalmers was appointed an Officer of the Order of Australia on 26 January 2019. He received the NHMRC Ethics Award, the University of Tasmania Distinguished Service Medal and the Australian Red Cross Distinguished Service Award in 2010 and was appointed as a Fellow of the Australian Academy of Health and Medical Research in 2015.

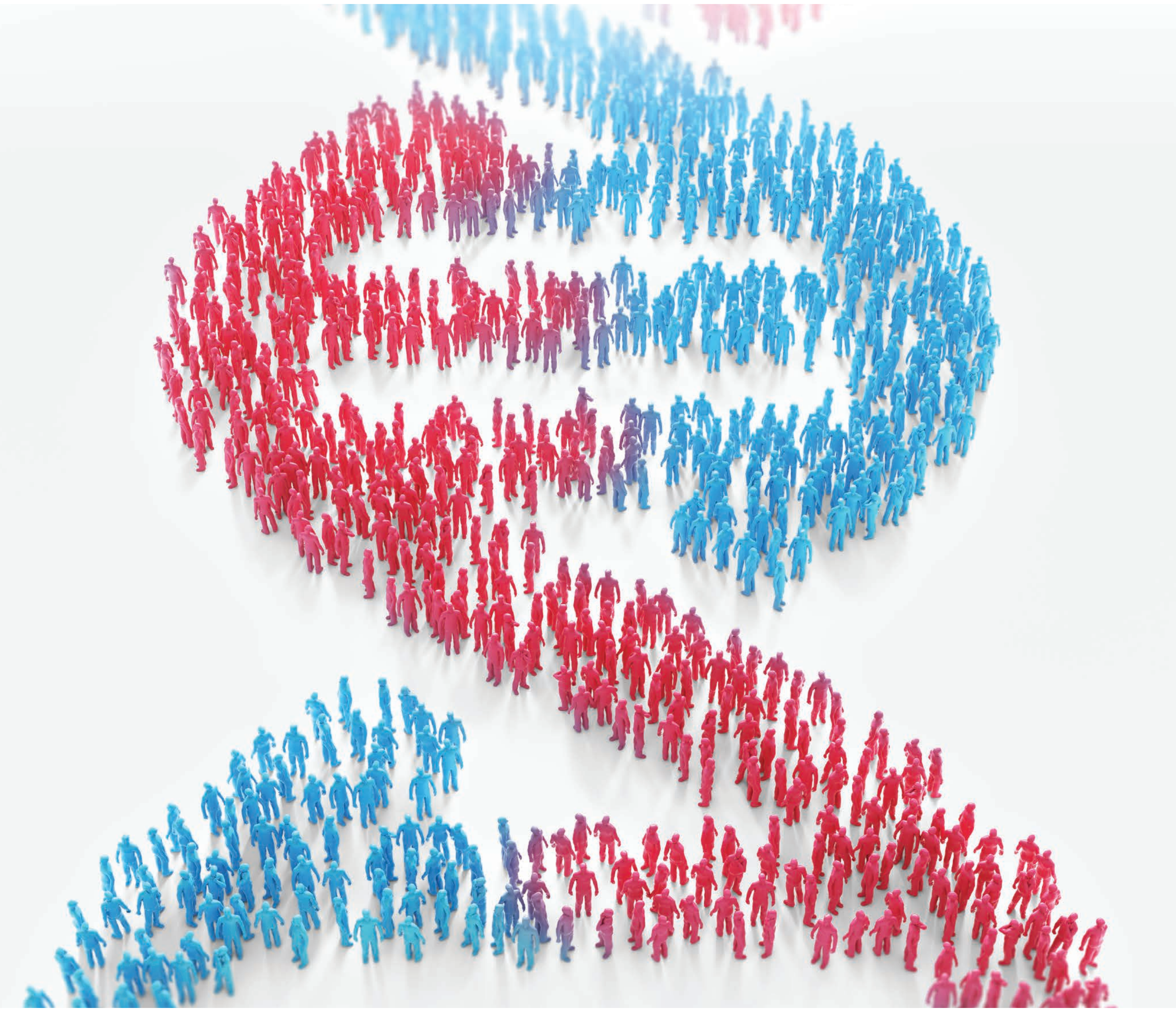
Nicol was a Visiting Research Fellow at the Regulatory Institutions Network, Australian National University, Canberra, from 20 July 2009 to 31 December 2009 and at the Centre for Intellectual Property Rights at KU University, Leuven, Belgium, 4 December to 16 December 2006. She was a Distinguished Visiting Research Fellow, ESRC Genomics Policy and Research Forum, Edinburgh, Scotland, 29 May to 3 June 2006.

Teaching and Postgraduate Studies

Teaching is intrinsically linked to the CLG's research. Over the past 25 years, members of the CLG have been involved in teaching students at undergraduate, master's and postgraduate levels. Faculty of Law units such as Biotechnology Law, Torts, Intellectual Property Law, Law and Ethics of Health Care, Ethical and Legal Aspects of Dementia Care and Competition Law have been taught by CLG members. Members have also been involved in teaching first and second-year students at the School of Medicine.

The CLG has an extensive record of supervising research papers by honours students in law across diverse topics, including the role of the court in treating adolescent gender dysphoria, predictive genetic testing for Huntington's Disease, maternal responsibility for pre-natal harm in Australia, embryonic stem cell research and human cloning, enabling greater access to cheaper drugs in developing countries via improved compulsory licensing and combating biopiracy in Australia. The team has supervised over 50 students in the past 25 years.

The CLG has also been active in recruiting and training future generations of academics and experts through our postgraduate program, as listed below.



Completions

Dianne Nicol, LLM, 1997, currently Professor, University of Tasmania and Director of the CLG (supervised by Chalmers), ‘Legal and ethical aspects of patenting of human genetic information’.

Jane Nielsen, PhD, 2005 currently Senior Lecturer, University of Tasmania (supervised by Chalmers and Nicol), ‘Mapping the Intersection of Intellectual Property and Competition Law: Misusing Market Power when Refusing to License Biomedical Patents’.

Brenda McGivern, PhD, 2005 currently Senior Lecturer and Deputy Law Dean, University of Western Australia (supervised by Chalmers), ‘Interventions in Perinatal Medicine: A Jurisdictional Analysis’.

Imogen Louise Goold, PhD, 2005 currently Associate Professor, University of Oxford (supervised by Chalmers and Nicol), ‘A Twitch upon a Thread: Regulation of Human Tissue use in Australia and the Application of Property Law’.

Brendan Gogarty, PhD, 2006, currently Senior Lecturer, University of Tasmania (supervised by Chalmers and Nicol), ‘Gene Technology, Risk, Regulation and Communication’.

Samantha Jane Hardy, PhD, 2006 currently Associate Professor, James Cook University (supervised by Otlowski), ‘The Legal Injury Narrative: Personal Injury Litigation and Melodrama’.

Collins Okpanum, PhD, 2007, currently legal practitioner, Lagos, Nigeria (supervised by Nicol and Dr Gail Lugten), ‘Group Resource Rights and the Protection of Indigenous Knowledge Systems in International Law’.

Oksana Mitnovetski, LLM, 2008, currently legal practitioner, Melbourne (supervised by Nicol) ‘An Historical and Contemporaneous Analysis of Patenting of Methods of Medical Treatment of Human Beings in Australia and Overseas’.

Bruce Newey, LLM, 2009, currently legal editor, Hobart (supervised by Nicol and Dr Peter Lawrence), ‘A Critical Analysis of EC - Biotech: The Panel’s Approach to Other Rules of International Law and the Application of the SPS Agreement’.

Warwick Edward Marshall, LLM, 2011, currently public servant, Canberra (supervised by Otlowski, Emeritus Professor Kate Warner and George Zendowski), ‘Circumcision in Australia: Reforming the Law’.

Anton Hughes, PhD, 2012, currently barrister, Sydney (supervised by Nicol), ‘Dissecting the Software Patent Problem: An Argument Against Patentability based on the Relationship between Software and Mathematics’.

Foong Chee Kuen, PhD, 2012, currently Senior Lecturer, Western Sydney University (supervised by Chalmers and Nicol), ‘A Comparative Analysis of the Medico-legal and Ethical Issues Associated with Embryonic Stem Cell Research in Australia and Malaysia’.

Joseph Ming Yong Lee, LLM, 2012, currently PhD candidate ANU (supervised by Chalmers and Otlowski), ‘The Standard of Medical Care in Malaysia: The Case for Legislative Reform’.

Olasupo Owoeye, PhD, 2014, currently Senior Lecturer, RMIT University (supervised by Nicol and Nielsen), ’Patents for Pharmaceuticals and Access to Affordable Medicines: Towards an All-Encompassing Access Paradigm for Africa’.

Vanessa Diaz Rodriguez, PhD, 2014, currently researcher, editor assistant at IIJ-UNAM, Mexico (supervised by Chalmers and Associate Professor Rick Snell), ‘Transborder Biometric Information Flow: Legal Challenges to Personal Privacy and the Need for Public Debate’.

Emma van Dyken, PhD, 2015, currently public servant, Canberra (supervised by Nicol and Associate Professor Jeremy Prichard), ‘Using Wastewater Analysis to Measure the Prevalence of Prison Drug Use and the Effectiveness of Prison Drug Use Supply Reduction Strategies’.

John Liddicoat, PhD, 2016, currently Senior Research Fellow, Cambridge University (supervised by Nicol and Chalmers), ‘Boundaries of Patent Infringement Law’.

Moshood Abdussalam, PhD, 2017, currently Lecturer, Auckland University of Technology, NZ (supervised by Nicol and Nielsen), ‘A Basic Economic Case for Reordering the Patent Market with Gain-based Remedies’.

Simone Blackman, PhD, 2019, currently Lecturer, University of Tasmania (supervised by Nicol and Dr Sonia Shimeld), ‘The Role and Effectiveness of Regulation in Dog Breeding in Australia’.

Current Postgraduates

Olumayowa Adesanya (supervised by Nicol and Nielsen), 'Patenting Bioprinting: An Ethical Dilemma in the Provision of Accessible Health Technologies'.

Jan Charbonneau (supervised by Nicol and Chalmers), 'Think Before You Spit: Consumer Protection in the Direct-to-Consumer Genetic Testing Market'.

Pratap Devarapalli (supervised by Nicol and Nielsen), 'Patenting Aspects of 3D Bioprinted Tissues and Organs: Proposing an International Legal Framework'.

Jurgen Gnoinski (supervised by Nicol and Nielsen), 'Australian Designs Law and Virtual Designs'.

Stephanie Green (supervised by Nicol, Nielsen and Eckstein), 'The Role of Data Access Committees and Research Ethics Committees in Setting the Boundaries of Genomic Data Sharing'.

Suzana Nashkova (supervised by Nielsen and Professor Gino dal Pont), 'An Analysis of the Thorny Issues within the Process of Drafting Know-How Licence Agreements'.

Olugbenga Olatunji (supervised by Nicol and Dr Heather Forrest), 'Using TRIPS Flexibilities to Build Regional Pharmaceutical Manufacturing Capacity and Improve Access to Essential Medicines in the East African Community'.

James Scheibner (supervised by Nicol and Nielsen), 'Open Source Licensing and the Genomic Research Commons'.

Alexander Thomsen (supervised by Nielsen and Dr Emily Hansen), 'Investigating the Complexity of Regulation and Integration for Naturopaths Working Within the Biomedical System'.

Vanessa Warren (supervised by Eckstein, Nicol, Critchley and Dr Emily Hansen), 'Translating Public Trust to Law Reform through Australian Genomic Data Sharing Scenarios'.

CLG Contributors

Academic Staff and Adjunct Academic Appointees

- Distinguished Professor Don Chalmers (current)
- Professor Margaret Otlowski (current)
- Professor Dianne Nicol (current)
- Professor Christine Critchley (current)
- Dr Jane Nielsen (current)
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- Professor Loane Skene (1994-2006)
- Professor Joanne Dickinson (current)

Research Fellows

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- Dr Eric Iversen (2009-2010)
- Dr John Liddicoat (2015-2017, research assistant from 2010 to 2015)
- Tess Whitton (2017-2018, research assistant from 2013 to 2017)
- Dr Rebekah McWhirter (current)
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Key Australian Collaborators

- Professor Simon Foote (Australian National University – genomics).
- Dr Janet Hope and Professor John Braithwaite (Australian National University – intellectual property).
- Professor Kristine Barlow-Stewart (Sydney Medical School), Dr Sandra Taylor (University of Queensland), Dr Paul Lacaze and Jane Tiller (Monash University), Dr Mark Stranger and Associate Professor Sue Treloar (University of Queensland – genetic discrimination).
- Professor Cameron Stewart (Sydney University – health regulation).
- Professor Jane Kaye, Dr Jessica Bell, Dr Megan Proctor, Associate Professor Mark Taylor and Tess Whitton (University of Melbourne – ethical and legal implications of genomics).
- Amber Johns (Garvan Institute – genomic data sharing).

Major International Collaborators

- Ethical and legal implications of genomics: Professor Graeme Laurie and Dr Ted Dove (Edinburgh University, Scotland), Professor Kazuto Kato, (Osaka University, Japan), Professors Bartha Knoppers and Yann Joly (McGill University, Canada), Professor Tim Caulfield (University of Alberta, Canada), Professor Mike Burgess (University of British Columbia, Canada), Professor Eric Meslin (Council of Canadian Academies, Canada).
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- Regulation of innovative health technologies: Associate Professor Michael Morrison (Oxford University, UK).
- Health law: Professor Sheila McLean (Glasgow University, UK).

Research Assistants

- Catherine Hughes (1994)
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- Dr Brendan Gogarty (1997-2000)
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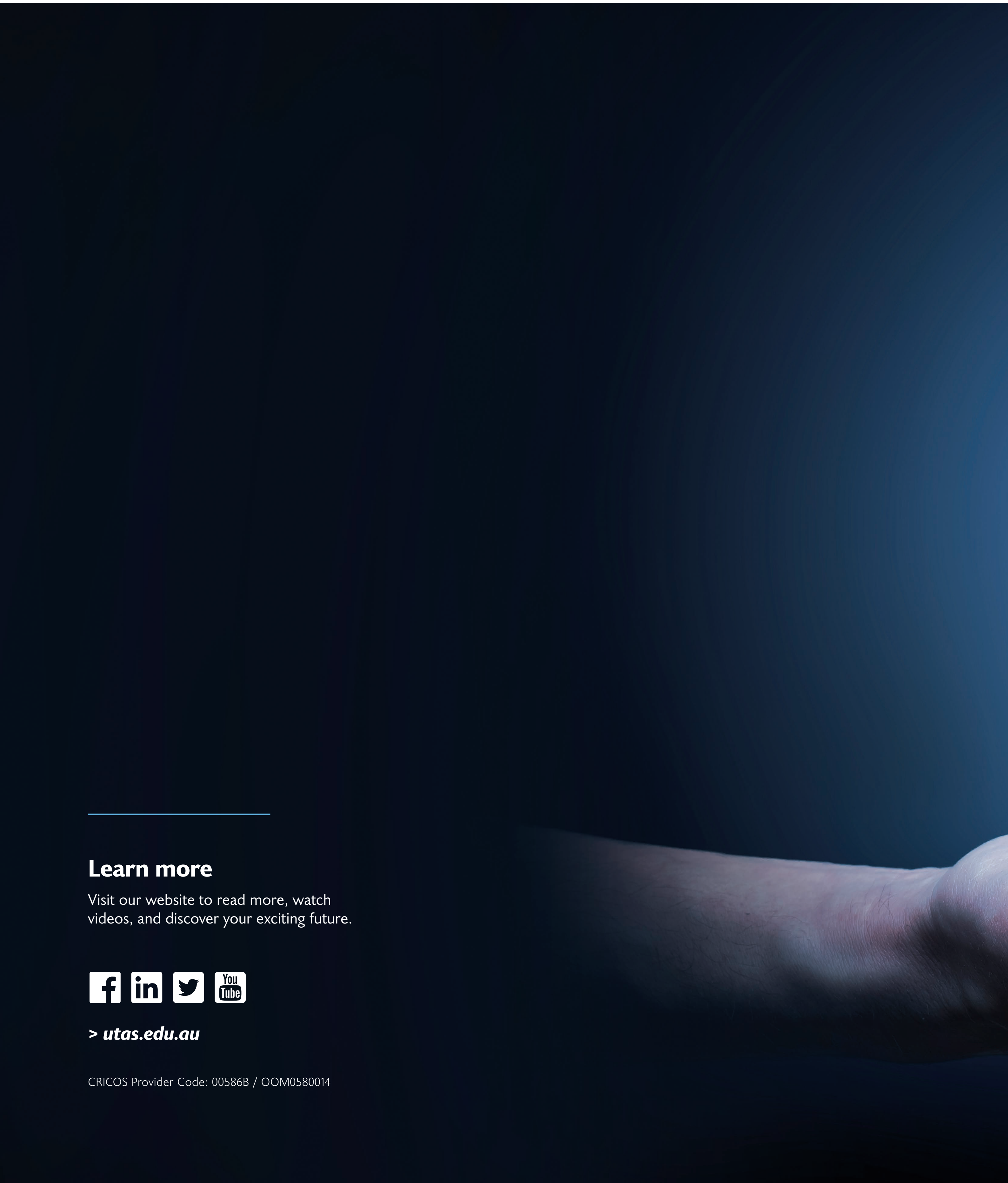

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