

Centre for Law and Genetics

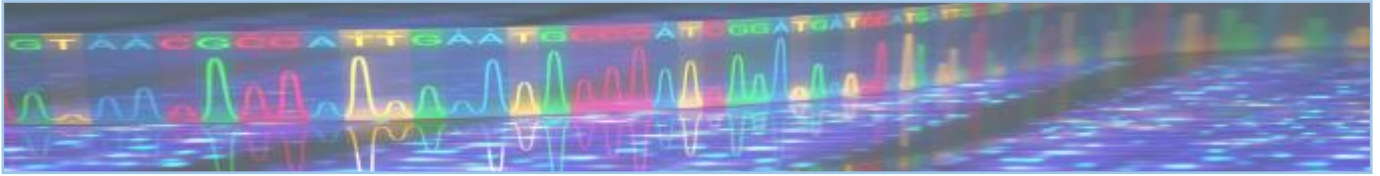
Report 2016-2017



UNIVERSITY of
TASMANIA

Centre for Law and Genetics





From the Director



Highlights

- *Hosted two international workshops on material transfer agreements and genome editing in November 2016*
- *Made submissions to reviews by the NHMRC, Office of the Gene Technology Regulator and World Health Organisation and provided feedback on the draft National Genomics Framework*
- *Nicol appointed to the Gene Technology Ethics and Community Consultative Committee and an expert group of the Food Standards Australia New Zealand*
- *Received funding from IP Australia to analyse patents and diagnostic testing*
- *Continued publication in high ranking journals and applied for funding for a number of projects*
- *4 new PhD candidates enrolled*
- *1 PhD completion – appointed as Law Lecturer at Auckland University of Technology*
- *1 honours student awarded first place in international essay competition.*

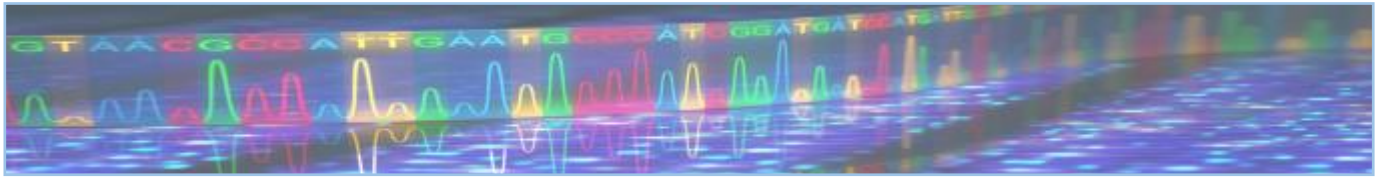
I continue to be proud of the efforts of the research team at the Centre for Law and Genetics (CLG). 2016-2017 saw our team expand to 17 (nine core staff, eight postgraduates).

This year marks another excellent period in the development of the Centre, with a good publication record, expansion of our postgraduate cohort and development of new research initiatives. We have also renewed a number of our existing research partnerships and expanded our collaborative networks, particularly through the two workshops we hosted in November 2016, bringing together colleagues from around the world. We have likewise been invited to attend various workshops and conferences.

I am pleased to report that we have submitted funding applications to the two major government grants bodies, the Australian Research Council and the National Health and Medical Research Council. We have also explored other funding sources, including smaller grants schemes and contract research. CLG members have also been named collaborators on other funding applications, including a successful bid for funding from the Queensland Genomics Health Alliance. The University of Tasmania has generously provided strategic funding to assist us in our research endeavours.

Our students continue to impress, with most presenting at national and international conferences and many publishing with us. CLG researchers are committed to preparing the next generation of law academics and professionals, and providing graduates with sound basis and skills for successful academic and other careers. We particularly congratulate our recent PhD Graduate Moshood Abdussalam on his completion and appointment as a Law Lecturer at Auckland University of Technology, Auckland, New Zealand.





CLG workshops

The CLG has, from its formation in 1994, been involved in foresighting and formulation of legal, ethical and regulatory responses to developments in the genomic sciences. In maintaining its commitment to facilitating the beneficial developments of genomic research, the CLG hosted two special workshops in 2016. One contemplated the state of material transfer agreements which are aimed to facilitate the transfer of materials amongst researchers. The other was in response to the emergence of new genome editing techniques. Both workshops brought international experts from the fields of science, medicine, ethics, social science, law and policy to discuss the way forward.

Genome editing

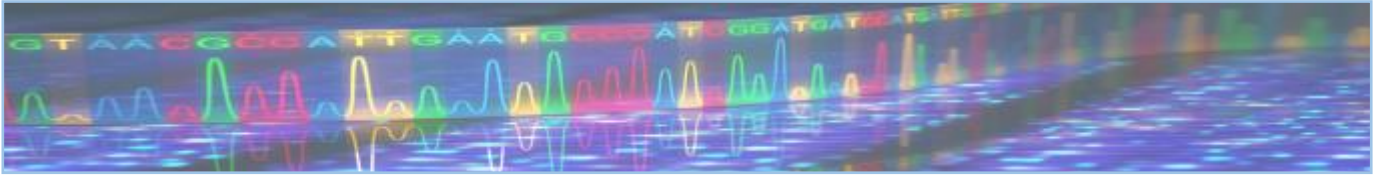
There have been significant developments in genome editing technology over the past few years, particularly the new 'CRISPR' technology, which significantly increases safety and efficacy. Therapeutic applications of CRISPR are becoming a reality, and germline applications are also on the horizon, raising concerns about ethical, legal and social implications. While much of the academic and popular commentary focuses on concerns about germline applications, workshop participants argued that attention also needs to be paid to the more immediate issues associated with bringing somatic cell gene editing into the clinic. Although existing regulatory and ethical obligations will apply, there are many uncertainties as to **how** they will apply. This could result in inconsistent outcomes and uncertainty for innovators and commercial partners. Workshop participants called for greater clarity in these regulatory requirements.



Material transfer agreements

Most exchanges of biological and other materials tend to occur through formalised contractual material transfer agreements (MTAs), whether for research, clinical or commercial purposes. There are growing concerns that MTAs could interfere with the progress of biological research, not only because of restrictive terms but also the time taken to negotiate what are often far too complex agreements. The collective experience of workshop participants led us to conclude that: (a) the main purpose of material transfers is to facilitate research; (b) the main purpose of *formalised* MTAs should be simply to establish provenance, the pathway that the material takes from its point of origin; and (c) the core problem that interferes with achievement of (a) and (b), is unnecessary risk aversion. This can be avoided if those involved in material transfers keep true to their purpose, noting that different considerations apply in commercial and clinical contexts.





New research directions

Genomic data sharing

Widespread genomic data sharing (GDS) is becoming an essential component of clinical and research practice. There is already evidence of this new wave of genomic data improving clinical care, with precision medicine offering targeted treatments tailored to the individual patient's genetic characteristics and medical history. Regulatory frameworks designed to protect the public could potentially constrain GDS. This project will map the legal and quasi-legal facilitators and barriers to globalised GDS, and to assess the role of these elements in promoting public trust.

Bringing innovative technologies to the clinic

It is now possible to manipulate the human body in ways that were previously the province of science fiction. The law should play a key role in ensuring that the entry of innovative personalised technologies into the clinic is regulated in ways that are responsive to societal values and needs, ensuring safety, effectiveness, access, affordability, allocative efficiency and fairness. It is not clear that the law is currently meeting this challenge. This project will examine whether Australia can improve the way it regulates clinical translation of these innovative, personalised health technologies, focusing on genome editing, bioprinting and complementary diagnostics.



Clinical trials safety

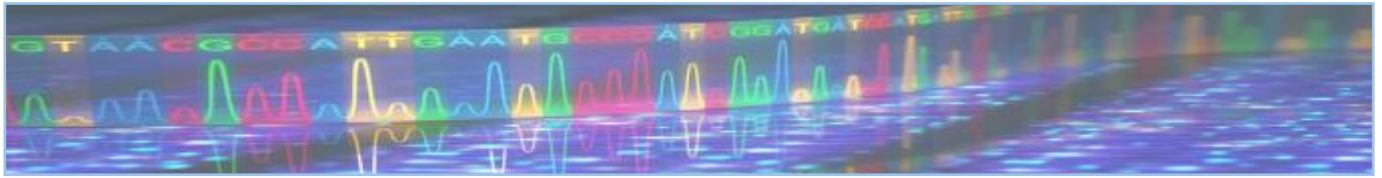
Clinical trials are essential to ensuring that patients receive safe and effective medical care, yet trials of new products and devices can pose risks to research participants. In Australia, frameworks are in place to ensure that research only proceeds where its benefits outweigh any risks. Research involving humans is reviewed at its inception by Human Research Ethics Committees in accordance with NHMRC guidelines, and Data and Safety Monitoring Boards are often established to assess emerging safety or efficacy issues. Little is known about how effectively these processes are functioning and how they may be improved.



Implications of patents on diagnosing testing

There have been widespread concerns for many years that patents over foundational technologies like gene sequences and diagnostic methods could impact on the cost of diagnostic testing. Notably, in 2015, the High Court decided in *D'Arcy v Myriad Genetics Inc* to invalidate patent claims to isolated gene sequences. Our research to date indicates the impact of *D'Arcy* on the cost of testing will be minimal because there is little evidence of enforcement of relevant patents and rapid technological changes like next generation sequencing have a more profound impact. However, the impact of method patents is still unclear and our research is continuing.





Expanding horizons

- Building on a previous international project on privacy with Professor Knoppers, McGill University, Canada, and Professor Mark Rothstein, University of Louisville, USA, the CLG is participating in an application to study the regulation of international direct-to-participant research and ethics approval.
- Existing CLG links with Japanese researchers are being further consolidated with new projects on ageing, exploring legal measures to support the elderly in super-ageing societies and elders' decision-making in medicine and care with colleagues at Tokyo and Sophia Universities.
- Building on previous collaborations in genetic eye disease research with Professor David Mackey and his team, CLG members are involved with the NHMRC Centre for Research Excellence, 'From discovery to therapy in genetic eye diseases' led by Professor Mackey as Chief Investigator and as member of the Scientific Advisory Committee.
- The CLG has been invited to join the GEMINI Consortium for genomics research in Africa (GEnomic Medicine & Integrated Health Research Network Initiative for Africa), a project with other local and international partners.
- CLG members are working with long-term colleague Professor Jane Kaye, who has recently taken up a position at Melbourne Law School, to develop a new project on adaptive governance of innovative health technologies. The project will include a workshop at the Brocher Foundation in Switzerland in 2018. Collaborative funding opportunities are also being explored.



CLG Presentation Locations 2016-2017



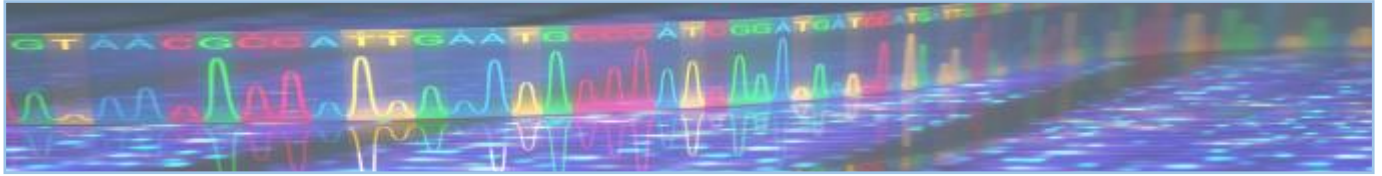
Outcomes and projects coming to a close

Consent project – Drs McWhirter and Eckstein This project developed an innovative tool to gain informed consent from research participants. The code for this tool is available on request.

3D Printing project – Dr Nielsen and Prof Nicol Dr Nielsen led this project, focusing on bio-applications of 3d printing. Their research continues, with Nielsen and PhD Candidates continuing their work through collaborative works with ACES (based at *University of Wollongong*).

TasBioGrid/ReD Tiger – CLG The CLG has been involved in a collaborative project with Menzies to establish a biorepository since 2015, and has been researching the ELSI of biobanking for almost two decades, dating back to an NHMRC program grant. This collaborative project has now been selected as a Menzies Flagship project and the University is progressing its development.





HDR updates – New students

Olumayowa Adesanya



Olumayowa Adesanya joined the Centre for Law and Genetics late 2016 when she commenced her PhD at UTAS. She is conducting her thesis: *Patenting Bioprinting - An Ethical Dilemma in the Provision of Accessible Health Technologies* under the supervision of Professor Nicol and Dr Nielsen. She hopes that in the absence of regulations on bioprinting currently, her thesis will provide a useful guideline for the formulation of policies and regulations in the field especially as it relates to patents.

Diana Girle



Diana Girle has been a part-time PhD student at the Centre for Law and Genetics since late July 2016. The working title of her topic is *Exploring the boundaries of privacy and related informational controls of data collected by personal fitness devices*. Diana is exploring the extent to which current legislation, such as the *Privacy Act 1988 (Aust)* and the *Australian Privacy Principles* are relevant in the era of Big Data collected from personal fitness devices and other sources and data-mined to produce health-related information. Diana's supervisors are Professor Chalmers, Professor Otlowski and Dr Eckstein.

Jürgen Gnoinski



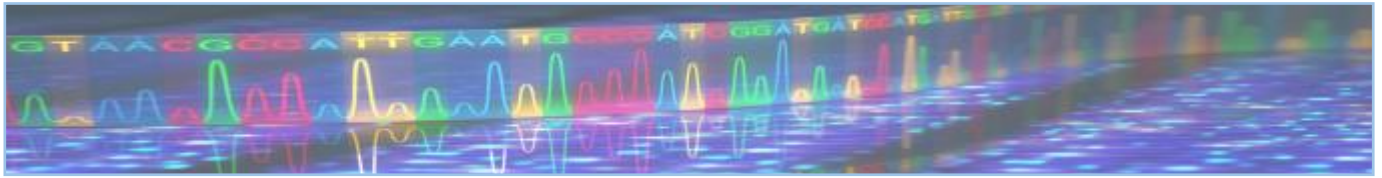
Jürgen Gnoinski joined the CGL in the early July 2016 to undertake a PhD under the supervision of Professor Nicol and Dr Nielsen. The title of this thesis is *Australian Designs Law and Virtual Designs*. His research is an in-depth analysis of the designs law and copyright, patent and trade mark approaches 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.

Olugbenga Olatunji



Olugbenga Olatunji commenced his PhD candidature with the CLG in December 2016. His research examines how the six partner states of the East African Community (EAC) can deploy the WTO TRIPS flexibilities to solve the patent access conundrum within the Community. Beyond relying on compulsory licensing and parallel importation, both of which are currently threatened by free trade agreements, he advocates particularly for the use of TRIPS flexibilities to build a viable local pharmaceutical manufacturing capacity within the EAC. He conducts this research under the supervision of Professor Nicol and Associate Professor Forrest. He had previously obtained an LLM degree in International Law from the University of Cambridge and a WIPO-sponsored Master of Intellectual Property (MIP) degree from the Africa University, Zimbabwe.

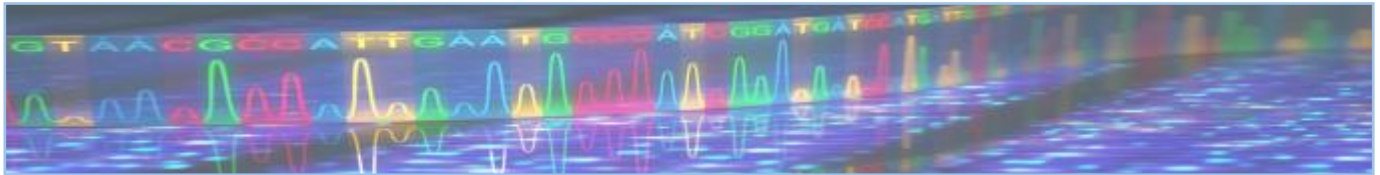




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