Human Research Ethics Committee Conference

5th National HREC Conference

27 - 29 November 2024

V4 November 2024

Brought to you by: Health Translation Queensland

Sponsored by: SalingerPrivacy a helios business; Bellberry Limited supporting research and ethics; PRAXIS AUSTRALIA Promoting Ethics and Education in Research

Contents

Foreword

Dear Friends, Colleagues and attendees

This is the 5th National HREC Conference that originally sprung from a need to provide information and opportunity for discussion to a community that had largely been starved of this opportunity. From humble beginnings in 2020 (Yr1), with 600 registrants, last year (Yr4) we topped 1800, demonstrating that this conference filled a niche which was not able to be filled by any other means. Still free and online, we hope that this year we can top the 2000 registrant mark and provide a source of information and resources for the around 200 HRECs in Australia.

Personally, I feel that last year was the best conference so far due to the variety and quality of presentations. I believe that this will be surpassed this year because of the focus on topics that are practically relevant to HRECs. We have managed to accommodate all the abstracts and have a significant focus on practical strategies for HRECs, Consumer engagement, Use of data and artificial intelligence in research. Let history and feedback be the judge rather than one slightly biased observer.

We are delighted to have 3 fascinating plenary talks this year: Amir Mehrkar (UK) talking about using data from 10s of thousands of UK research participants; A/Prof Niushia Shafiabady providing insight into the use of AI and the ethical implications; and A/Prof Mandy Downing providing lived experience of the importance of positionality in research involving Indigenous People and Indigenous Research in general. These, I'm sure will stimulate and provoke thoughts and discussion around how we in Australia can guide researchers with the aim of producing the best research.

Once again, we will have a workshop on privacy and use of data, provided by Andrea Calleia, which has become a staple of this meeting. In addition, there will be a separate HREC Chairs meeting organised on the last day of the conference.

I am grateful to the members of the organising committee, listed in this booklet, but especially to Sara Gottliebsen for her enthusiastic approach and unwavering upwards management to ensure that the conference runs smoothly.

We look forward to your attendance and interaction and hope that once again you will experience a broad range of interesting and informative presentations that will assist all HREC members, coordinators and researchers in the never-ending quest for continuous improvement.

Best wishes for the conference

Gordon McGurk PhD, JD, FGIA, GradDipLP, GAICD
Convenor HREC Conference
Chairperson UQ HREC A
Director, OmniAdvisory Consulting

Organising Committee

Gordon McGurk	University of Queensland HREC Chair
Sara Gottliebsen	Health Translation Queensland
Hudson Birden	Townsville Hospital and Health Service HREC
Sophie Gatenby	The Royal Children's Hospital Melbourne
Sara Hubbard	Torres & Cape Hospital and Health Service
Natasha Roberts	University of Queensland
Paula Swatman	Swinburne University of Technology
Nik Zeps	Monash University

Day 1 – Wednesday 27 November 2024

All times in AEST (QLD)

08:30–09:00	**Conference opening**
08:30–08:40	Welcome Gordon McGurk, Conference organiser
08:40–08:50	Acknowledgement of Country Greg Pratt, Central Queensland University
08:50–09:00	Opening remarks Colin Thomson AM, Former Professor in Health Law and Ethics in Graduate Medicine, University of Wollongong
09:00–10:00	**Plenary** *Chairperson: Gordon McGurk*
09:00–09:45	Responsible AI: Challenges and responsibilities Niusha Shafiabady, Australian Catholic University
09:45–10:00	Reimagining ethics pre-review Emma Moloney, University of Tasmania
10:00–10:15	**Break**
10:15–11:45	**Data** *Chairperson: Lynne Woodward*
10:15–10:35	Navigating the rich tapestry of Australian privacy legislation: A survival guide for HRECs and researchers Nik Zeps, Monash University
10:35–10:55	Waivers of consent and how much more cautious HRECs should be Mark Taylor, The University of Melbourne
10:55–11:15	The digital disruption of research Clair Sullivan, The University of Queensland
11:15–11:30	Enhancing clinical data sharing and reuse: Balancing FAIR principles with sensitive data protection Rudolf Schnetler, Townsville Hospital and Health Service
11:30–11:45	Preferences of individuals for future research use of samples and data in the Australian Reproductive Carrier Screening Study (Mackenzie's Mission) Matilda Haas, Australian Genomics
11:45–12:00	**Break**
12:00–13:00	**HREC quality assessment**
12:00–12:30	Quality vs quantity in HREC review in Australia Gordon McGurk, University of Queensland HREC
12:30–13:00	Clinical Research Data Sharing Frameworks: Supporting trustworthy and efficient practices Lisa Eckstein, Clinical Trials: Impact and Quality (CT:IQ)
13:00–13:15	**Break**
13:15–14:30	**Practical strategies session 1** *Chairperson: Tam Nguyen*
13:15–13:30	Empowering human research ethics committee members to review genomics applications: Pilot testing of a custom online educational resource Aideen McInerney-Leo, The University of Queensland

13:30–13:45	Indigenous genomics research: Ethical considerations for HRECs Annalee Stearne, Telethon Kids Institute
13:45–14:00	An ethical evidence-based program supporting researchers to return clinically actionable genomic information to research participants Mary-Anne Young, University of New South Wales
14:00–14:15	A review on the WHO tool for benchmarking ethics oversight of health-related research involving human participants and its potential implications for the Australian context Ehsan Shamsi Gooshki, Monash University
14:15–14:30	Considerations in acquiring ethics approvals for research involving artificial intelligence: Development of a therapist assisted AI powered chatbot to increase gamblers' awareness of risky gambling and overcome barriers to help-seeking Tara Thornhill, Flinders Centre for Gambling Research
14:30–14:45	**Break**
14:45–16:00	**Practical strategies session 2** *Chairperson: Kim Alexander*
14:45–15:00	Practical strategies for safeguarding researchers engaging in sensitive research Renee Fiolet, Deakin University
15:00–15:15	Beyond the form: What types of communication with clinical research participants need ethical review? Gudrun Wells, Clinical Trials: Impact & Quality (CT:IQ)
15:15–15:30	In pursuit of ethical and inclusive research: What ethics committees and disability researchers can learn from each other Megan Walsh & Victoria Stead, Deakin University
15:30–15:45	Lived experience and the HREC review process – Opportunities Penelope McMillan & Brian Beh, AccessCR Pty Ltd
15:45–16:00	Ethical diligence or gatekeeping: The quandary when vulnerable populations are involved Heather Lovatt, Central Queensland University
16:00–16:30	**Plenary** *Chairperson: Gordon McGurk*
16:00-16:30	Ethics review equivalency, or do we *always* need local committee review? Edward Dove, Professor of Law, Maynooth University, Ireland
16:30	**Close**

All times in AEST (QLD)

08:00–09:00	**Plenary** *Chairperson: Gordon McGurk*
08:00–09:00	The entire English nation's (58+ million) patients records for research: How we finally got there! Amir-Reza Mehrkar-Asi, The University of Oxford, United Kingdom
09:00–10:00	**Problem solving for HRECs** *Chairperson: Gordon McGurk*
09:00–10:00	A panel discussion on problem solving for HRECs
10:00–10:30	**Break**
10:30–12:00	**Privacy training** *Chairperson: Gordon McGurk*
10:30–12:00	Privacy essentials for HRECS [This session will not be recorded] Andrea Calleia, Director of Learning, Salinger Privacy (Helios)
12:00–12:30	**Break**
12:30–14:30	**Consumer engagement** *Chairperson: Natasha Roberts / Janelle Bowden*
12:30–12:45	Conducting research with adolescents experiencing marginalisation and vulnerability Jess Heerde, The University of Melbourne
12:45–13:00	More than just the paperwork: Embedding ethical practices into how we engage and work with health consumers in research Adrienne Young, The University of Queensland, will be joined by - Dr Kristiana Ludlow - Ms Mary Denver - Ms Anja Christoffersen
13:00–13:15	*Involve Australia* in an innovative and systematic approach to community involvement in genomic research Keri Finlay, Australian Genomics & Anne McKenzie AM
13:15–13:30	The GenV participant advisory panel: Consumer engagement at scale in a large birth and parent cohort Kate Wyatt, Murdoch Children's Research Institute
13:30–14:30	Consumer engagement panel discussion
14:30–15:00	**Break**
15:00–15:45	**Psychedelic drugs** *Chairperson: Hudson Birden*
15:00–15:30	Psychedelic panel discussion Hudson Birden (Townsville HREC), Ian Tindall (QIMRB HREC) and Paul Gatenby (ACT HREC)
15:30–15:45	The use of psilocybin for prolonged grief Thomas Kennedy, Queensland Institute of Medical Research Berghofer

15:45–15:50	**Break**
15:50–16:50	**Guidelines** *Chairperson: Gordon McGurk*
15:50–16:10	Cultural safety Karl McKenzie, Queensland
16:10–16:30	Challenges of recruiting and sustaining, equitable representation on a Northern Territory ethics committee Hayley Germaine, Northern Territory
16:30–16:50	Human remains, research and Indigenous peoples: A perspective from the Human Remains Committee in Norway Lene Os Johannessen, Norway
16:50-17:00	HREC Accreditation update Conor Brophy
17:00	**Close**

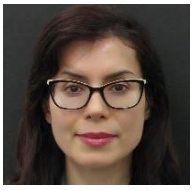
All times in AEST (QLD)

08:00–09:15	**Professionalisation (Concurrent session – Stream 1)** *Chairperson: Hudson Birden*
08:00–08:15	Professionalising the scientific review Melvin Chin, NSW Government - Health, South Eastern Sydney Local Health district
08:15–08:30	Barriers and facilitators to retention in long term paediatric clinical trials Jessie Head-Gray, Murdoch Children's Research Institute
08:30–08:45	Clinical trials (e.g. adaptive platform trials and whether they need new applications as they are modified) Melina Willson & Peta Skeers, The University of Sydney
08:45–09:00	Facilitating up-to-date information on clinical trials: A case for collaboration between ethics committees and the Australian New Zealand Clinical Trials Registry (ANZCTR) Angie Barba, The University of Sydney *(Presented by Ava Grace Tan-Koay and Melina Willson)*
09:00–09:15	What is the national prevalence of statisticians as full members of human research ethics committees in Australia? Adrian Barnett, Queensland University of Technology
	Parallel session
08:30–09:30	**Specific participant groups (Concurrent session – Stream 2)** *Chairperson: Conor Brophy*
08:30–08:45	Geographies of ethics, rural communities and education research: A struggle for ethical research Dipane Hlalele, University of Kwazulu-Natal, South Africa
08:45–09:00	Visual consent tools for participant information and consent in health research with First Nations peoples Mina Kinghorn, The University of Queensland
09:00–09:15	Ethical issues in conducting health research with people in prison: Results of a deliberative research project conducted with people in Australian prisons Paul Simpson, University of New South Wales
09:15–09:30	Ethical barriers and opportunities to facilitate effective involvement of people with a living experience of dementia in research Sarah Jay, Dementia Australia
09:30–10:00	**Plenary** *Chairperson: Gordon McGurk*
09:30–10:00	Positioning positionality [This talk will not be recorded] Mandy Downing, Curtin University
10:00–10:15	**Break**
10:15–12:15	**HREC coordinators** *Chairperson: Sophie Gatenby & Sara Hubbard*
10:15–12:15	A session for all HREC coordinators and administrators
12:15–12:45	**Break**

12:45–14:00	**Consent** *Chairperson: Gordon McGurk*
12:45–13:00	What constitutes ‘informed’ in informed consent Ian Pieper, Chair of The University of Canberra Human Research Ethics Committee
13:00–13:15	Determining decision-making abilities of people with intellectual disability consenting to participate in qualitative research: Moving from substitutes to supporters Rhonda Beggs, Logan and Beaudesert Hospital
13:15–13:30	Inclusive consent practices: Learnings from Generation Victoria Libby Hughes, Murdoch Children's Research Institute
13:30–13:45	Health Information and bundled consent in primary care [This talk will not be recorded] Helen Deuchar, Auckland, New Zealand
13:45	**Closing remarks**

Abstracts & biographies

09:00–09:45	Plenary	Wednesday 27 November



Responsible AI: Challenges and responsibilities

Niusha Shafiabady

Australian Catholic University

Abstract

AI is becoming a big part of our lives. As users of AI algorithms and tools, there are many ethical responsibilities to consider. During this session, we are going to explore AI algorithms and their capabilities in conducting research, the challenges with using AI and AI tools and how to apply the principles of responsible AI to ensure complying with ethical foundations.

Biography

Niusha Shafiabady is an Associate Professor at the Department of Information Technology – Peter Faber Business School at the North Sydney Campus of the Australian Catholic University. She is an internationally recognised expert in the field of Computational Intelligence with many years of professional experience in both academia and industry. She is the inventor of a computational optimisation algorithm and has developed Ai-Labz (https://www.cognobit.com/ai-labz) which is a simple Computational Intelligence predictive analysis tool. She has published many research articles in high-ranking journals, supervised many HDR candidates and is the recipient of several awards and credentials.

She is a Fellow of the Higher Education Academy of the United Kingdom. Her key areas of expertise are design and development of smart algorithms for data analysis and interpretation, prediction of different phenomena, clustering and classification of unorganised data and creating smart decision-making systems for different applications.

09:45–10:00	Plenary	Wednesday 27 November

Reimagining ethics pre-review

Emma Moloney

University of Tasmania

Abstract

Complex changes to national guidelines and the establishment of the ‘grant of exemption pathway’ present challenges to researchers applying for ethics approval. This has led to increased traffic of enquiries and triaging difficulties for our unit when conducting a pre-review. We have developed an interactive Decision Support Tool. The tool provides a recommendation for the type of ethics application required, the associated review pathway and links to essential resources, thus supporting researchers to navigate the ethics application process. The tool has transformed the ethics pre-review conducted by our unit. Firstly, we applied our university ethics review framework, alongside guidance from the National Statement to develop a dynamic flow-chart. This served as the background branching logic for the tool, that we then built using H5P software. We partnered with university leadership and ethics

experts to co-design the tool. Implementation of the tool reduces administrative burden and creates efficiencies in the unit.
The tool empowers researchers to make assured decisions, supported by useful resources. This has led to improved quality of applications and faster review times. This process also helped to bridge a gap in understanding the importance of research ethics and has led to a cultural shift in the university. Although a very effective mechanism, due to the complexity of research and the risk continuum, the tool does not cater to every scenario and cannot entirely replace the need for experienced and highly qualified ethics officers to conduct a pre-review. The tool is complimentary to the pivotal role of ethics staff and aims to free up their time to focus on important critical thinking and moral reasoning. It is our hope that the Decision Support Tool may lead the way for other institutions to adopt a similar concept and reimagine the ethics pre-review process.

Biography

Emma is a research ethics subject matter expert at the University of Tasmania. Emma provides support to the Human Research Ethics Committee and Chairs, as well as to the Tasmanian research community. Most recently, Emma has developed a toolkit to help researchers navigate the ethics process and to improve knowledge regarding conducting ethical research. Emma is dedicated to continuous improvement and currently works with the Research Management Platform team to re-design ethics application forms and management systems. She strives to make a difference to the sector more broadly through her work as a committee member with the Australasian Research Management Society Tasmania Chapter. With over 7 years of experience as a clinical trials coordinator, Emma has worked on a variety of national medical research projects spanning across oncology, cardiology, lymphatic diseases, and dementia.

10:15–10:35	Data	Wednesday 27 November

Navigating the rich tapestry of Australian privacy legislation: A survival guide for HRECs and researchers

Nik Zeps

Monash University, Melbourne

Abstract

In this talk Nik Zepps will summarise how the various pieces of legislation are being used for differing types of research, how they align and where there are important variances. Nik will illustrate with examples on how this can create confusion but is ultimately soluble.

Biography

A cancer biologist by background Nik has most recently led national initiatives to develop and implement research infrastructure, policy and practice. He has been an expert advisor to the TGA, served on the Research Committee and Australian Health Ethics Committee of the NHMRC and serves on national and international advisory boards across a diverse range of clinical trials and biomedical research activities. His expertise includes a deep practical knowledge of conducting research in health services and a demonstrated capability of implementing functional change in organisations that improve productivity through positive and sustainable cultural change.

Nik retains an academic role through the Eastern Health Clinical School of Monash

University where he is an adjunct Professor and a Clinical Research Lead of Monash Partners through engagement with Chrysalis. He is a current Chief Investigator on grants of over $5 million and still co-supervises postgraduate students and publishes academic papers.

10:35–10:55	Data	Wednesday 27 November

Waivers of consent and how much more cautious HRECs should be

Mark Taylor

The University of Melbourne

Biography

Mark Taylor is Associate Professor in Health Law and Regulation at Melbourne Law School and Director of the research group HeLEX at the University of Melbourne. HeLEX focuses on the legal and regulatory frameworks governing new health technologies. Mark's own research considers the regulation of personal information with emphasis on health and genetic data. He seeks to challenge the idea that privacy interests are necessarily antithetical to the public interest and to develop a concept of privacy that is capable of reconciling individual and community (privacy) interests with a broader (public) interest in access, use and management of personal health information. Mark was awarded a mid-career Fellowship of the British Academy and authored the book Genetic Data and the Law (CUP, 2012). He is recognised internationally as an authority on health data governance and was a member of the drafting group for the OECD Recommendation on Health Data Governance.

10:55–11:15	Data	Wednesday 27 November

The digital disruption of research

Clair Sullivan

The University of Queensland

Abstract

The integration of real-world data (RWD) in health care research has significantly advanced the field, offering comprehensive insights beyond clinical trials. Sourced from electronic health records, wearable devices, and patient registries, RWD drives innovation and improves patient outcomes.

Professor Clair Sullivan will highlight the pioneering efforts of the Queensland Digital Health Centre (QDHeC) at The University of Queensland. QDHeC's work includes cutting-edge projects such as the National Infrastructure for Federated Learning in Digital Health (NINA), the Digital Infrastructure for Improving First Nations Maternal and Child Health (DIFFERENCE), and the National Infrastructure for Real-Time Clinical AI Trials (NASCENT), which leverage advanced machine learning and data integration to enhance health outcomes while maintaining data privacy. Additionally, QDHeC's SMART Hub centralises data extraction from Queensland Health's integrated electronic Medical Record system, empowering researchers with secure and efficient access to vast health care data.

Biography

Professor Clair Sullivan is an internationally recognised leading practising and academic clinical informatician and is helping drive digital health transformation in

Queensland. Clair is Director of UQ's Queensland Digital Health Centre, a collaboration across UQ and major Australian and international partners. She is a Consultant Endocrinologist at Metro North Hospital and Health Service. Clair serves on several national advisory boards for digital health and has generated $66 million in funding. Clair is widely published in clinical informatics and is ranked in the top 1% of Medical Informatics researchers globally. In 2024, Clair was appointed as the inaugural Professor of Digital Health at the University of Queensland. Clair's work has been recognised with multiple honours including a 2022 Telstra Brilliant Women in Digital Award. She chairs the Australian Council of Senior Academic Leaders in Digital Health.

11:15–11:30	Data	Wednesday 27 November

Enhancing clinical data sharing and reuse: Balancing FAIR principles with sensitive data protection

Rudolf Schnetler

Townsville Hospital and Health Service

Abstract

In recent years, the Australian Government has taken a decisive step towards enhancing the accessibility and sharing of research data by emulating the initiatives of European and North American counterparts. This strategic direction has been recognised as a priority at the national level, with considerable investments being directed towards the development of infrastructure, data analytics, and data linkage capabilities. Notably, the Australian Research Data Commons (ARDC) has played a pivotal role in providing researchers with essential services, procedures, and tools required for implementing the FAIR principles (Findable, Accessible, Interoperable, Reusable) on clinical data. Furthermore, national and state government bodies have established open data policies to enable researchers navigate data sharing and reuse. However, despite these advancements, growing privacy concerns have led to a significant challenge: research datasets commonly remain unavailable outside of their institutions, making it difficult to fully implement FAIR principles for clinical data. There is a clear conflict between the imperative to safeguard sensitive information objectives of open science to generate clinical data that conforms to the FAIR principles. To address the tension between FAIR principles and sensitive data protection, the presentation will explore prevalent common data models, with a particular emphasis on the OMOP (Observational Medical Outcomes Partnership) model. We will discuss how common data models, such as OMOP, can promote data interoperability, reusability and addressing alleviate the administrative and technical complexities involved in anonymising data. By showcasing these models, we aim to demonstrate potential pathways for balancing the implementation of FAIR principles with the crucial need to safeguard sensitive clinical information.
Lastly, we will explore key ethical considerations surrounding research datasets, focusing on privacy concerns and promoting data sharing. We will provide contemporary approaches for researchers and institutions to meet a balance between privacy and FAIR datasets.

Biography

Rudolf J Schnetler is currently the Research Data Laboratory Lead at the Townsville Hospital and Health Service, where he focuses on empowering researchers to utilise large datasets for innovative health research. In 2022, Rudolf founded the Research Data Laboratory with the aim of driving research outcomes by providing researchers access to clean, accessible, and curated data within a secure environment. As the Data Laboratory Lead, he oversees data governance for research activities,

manages secure research environments, and assists researchers with data management and planning. Rudolf's expertise extends to research ethics, where he serves as a Human Research Ethics Committee member at the Townsville Hospital and Health Service. In this capacity, he provides subject matter expert advice on data management, research data ethics and open data sharing.

11:30–11:45	Data	Wednesday 27 November

Preferences of individuals for future research use of samples and data in the Australian Reproductive Genetic Carrier Screening Study (Mackenzie's Mission)

Matilda Haas

Australian Genomics

Abstract

Mackenzie's Mission investigated the feasibility and acceptability of population reproductive carrier screening for severe recessive genetic conditions occurring in childhood. Consent for participation was completed digitally using an online portal or REDCap. Consent included an option to complete questions about preferences for future research use of samples and data, based on the Global Alliance for Genomics in Health's Data Use Ontology (DUO) standard. These questions had already been implemented in the CTRL dynamic consent platform in a previous rare disease cohort study.

The aim of this research was to apply the same questions to a population cohort which included 9,106 couples (18,212 individuals). Preferences for future research were completed by 23.5% (4,288) of individuals in Mackenzie's Mission. The remaining 76.5% gave broad consent to data sharing. Those who chose to complete the questions shared similar demographics to the rest of the cohort, except they were in a younger age category (25-29). Individuals were most permissive of sharing with not-for-profit (78.0%) and university (78.2%) research organisations, for general (79.8%) and health/medical/biomedical research (82.2%). People were less likely to consent for use by governments (59.2%) and commercial organisations (33.7%). Nearly 60% of people wanted to be notified every time their data was shared. Updates to consent preferences were made 1,785 times, by 282 people. Updates were mostly made within the initial session, but changes were made up to 3 years after initial consent. Forty-two individuals made changes in the 7 days following carrier screening test result disclosure. An individual who was part of a couple who made a data-related enquiry to the study during the consent process was likely to be more restrictive in their sharing permissions.

This study builds upon our research about participant preferences for use of their data. While most people agreed to broad consent for data sharing, almost a quarter of participants were motivated to make future research data sharing decisions and made changes to preferences over time. This supports the need for research programs to facilitate flexible models of consent, including granular and dynamic consent. It also shows that an internationally developed ontology for data sharing can be implemented as participant-led choices in health genomics research, removing ambiguity about data sharing permissions.

Biography

Dr Matilda Haas is the Research Projects and Partnerships Manager with Australian Genomics, an organisation supporting research and progressing policy priorities

across health genomics. In recent years she has published in the areas of health policy, bioethics, and patient experience research. Matilda is committed to exploring ways to improve patient consent processes for genomic testing. Consent for secondary use of data is an important part of this and Matilda has led the adoption of international standards for data use and has been a member of the Australian Genomics Data Access Committee since its inception.

12:00–12:30	Quality vs quantity	Wednesday 27 November

Quality vs quantity in HREC review in Australia

Gordon McGurk

University of Queensland HREC Chair

Abstract

Australia currently has around 200 HRECs registered by the NHMRC. Despite accreditation and certification schemes and draft quality standards, no consideration of the quality of review exists. How do we engender this? Is it time for less HRECs and more quality?

12:30–13:00	Practical Strategies – session 1	Wednesday 27 November

Clinical Research Data Sharing Frameworks: Supporting trustworthy and efficient practices

Lisa Eckstein

Clinical Trials: Impact and Quality

Abstract

Authorising waivers of consent for the sharing of research information are one of the most legally and ethically consequential decisions made by Australian HRECs. In granting a waiver, HRECs are required to consider specific criteria set out in the *National Statement on Ethical Conduct in Human Research* (2023). Additional criteria apply to the sharing of personal information without consent under Commonwealth, and some state and territory privacy laws. Notably, the release of personal information by a Commonwealth agency or organisation without an (adequate) HREC authorisation would constitute a breach of the *Privacy Act 1988* (Cth), potentially subject to remedies.

Despite these legal and ethical complexities, secondary sharing of research data offers compelling benefits for health and medical research. These include facilitating accurate reporting of trial results, accelerating scientific discovery, and allowing answers to scientific questions unanswerable from individual studies.[1] How to best balance these benefits with individual privacy protections poses an ongoing challenge to the Australian medical research ecosystem, with HRECs being a key component of this regulatory balancing act.

The Australian Research Data Commons (ARDC) is partnering with CT:IQ to develop a governance framework for clinical research data sharing. The project will provide informational resources on the legal and ethical aspects of data sharing to support secondary use of clinical research data. The project includes a bench-marking activity with Australian HRECs to assess their current practices regarding secondary sharing of clinical research data.

The proposed panel will comprise members of this project team. The panel will provide an opportunity for project team members to:

- share early project findings with the Australian HREC community
- poll attendees on their informational needs to feed into resource development decisions
- inform attendees and answer any questions about the HREC benchmarking exercise.

[1] Michelle M. Mello, Van Lieou, and Steven N. Goodman, 'Clinical Trial Participants' Views of the Risks and Benefits of Data Sharing', *New England Journal of Medicine* 378, no. 23 (7 June 2018): 2202–11, https://doi.org/10.1056/NEJMsa1713258

Biography

Dr Lisa Eckstein is the Program Director at CT:IQ and is a Senior Lecturer in Law and Medicine/Health Law in the Faculty of Law in the College of Arts, Law and Education, University of Tasmania. Her area of specialisation is ethical and legal issues associated with medical research, with a focus on clinical trials and innovative technology. With national and international colleagues, she is researching how clinical trials and other forms of research should be governed, including the role of HRECs and Data and Safety Monitoring Boards.

13:15–13:30 | **Practical Strategies – session 1** | **Wednesday 27 November**

Empowering human research ethics committee members to review genomics applications: Pilot testing of a custom online educational resource

Aideen McInerney-Leo
The University of Queensland

Abstract

Background: There has been an exponential expansion in the complexity and utilisation of genomic technologies in research. However, HREC members have reportedly low confidence in reviewing genomics applications.

Aim: To develop and evaluate an online educational resource comprehensible by both non-scientific and scientific HREC members, capturing education on genomics and the ethical, social and legal implications of genomic research.
Methods: We developed an online resource in accordance with the Program Logic Model for Genomics Education Interventions and guided by adult online learning principles. This pilot-test is the first step of a multi-staged evaluation, grounded in the Kirpatrick Model. Qualitative semi-structured interviews with HREC members/experts elicited feedback regarding utility, impact on confidence, and suggestions for refinement. Transcribed interviews were analysed using deductive content analysis.

Results: 29 participants (27 HREC members and 2 genomics experts) reported that the resource was easy to access and intuitive to navigate. Most found the content comprehensive, appropriately pitched, with a manageable/optimal quantity of information. Key recommendations included a progress bar, completion certificate, active learning elements, more clearly visible navigation menu, and more detail regarding data storage and community risk. HREC members perceived improved genomic confidence and reported intentions to re-access the resource in the future. Almost all participants would recommend this resource to other HREC members,

with some suggesting its additional utility for genomic researchers developing ethically-defensible plans.

Conclusion: This is the first study to develop and evaluate a genomic education resource tailored to Australian HREC members. Participants reported that the resource was easy to navigate, and the nature and volume of content was appropriate and useful in practice. Results will inform resource refinement prior to quantitative evaluation by HRECs nationally.

Biography

Aideen McInerney-Leo is a clinician-academic whose interactions with patients have shaped her research questions and fuelled her enthusiasm for the importance of clinical research. She trained as a genetic counsellor and her research now focuses on the integration of genomics into clinical care. Aideen's research program has had 3 primary themes: evaluating the psychosocial impact of genetic conditions and/or genetic testing; evaluating genetics education preferences for patients and health care providers; and using next-generation sequencing to increase diagnostic yield for rare disorders.

13:30–13:45 | **Practical Strategies - session 1** | **Wednesday 27 November**

Indigenous genomics research: Ethical considerations for HRECs

Annalee Stearne
Telethon Kids Institute

Abstract

Genetics and genomic science research are rapidly increasing. While the human genome has been mapped, the full extent of the diversity of the world's population is yet to be identified. The application of these data for genome wide association studies (GWAS) highlights the absence of minority population groups, which raises several considerations, especially when the potential benefits for improved health outcomes are considered.

Understandably, Indigenous peoples globally have approached involvement and inclusion in genomic related research with caution. However, the potential benefits of genomic research for the health and wellbeing of Indigenous Peoples, including First Nations Australians, is significant. Indigenous researchers and communities have recognised the importance of Indigenous leadership and sovereignty over the use, management and application of genomics research.
The aim of this presentation is to discuss some of the additional complexities that HRECs need to consider when considering genomics research that includes First Nations Australians' data (intentionally and incidentally). These include:

- importance of Indigenous self-determination in research and how this principle is executed through Indigenous data sovereignty and Indigenous data governance
- complexities of consent
- potential harms of the research being greater than the benefit to the individual.

Importantly, this presentation will discuss how HRECs can prepare and upskill in preparation for Indigenous genomics research, and what international guidelines and supports are available for the review and assessment of such research.

Biography

Annalee Stearne, a Wardandi-Nyoongar woman living on Whadjuk-Nyoongar country (Perth, Western Australia). She is presently the Operations Manager for the Australian Alliance for Indigenous Genomics. Annalee has a background in education and public health research focusing on Aboriginal-led alcohol and other drug interventions and related policy issues. She has extensive experience in both the tertiary research sector as a researcher, as well as with Aboriginal community-controlled organisations. She serves on the Curtin University Human Research Ethics Committee, as well as several advisory committees and boards. Annalee has a passion for ensuring Indigenous Australian leadership in the efforts towards improving their health and wellbeing.

13:45–14:00	Practical Strategies - session 1	Wednesday 27 November

An ethical, evidence-based program supporting researchers to return clinically actionable genomic information to research participants

Mary-Anne Young

University of New South Wales

Abstract

Increased use of genomic sequencing in research generates large volumes of data, including clinically actionable genomic information. This clinically actionable genomic information can inform research participants of disease risks they are not otherwise aware of and enable action to improve their health. These benefits also extend to their family and can ultimately reduce disease morbidity/mortality in the community. Research indicates that research participants want to be notified of this information, given the potential benefits for themselves and their family members. Researchers also support return of clinically actionable genomic information to participants, although often do not have the expertise, resources or pathways to facilitate return of results.

The National Statement on Ethical Conduct in Human Research provides high level guidance for researchers. However, it does not provide information regarding return of results pathways that address the needs of research participants. These pathways, from the way research participants are notified of the information through to result disclosure and subsequent referral for ongoing care, can influence uptake and use of the information.

My Research Results (MyRR) was developed in response to the identified need for an ethical, practical pathway to return research results. MyRR is led by genetic counsellors who facilitate the return of clinically actionable genomic information to adult research participants or their next of kin Australia-wide. The MyRR return of results pathway is evidence-based, flexible, collaborative, client centred and supports research participants to make an informed choice about receiving/not receiving results.

This presentation will outline the novel centralised program, My Research Results, including the role of genetic counsellors in supporting HREC Committees, researchers and research participants through planning, notification, result disclosure and subsequent ongoing management.

Biography

Mary-Anne Young is a recognised leader in genomic health in Australasia with advanced clinical and research genetic counselling expertise. Her research

contributes evidence on patient experiences of new genomic technologies and translation of genomics into clinical care.

She has established a national genetic counselling led platform at the Garvan in Australia supporting researchers and facilitating the return of genomic research results to research participants. Her research examines research participants response and adaptation to unexpected genomic information.

14:00–14:15	Practical Strategies - session 1	Wednesday 27 November

A review on the WHO tool for benchmarking ethics oversight of health-related research involving human participants and its potential implications for the Australian context

Eshan Shamsi Gooshki
Monash University, Melbourne

Abstract

The WHO, as the leading international agency for global health within the United Nations (UN) system, has been striving to enhance ethical standards in biomedical research, one of the core pillars of its mandate. In 2011, WHO introduced the first set of standards titled 'Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants' aimed at providing guidance to research ethics committees and researchers. Recognising the importance of regulating medical products, WHO has also developed the Global Benchmarking Tool (GBT) for evaluating national regulatory systems of medical products, with its latest version published in 2021. Clinical trial oversight is a crucial component of this tool. The benchmarking of regulatory systems, referenced in a World Health Assembly resolution, involves a structured and documented process by which WHO Member States can identify and address gaps to achieve regulatory oversight that corresponds to a stable, well-functioning, and integrated regulatory system. HRECs play a key role in clinical trial oversight, making their effective supervision essential for ensuring robust regulatory systems in each country.

This paper introduces the WHO tool for benchmarking ethics oversight of health-related research involving human participants, released by WHO as a joint project of the regulatory and ethics units of the organisation. The tool aims to assist WHO Member States in evaluating their capacity to provide appropriate ethical oversight by identifying strengths and limitations in their laws, organisational structures, policies, and practices of the bodies responsible for research ethics oversight. This tool is designed for use by all entities involved in the ethics oversight of health-related research involving humans, including government agencies, research ethics committees (RECs), and institutions conducting health-related research. Australia, which primarily relies on HRECs for ethical oversight of research, could significantly benefit from this WHO tool, so this paper tries to address some implications of this tool for the Australian human research ethics system.

Biography

Dr Ehsan Shamsi Gooshki embarked on his professional journey upon graduating as a physician in 2005, with a keen interest in medical ethics cultivated during his MD program. His career took a significant turn when he enrolled in a PhD program in medical ethics in 2009. Since then, he has been actively involved in teaching various undergraduate and postgraduate educational programs and conducting extensive research in diverse fields of bioethics, including research ethics and governance. He

has been a featured speaker at numerous national and international workshops and conferences, often delivering keynote addresses.

14:15–14:30	Practical strategies - session 1	Wednesday 27 November

Considerations in acquiring ethics approvals for research involving artificial intelligence: Development of a therapist assisted AI powered chatbot to increase gamblers' awareness of risky gambling and overcome barriers to help-seeking

Tara Thornhill

Flinders Centre for Gambling Research

Abstract

Cognitive behaviour therapy (CBT) is an effective intervention for individuals experiencing gambling disorder, however, help-seeking rates remain low. The challenge is to create opportunities and to intervene earlier in the problem gambling trajectory before gambling disorder has become established or entrenched. Whilst each state and territory have gambling help websites and national and local gambling help phone lines, these are usually accessed when someone seeks information or help when the gambler or significant other is experiencing distress at gambling losses. We believe that AI technology supported by a gambling therapist may offer a 24-hour, anonymous bridge between those engaged in harmful gambling behaviours and triage the level of help they require. Through the successful tendering of 2 research grants from the Department for Human Services totalling more than $120,000, our team is nearing the completion of phase 1 of this project, the co-design and development of the AI assisted bot named 'Gabi' and is about to embark on phase 2. Phase 2 will comprise a randomised control trial (RCT) to answer the research question, 'Does an AI assisted chatbot increase user engagement in CBT homework and subsequent clinical outcomes for individuals receiving CBT for gambling disorder?'. In line with the goals/focus of this conference, this presentation will highlight the unique and varied ethics considerations the team have encountered and had to accommodate in this new and ever developing field of technology, along with international ethics considerations.

Biography

Tara Thornhill is based in South Australia and is a cognitive behavioural therapist, who works at Flinders Psychological Therapy Services, specifically in the Statewide Gambling Therapy Service. She has bachelor degrees in psychology and social work and a Masters in CBT. Tara has a very keen interest in mental health, and particularly enjoys being able to support individuals achieve positive outcomes. As part of her role, Tara is a member of the Southern Adelaide Local Health Network HREC and enjoys learning about the amazing research being done in the state and exploring new technologies that can enhance the patient/client experience.

14:45–15.00	Practical strategies - session 2	Wednesday 27 November

Practical strategies for safeguarding researchers engaging in sensitive research

Dr Renee Fiolet

Deakin University

Abstract

Background: Engaging in research into sensitive areas is essential to understanding and tackling complex societal issues, however, it carries a degree of risk for

researchers doing the work. Working in the fields of violence, mental health, addiction, homicide and paediatric death – or carrying out studies with marginalised peoples – can expose researchers to traumatic content and increase potential to experience secondary stress and/or vicarious trauma.

Methods: This project began with 42 interviews of Australian researchers engaged in sensitive and traumatic research in 2023. During 2024 the research team have engaged in 3 phases of co-design workshops with Australian researchers to establish recommendations and strategies for stakeholder groups (for example, HRECs, funding bodies, and research organisations) to implement in an effort to support researchers undertaking sensitive research.

Findings: The work undertaken in 7 co-design workshops led to the development of recommended strategies, including many that are relevant for HRECs to consider when reviewing applications outlining sensitive or emotional research. This presentation will provide an overview of the strategies suggested for adoption by HRECs. A suggested template for assessing risk and a script HRECs can use to ensure risk mitigation is considered by research teams will be discussed, therefore supporting HRECs to play a vital role in the prevention of secondary stress and/or vicarious trauma in research.

15:00–15:15	Practical strategies - session 2	Wednesday 27 November

Beyond the form: What types of communication with clinical research participants need ethical review?

Gudrun Wells

Clinical Trials: Impact & Quality

Abstract

How effectively research teams and participants communicate during a project and at its end is crucial both to the integrity of the research project and to the participant experience. The CT:IQ/VCCC Alliance Beyond the Form project has investigated how clinical researchers plan to communicate with their research participants, and participants expectations for such communication. Both groups would like to communicate more freely, but research staff are often restricted in what channels and materials they can use to communicate. This in turn can compromise the participant experience, and potentially the completeness of patient reported data collection.

Channels for communication between researchers and participants can be enhanced through setting up flexible communication methods that suit participants' needs (e.g. using SMS text rather than exclusively phone calls or emails), and respecting participants' preferences for the types of information they want. Examples of communication materials include updates about the progress of the study, sharing a participant's individual results, providing opportunities for the participant to understand their health condition, thank you notes, and access to lay summaries of the research findings.

One of the challenges researchers have raised is uncertainty about the ethical review requirements for ongoing communication materials, including which channels and materials require ethical review. While the National Statement requires that all participant facing materials related to recruitment and consent need to be approved

before a trial, the review of communication materials at other stages of the trial (such as updates on study progress and the lay results of the project) is at the discretion of the research team and ethical review bodies.

In this presentation we will provide preliminary results from our project on ongoing communication strategies in Australian clinical research. We go on to discuss the ethical benefits and challenges of communication activities, before setting out a proposal to clarify the role of ethical review bodies in reviewing communication materials.

Biography

Gudrun Wells is a Research Officer with CT:IQ and is the Project Manager for the Beyond the Form project. She has worked as a clinical trial coordinator and senior project manager in clinical research on a range of health conditions, and has also worked in Research Governance, where she focused on simplifying her university's clinical research approval processes. At CT:IQ Gudrun is inspired to make it easier to conduct good clinical research that delivers great results and is respectful of all participants.

15:15–15:30	Practical strategies – session 2	Wednesday 27 November


In pursuit of ethical and inclusive research: What ethics committees and disability researchers can learn from each other

Victoria Stead & Megan Walsh

Deakin University

Abstract

Human research ethics review responds to the very real histories of sometimes harmful and exploitative encounters between researchers and the populations they engage, including people with disabilities. Yet many critiques of ethics committees suggest that the intention to protect people from harm may in fact give rise to harm itself, including through the exclusion of people categorised as 'vulnerable' from research that concerns them. These critiques, which also need to be taken seriously, nonetheless often frame committees and researchers as antagonistically-positioned actors, and principles of inclusion and protection as starkly counter-posed. In this paper we present findings from an innovative collaboration between a former HREC Chair and a team of disability researchers, which has sought to move beyond this reductive and oppositional framing. Together, we reflect on a shared, challenging experience of human research ethics review of a project examining the experiences of adolescents with complex communication needs, in relation to conversations about sexuality. We identify and address 3 key tensions—related to conceptualisations of vulnerability, a priori versus open research methodologies, and the parameters of 'participation'—and propose actionable steps through which committees and researchers, as well as the institutions within which both are based, might more productively work together in shared pursuit of ethical and inclusive research.

Biography

Victoria Stead is Associate Professor in Anthropology in the School of Humanities and Social Sciences. Her own research engages with themes of race, labour, place-making and postcolonialism, with a particular focus on Australia-Pacific relationships. From 2018-2022 Victoria was Chair or Deputy Chair of Deakin's

Human Research Ethics Committee and retains a strong interest in the tensions and possibilities of research ethics both within and outside of institutional contexts.

Megan Walsh is an experienced speech pathologist and a PhD candidate with Deakin University and the CP-Achieve Centre for Research Excellence at the Murdoch Children's Research Institute. She is researching with adolescents with cerebral palsy and complex communication access needs about their experiences of conversations about sexuality. Megan's research is participatory and involves creative, accessible methodologies.

15:30–15:45	Practical strategies – session 2	Wednesday 27 November


Lived experience and the HREC review process – Opportunities

Penelope McMillan & Brian Beh

AccessCR Pty Ltd

Abstract

HRECs perform an important ethical function in ensuring the wellbeing and protection of research participants, that benefit outweighs risk, that information is balanced and communicated objectively, that vulnerable populations are not exploited or inappropriately incentivised to participate. Ensuring the research's target population's views are taken into consideration as part of that review has the potential to help both improve and avoid negative consequences from research.

This session will provide a whistle-stop of examples and reflections from a number of consumer conversations on the potential for 'lived experience' to help HRECs avoid assumptions and enhance their decision-making in areas such as:

- Evaluating benefits vs risk: Understanding those living with a condition may want agency to make their own decisions about acceptable risk in the context of their own health.
- Evaluating protocol mandated activities: Understanding the capacities and accessibility requirements of a given population.
- Evaluating objectives and outcome measures: Do these correlate with what is relevant to or matters to the target population?
- Assessing safety upfront and ongoing: Understanding safety in the context of quality/quantity of life considerations for the target population, and potential for long-term impacts from research participation.
- Communication with trial participants: Understanding the information needs and preferences of the trial participant and their carers/families, throughout and post-study.
- Respect for trial participants: Weighing up reimbursement/compensation in the context of the potential time, caring, work and financial burden of participation (and implications therefore to access and diverse inclusion).
- Recruitment: Understanding how a protocol (eligibility criteria, practical requirements, planned communication) can create barriers or enablers to recruitment.

Further, this session will share ideas on how HRECs can look to incorporate the appropriate lived experience as part of their process.

Biography

Brian A Beh, at the age of 68 sustained a 'significant' left lacunar stroke in April 2016. A management consultant, he retired in 2012 after a long career spanning [in part] 3 decades in Corporate Communications in the Australian Financial Services Industry. During the 90s and early 2000s he became involved in Management Consulting (mergers, acquisitions, and downsizing) and Change Management – a business activity that he is now regarded as one of the pioneers within the Australian corporate environment. His post-stroke activities include his role as a stroke advocate/survivor, sharing his lived experience coupled with his learnings and insights with various groups/stakeholders across the stroke landscape. In December 2021, he was appointed the Inaugural Chair of the Consumer and Community Advisory Group of The George Institute for Global Health in Australia and currently is a consumer representative/investigator on 9 research trials in various aspects of Stroke in Australia and the UK. In 2021, Brian was the award winner in the Stroke Foundation's National Awards in the 'Improving Life After Stroke' category.

Penelope McMillan is a retired psychologist, with extensive volunteer experience as an advocate across ageing, carers, disability, chronic illness, and specifically ME/CFS, where she is spokesperson for ME/CFS Australia. Lived experience has led Penelope into various roles within research teams, from consumer representative through to consumer co-lead, and from benchtop research to systematic reviews and translational research. Penelope has also participated in grant assessment panels, including as an 'expert consumer'. While Penelope has never been a member of a HREC, she has experience of interactions with HRECs, including negotiating HREC requests for changes to study protocols.

15:45–16:00	Practical strategies – session 2	Wednesday 27 November

Ethical diligence or gatekeeping: The quandary when vulnerable populations are involved

Heather Lovatt

Central Queensland University Australia

Abstract

Literature identifies the agency used by survivors of domestic violence when they participate in research. However, HRECs can act as gatekeepers on research into survivors' lived experiences due to their perceived vulnerability. This presentation shares findings from a study of 16 survivors of intimate partner strangulation who participated in interviews about their lived experience. Transcripts were analysed guided by the question 'what factors influence the agency that survivors draw on when making decisions about participating in research interviews?'. The findings revealed 4 processes through which the self-efficacy of participants became apparent – cognitive, motivational, affective and selection processes. All indications are survivors who have left the abusive relationship, and have engaged with support, have the ability to assess their capacity to engage in research and make informed decisions about their research participation. The findings highlight the contested nature of the term 'vulnerability' and the dangers of research committees over-reaching when qualitative interviews with vulnerable populations are involved.

It is important that understandings related to self-efficacy and wellbeing of participants inform research ethics committees. The danger of diminishing the self-efficacy of survivors when ethics committees are overly risk averse can have an unintended and limiting impact on survivors who want their voice heard. This presentation provides considerations for HRECs and insights regarding engagement of lived experience in research.

Biography

Heather Lovatt was appointed Queensland Centre for Domestic and Family Violence Research Director in March 2018, after working at the Centre as a Senior Researcher for several years. Heather's undergraduate degree is in Community Work. With a background of working with community services in the government and non-government sectors in Queensland, Heather has held a diverse range of positions in the practice, program, policy and research realm. Her focus at the Centre is on applied or social impact research, education and training that is practice orientated, and developing tools and resources for the sector responding to gendered violence. Working within, and supported by, a national, dual sector and engaged University (CQUniversity Australia) is a fit for Heather's current role with a tangible intersect between research and practice in regional and remote areas. Ensuring the knowledge and wisdom of those impacted by gendered violence, priority populations and front-line practitioners are included in the development of all our work continues as a priority for Heather in this role.

16:00–16:30	Plenary	Wednesday 27 November

Ethics review equivalency, or do we *always* need local committee review?

Professor Edward Dove

Professor of Law, Maynooth University, Ireland

Abstract

In most countries today, research involving people and/or their identifiable information requires prior approval from an ethics committee, often at each project site where the research takes place. In this talk, I consider whether the current structure of site-specific local ethics review disproportionately burdens most projects, adds little to no benefit or added protection for participants, and reflects a model more fitting of a previous-era scientific paradigm. I propose several alternative ethics review models that could, on the whole, increase consistency and efficiency, and achieve a better balance of research promotion, without any material detrimental effect on the rights, interests, and welfare of participants.

Biography

Edward (Ted) Dove is Professor of Law at the School of Law and Criminology, Maynooth University (having joined the School in July 2024), and an Honorary Professor at Edinburgh Law School. He holds a Bachelor of Arts degree (BA) in Political Science and Civil Law and Common Law degrees (BCL, LLB) from McGill University, a Master of Laws degree (LLM) from Columbia University, and a PhD in Law from the University of Edinburgh. Ted's primary research interests are in the areas of health privacy law, research ethics governance, and medical law.

He is a member of Maynooth University's Social Research Ethics Sub-Committee and the University's Assisting Living and Learning (ALL) Institute.

Ted has been involved as a Co-Investigator of the Horizon Europe-funded project, Challenges and Innovative Changes in Research Ethics Reviews (CHANGER), which aims to promote changes in research ethics reviews that strengthen the capacities of researchers to incorporate ethical judgements in the project design and implementation, and to support research ethics committees to address new challenges posed by new technologies and new research practices.

Currently, Ted is a member of several ethics advisory boards of research projects (funded by Horizon Europe and other research funders) and is an Editor of the journal *International Data Privacy Law*. Ted is also currently an Editorial Board member of the *European Journal of Health Law* and the open access journal *Research Ethics*.

08:00–09:00	Plenary	Thursday 28 November

The entire English nation's (58+ million) patient records for research: How we finally got there!

Amir-Reza Mehrkar-Asi
The University of Oxford, United Kingdom

Abstract
Accessing England's patient records for research: 58 million and counting.

Biography
Amir is a practicing NHS GP with over 10 years of experience in senior leadership roles in health technology, including NHS England and NHS Digital, and internationally within the private sector. Most recently, as interim Chief Medical Officer of NHS Digital, Amir wrote the organisation's clinical informatics governance framework. Amir's digital health career has focused on breaking down clinical data silos for safer care and analytics. He led the development of one of the UK's biggest shared care records, covering 1.9 million patients; co-founded a free educational event (INTEROPSUMMIT) attended by over 300 clinicians and digital health experts; and co-founded INTEROPen, the UK's first interoperability community with over 300 supplier and NHS organisations as members. He also led the creation of the UK's first interoperability data standards to enable information sharing between clinical systems, which aligns with the Secretary of State's Tech Vision on open standards.

Amir's clinical experience spans 2 large surgery partnerships, one inner city and one rural, and later recruited as the lead GP with the task of establishing a new GP surgery on behalf of a community NHS Trust. He is also a founding doctor of an online private GP service, which is now partnering to support NHS practices.

Amir is currently a senior clinical researcher at the University of Oxford, where he has worked, from its inception, on building and scaling a new national secure analytics platform (OpenSAFELY) for electronic health records in the NHS, used to deliver urgent results for the global COVID-19 emergency, working across 58 million patient's pseudonymised primary care records. Amir works on platform design; governance (strategic direction and delivery; security and privacy; dataset acquisition; researcher onboarding); stakeholder engagement; and research (clinical informatics; COVID-19).

10:30–12:00	Privacy training	Thursday 28 November

Privacy essentials for HRECs

Andrea Calleia

Salinger Privacy, Helios

Abstract

To assess research proposals effectively, HRECs must be able to correctly apply the requirements of research exemptions under privacy laws. Join this webinar to understand how to navigate seemingly complex privacy rules, and apply them in a research context. This 1.5 hour webinar by leading privacy trainer Andrea Calleia, Director of Learning with Helios, offers a valuable opportunity for participants who want tips to understand how privacy compliance tests should be applied by HRECs to research proposals.

We will touch on topics such as:

- what privacy means and when it arises in the research context
- how HRECs should be thinking about privacy, and the scope of personal information
- what makes a consent valid, and when it is needed
- HRECs and the research exemption.

Biography

Andrea Calleia, Director of Learning, has extensive experience in the learning and development field, and has specialised in privacy training since 2003 when she managed the privacy education program for the NSW Privacy Commissioner's Office. Since joining Salinger Privacy in 2008, who recently joined Helios in 2024, Andrea has managed their e-learning privacy training program and delivers most of their face-to-face training. She has developed and delivered customised privacy training on behalf of clients including QANTAS, Sage Software, the Office of the Australian Information Commissioner, and PRAXIS Australia.

12:30–12:45	Consumer engagement	Thursday 28 November

Conducting research with adolescents experiencing marginalisation and vulnerability

Jess Heerde

The University of Melbourne, Royal Children's Hospital

Abstract

Globally, most adolescents thrive and achieve good health and wellbeing with high life expectancy ahead of them. However, those who face vulnerability and marginalisation during this period experience numerous health and social inequities that significantly influence their development during adolescence and their future life chances. Marginalisation and vulnerability occur in many different contexts including contact with child protection services due to childhood neglect and abuse, homelessness, involvement with the police, and significant life events such as early pregnancy and parenting, as well as the experience of living with gender and sexual diversity. Research with these different cohorts of adolescents who experience marginalisation and vulnerability is challenging. This stems from research ethics governance, the need to flexibly adapt to the complexity of their needs and contexts, and various structural challenges imposed by the service systems around access to some groups. Yet, research to address marginalisation, vulnerability, and related

inequities and test preventive interventions is critical to inform policy directions. This presentation will explore our collective experience conducting research with adolescents experiencing marginalisation and vulnerability, including recruitment and consent processes, practical strategies for HRECs and processes for consumer engagement and engagement of lived experience.

Biography

Jess Heerde is an Associate Professor and National Health and Medical Research Council Emerging Leadership Fellow at the University of Melbourne. She leads a program of research examining risk and protective factors that define pathways to and out of homelessness, as well as assessing health and mortality following contact with the homelessness service system in Australia.

12:45–13:00	Consumer engagement	Thursday 28 November

More than just the paperwork: Embedding ethical practices into how we engage and work with health consumers in research

Adrienne Young

The University of Queensland

Abstract

The National Statement on Ethical Conduct in Human Research by the NHMRC provides researchers with guidelines as to how to both demonstrate and achieve the values and principles of ethical conduct. The principles include research merit and integrity, justice, beneficence and respect which should all feature in researchers' thinking, planning, conduct, decision-making and interactions with health consumers. If we were to take these principles off the printed page and place them in reality, what does the realisation of these principles and values actually look like in the everyday of recruiting, engaging with and working alongside health consumers?

In this presentation, Adrienne Young and Kristiana Ludlow, both research fellows at the Australian Frailty Network (AFN), will be joined by Mary Denver and Anja Christoffersen, 2 of AFN's consumer contributors, to discuss how the AFN strives to adopt these values and principles of ethical conduct. Adrienne and Kristiana will outline how they seek to involve health consumers with diverse life experiences and from different backgrounds to ensure the achievement of the principles of research merit and integrity, justice and respect. They will present cases of consumer engagement across diverse AFN-led studies, including a clinical trial, a biomedical research project, and co-design projects. These cases will provide practical examples of the different ways that consumers can be involved across the research cycle, and strategies that can be adopted to make the process of consumer engagement accessible.

The AFN's consumer contributors will present on what the realisation of the values and principles of ethical conduct looks like through the lens of the consumer experience. Specifically, they will address the principle of beneficence and discuss the balance between protecting consumers in research, while affording them autonomy and opportunities to contribute to knowledge gain. Both consumer contributors will share personal examples of how they have experienced such opportunities during their involvement in research as consumers at the AFN.

This presentation will benefit researchers and practitioners who are keen to reflect upon how their own working practices embody ethical values and principles when

working with and interacting with consumers. It will also be extremely useful in empowering consumers to hear and see first-hand from peers as to how they can be more actively involved in shaping and leading ethical practices and policies alongside researchers.

Biography

Adrienne Young is an Advanced Accredited Practicing Dietitian (AdvAPD), and currently holds positions at the Royal Brisbane and Women's Hospital (Research Coordinator, Nutrition and Dietetics), and University of Queensland (Senior Research Fellow, Centre for Health Services Research).

Adrienne's research program aims to improve nutrition care in Australian hospitals to prevent avoidable hospital-acquired complications and optimise patient outcomes, particularly for older inpatients. Her research program consists of extensive observational research to establish the size and impact of the problem, qualitative research to understand patient, caregiver and staff perspectives and opportunities, and pragmatic implementation research to test, compare and evaluate different models of nutrition care in practice. Through her research, she is able to improve care of people accessing health services across the continuum of care, with a particular interest in frailty, preventing delirium and functional decline, and person-centred care.

13:00–13:15 **Consumer engagement** **Thursday 28 November**


Involve Australia in an innovative and systematic approach to community involvement in genomic research

Keri Finlay & Anne McKenzie AM
Australian Genomics / Consumer Advocate

Abstract

Background: *Involve Australia*, a community-led project coordinated by Australian Genomics, aims to give the community a stronger voice in genomic research and its translation into clinical practice. The community voice can influence research design, leading to more community-focused and translatable outcomes. This means research is more acceptable to the public. It is particularly important in genomics, where the application of testing in clinical practice is relatively new. Genomic research has a unique opportunity and responsibility to include community perspectives throughout all stages of research. Existing guidelines promoting community involvement (CI) in health care research rarely report on all aspects of co-designing research with community and none are genomics specific. This project partners with patient support and advocacy groups (PSAGs), patients and carers, the public, researchers and clinicians to prioritise community.

Objective: To create a set of practical, evidence-based CI guidelines for genomic researchers using co-design principles.

Methods: A mixed methods approach was undertaken using 3 data collection methods; 1) scoping review of existing health CI research guidelines, 2) survey of public perceptions on CI in health research, and 3) interviews with community members, CI program coordinators, researchers and institute leads.

Results: Based on the data collected and working group discussion, 5 domains with 17 recommendations were devised: 1) Building relationships – forming long-term

partnerships with community, 2) Setting expectations – creating awareness of team member roles and developing shared goals, 3) Valuing community members – acknowledging community member contributions to projects, 4) Evaluating and reporting on CI processes – importance of building an evidence base on CI impact, and 5) Translating research into real-world impact – the role of community members in translation and advocacy.

Conclusion: These guidelines are available for use and have been widely endorsed by PSAGs and research organisations. The guidelines are being piloted and evaluated in genomic and health research projects.

Biography

Keri Finlay (BBionf/BSc MGenCouns) is the Involve Australia Coordinator for Australian Genomics. Keri has trained as a genetic counsellor and has 15 years' experience in several facets of genetic/genomic research and patient support and advocacy. She joined Australian Genomics in 2016 as the Victorian Project Coordinator and was responsible for supporting the Victorian node of the Australian Genomics research network, coordinating ethics and governance at Victorian research sites and coordinating community-facing projects, such as Genomics in the Community. Currently, Keri manages the coordination and delivery of Involve Australia, an initiative that co-develops policies of patient, public, and consumer involvement in genomics research. In addition to this, Keri is responsible for other community-focused Australian Genomics activities, such as the Clinical Consent for Genomic Testing project, the Community Advisory Group and the online public genomic information repository Genomicsinfo.

Keri has previously held a role as the Support and Education Coordinator at the Genetic Support Network of Victoria, a state-wide service which supports people impacted by genetic, rare and undiagnosed conditions. This role included the development and delivery of genetic and genomic focused education seminars and programs, as well as providing support to members of the public impacted by genetic conditions.

Anne McKenzie AM has been a consumer advocate for three decades. From 2004-2021, Anne worked at The University of Western Australia and Telethon Kids Institute to increase the community's voice in research. She now consults for various Australian research organisations and is a consumer advocate on key national health research committees.

Anne was appointed to the Order of Australia for her advocacy work in 2015 and in 2021 she received the National Health and Medical Research Council's Biennial Award for Consumer Engagement.

13:15–13:30 **Consumer engagement** **Thursday 28 November**

The GenV participant advisory panel: Consumer engagement at scale in a large birth and parent cohort

Kate Wyatt

Murdoch Children's Research Institute / GenV Research Assistant – Design and Governance

Abstract

From design through to translation, consumer engagement has the potential to improve all stages of research. Indeed, consumer engagement is increasingly

expected throughout the research lifecycle, and even required by some funders and peak bodies. While some engagement efforts can be seen as tokenistic, true involvement and collaboration with research consumers can take many forms, such as committee membership, focus groups, surveys, co-investigation, and joint decision-making. Suitability will depend on many factors including the type of research being undertaken, and the benefits of engagement for both consumers and researcher will likewise vary.
Generation Victoria (GenV) is a large birth and parent cohort (>120,000 participants) led by the Murdoch Children's Research Institute. In this presentation, we will begin with an overview of our learnings from consumer engagement in other cohort studies and describe how we engaged consumers during the early design and implementation of GenV. We then describe how we have since formed the GenV Participant Advisory Panel. This group comprises over 1,000 GenV parent participants who have volunteered to give input into the ongoing design, implementation, and outcomes of GenV. We will report on the panel's make-up, activities and influence shaping GenV to date, plans for the panel's future engagement, and strategies for involving those less likely to participate in such activities.

Biography

Kate (Katherine) Wyatt is an experienced Research Assistant working with Generation Victoria (GenV), a statewide research initiative, led by the Murdoch Children's Research Institute (MCRI). Her role is central to supporting the design and implementation of GenV and enabling participation of families from across Victoria. In particular, Kate is involved with GenV's ongoing ethics and governance, and participant experience, engagement and retention strategy, including consumer engagement and involvement activities. Kate also serves as a research member for the Human Research Ethics Committee at Monash Health.

15:00–15:30	Psychedelic session	Thursday 28 November

Psychedelic panel discussion

Hudson Birden, Ian Tindall & Paul Gatenby
Townsville HREC, QIMR Berghofer HREC, ACT HREC

Abstract

In July 2023 the Therapeutic Goods Administration (TGA) authorised Psychedelic Assisted Therapy (PAT), the prescribing of psilocybin and MDMA for treatment of depression and Post Traumatic Stress Disorder respectively. TGA required that a psychiatrist be he prescribing doctor and that an HREC approve all applications.

This presentation will review the experience of several HRECs with the approval process, and recent developments in the science and approval mechanism for these drugs, including the recent US Food and Drug Administration denial of approval for MDMA.

Members of HRECs who have approved PAT are encouraged to attend and share their experience.

15:30–15:45	Psychedelic session	Thursday 28 November

The use of psilocybin-assisted psychotherapy for prolonged grief disorder

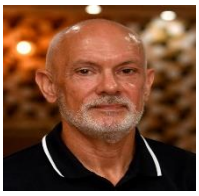
Thomas Kennedy

Queensland Institute of Medical Research Berghofer

Biography

Tom Kennedy holds a Bachelor of Psychological Science with Honours from the University of Queensland and joined the Psychedelic Medicine and Supportive Care Lab at QIMR Berghofer Medical Research Institute in early 2024 as a PhD student. Tom's research is embedded within the Psilocybin-Assisted suppoRtive Therapy IN the treatment of prolonged Grief (PARTING) trial where he has had the privilege of conducting evaluative interviews with participants and their therapists to explore their experiences in the intervention, assess its safety, feasibility, and acceptability, and investigate its potential impact as a treatment for prolonged grief.

15:50–16:10	Guidelines	Thursday 28 November



Cultural safety

Karl McKenzie

Chair of the Townsville Justice Group and Queensland Parole Board member

Abstract

How to improve your research outcomes when working with First Nations people.

Biography

Karl McKenzie is an Aboriginal man working in the Justice and Corrections space and Chair of the Townsville Justice Group as well as a Queensland Parole Board member.

16:10–16:30	Guidelines	Thursday 28 November

Challenges of recruiting and sustaining, equitable representation on a Northern Territory ethics committee

Hayley Germaine

Charles Darwin University

Abstract

This talk will present the challenges of recruiting, sustaining, equitable representation on a Northern Territory ethics committee, given that 26.3% of the population identifies as First Nations. The talk will focus on committee membership, how to ensure culturally appropriate reviews of ethics applications involving First Nations research and more specifically of proposed changes following a recent review of the CDU HREC.

Biography

Hayley studied law at Monash University (1996-2000), after which she began diving with Great White sharks in South Australia, where she developed a passion for research. With a family of research nurses, including her husband, her passion for research ethics and integrity expanded. Hayley has over 7 years' experience

coordinating and managing Research Ethics Committees and began in Human Research Ethics and Governance at the Royal Melbourne Hospital. For the past four years, at CDU, she had the privilege of coordinating both the Human Research Ethics and Animal Ethics Committees. Recently the ethics team has expanded and Hayley now coordinates the Human Research Ethics Committee and Research Integrity for CDU.

16:30–16:50	Guidelines	Thursday 28 November

Human remains, research and Indigenous peoples: A perspective from the Human Remains Committee in Norway

Lene Os Johannessen

National Committee for Research Ethics on Human Remains, Norway

Abstract

Ancient human remains are both the remains of individuals deserving of respectful treatment and a scientific resource for improving our understanding of past societies and its people. This duality can give rise to a wide range of ethical dilemmas, in particular, when the remains also represent marginalised or vulnerable ethnic, religious or minority groups. In Norway, the National Committee for Research Ethics on Human Remains (the Human Remains Committee) deals with ethical dilemmas that arise on this area. It sets out ethical guidelines and provides advice to researchers, research institutions and authorities. This presentation will discuss an advisory research ethics committee's role and present 2 cases the committee has handled; one on human remains from Norway's Indigenous group, the Sami, and one on human remains from Rapa Nui (Easter Island).

Biography

Lene Os Johannessen is a senior adviser in the National Research Ethics Committees in Norway and head of secretariat of the National Committee for Research Ethics on Human Remains (the Human Remains Committee). She has a PhD in archaeology.

08:00–08:15	Professionalisation – Zoom stream 1	Friday 29 November

Professionalising the scientific review

Melvin Chin

NSW Government - Health, South Eastern Sydney Local Health district

Abstract

To enhance the quality and efficiency of the ethics review process, the South-Eastern Sydney Local Health District Human Research Ethics Committee (SESLHD HREC) has used several models for the scientific review of applications submitted to the HREC.

Scientific review to assess scientific merit first removes applications that are underprepared or infeasible and reduces the administrative load of presentation and review by the HREC.

Since 2010, the HREC has done the scientific review in several ways, including having a separate scientific review committee vet applications before the HREC, assigning a scientific reviewer and ethics reviewer at each HREC meeting, pre-vetting with an Executive Committee and most recently employing a scientific reviewer.

A scientific review committee allowed in-depth scientific review but was resource intensive and added considerably to the review time. Reviewing unvetted applications at the HREC meetings with a scientific and ethical reviewer put significant pressure on the research members of the Committee and emphasised the scientific over the ethical aspects in discussions at HREC meetings. Pre-vetting with an Executive Committee comprising the Chair and a Research member required a significant and unsustainable time commitment from those individuals.

Recently, SESLHD contracted a scientific reviewer to review all submissions. Investigators are provided with a minimum of one week to address preliminary feedback before their applications are listed for discussion at the HREC meeting. From December 2021 to August 2023, 255 applications were pre-reviewed, with second pre-reviews required for some. 50 were rejected. Significant feedback including recommendations for major revisions were provided to 80 applications (including the rejected ones).

This measure has significantly improved the preparation and quality of applications presented to the HREC to review. It has alleviated the burden on HREC members. It facilitates more focused and productive discussions during the HREC meetings, leading to more efficient and effective decision-making. The approach is well accepted by both the Research Support Office and HREC members and has set a new standard for ethics review within the district.

Biography

Melvin Chin joined the South Eastern Sydney Local Health District HREC in 2011 as a professional care member and was appointed the Chair in 2022. He is a clinical academic medical oncologist at the Prince of Wales Hospital and cares for patients with cancer and teaches UNSW medical students. He has 6 active projects in REGIS as Principal Investigator.

08:15–08:30	Professionalisation – Zoom stream 1	Friday 29 November

Barriers and facilitators to retention in long term paediatric clinical trials

Jessie Head-Gray

Murdoch Children's Research Institute

Abstract

Background: Paediatric clinical trials have historically been limited due to a reluctance to conduct trials including children. Limited research is available focusing on recruitment and driven by researchers. No literature is present to describe family experience of participation in a long-term paediatric clinical trial for rare diseases. The family voice and patient experience are missing from this space.

Aim: This study seeks to understand the barriers and facilitators to continuing participation in long-term high-burden paediatric clinical trials for children with achondroplasia.

Method: Families of children with achondroplasia participating in a clinical drug trial for more than one year where the investigational product is a daily subcutaneous injection were approached to participate. Families participating in HREC 80875 were excluded. Interviews were conducted with a parent from 7 different families. Transcripts were reviewed using reflexive thematic analysis supported by reflexive journaling and thick description.

Results: Participation is motivated by altruism and a desire to mitigate future health complications for this incurable rare disease. Relationships developed with the Principal Investigator, hospital and clinical trial team positively impacted experience. Experience and retention were positively correlated. Families highlighted gaps in care and barriers to services as negatively impacting overall experience. Communication from the sponsor was perceived as minimal with families wanting more correspondence at program and individual levels.

Conclusion: Family experience of participating in a long-term paediatric clinical trial for an experimental drug was directly influenced by relationships with the clinical trial team and nurses' ability to balance sponsor requirements, protocol operationalisation and rapport with families.

Biography

Jessie is an experienced research coordinator, paediatric nurse, and program manager with expertise in clinical trials, health and research communications with a focus on research impact.

08:30–08:45	Professionalisation – Zoom stream 1	Friday 29 November


Approaches for registering adaptive trials in the Australian New Zealand Clinical Trials Registry (ANZCTR)

Peta Skeers & Melina Willson

The University of Sydney

Abstract

Aim: Adaptive trials, including platform and multi-arm multi-stage trials, are complex in design but offer great flexibility to researchers and can accelerate the delivery of beneficial treatments to people. The approach of registering adaptive trials in the ANZCTR is not always straightforward and HRECs may face similar procedural challenges. Our aims are to share current registration guidance for these trials in the ANZCTR and recommendations raised within the World Health Organization (WHO) clinical trial registry network.

Methods: We searched the ANZCTR (2005-2023) to identify adaptive trials, defined as multi-arm trials that add or remove treatment arms based on preplanned criteria. We recorded the approach taken by each trial at registration and key features. We discussed registration practice for adaptive trials with ClinicalTrials.gov (USA), ISRCTN (UK) and the WHO and potential areas of harmonisation across trial registries.

Results: We identified 12 adaptive trials on the ANZCTR since 2016. Of these, 6 trials were each presented as a single registration record, describing on average 4.7 treatment arms per record. The other 6 trials involved 36 separate registration records for the master protocol and its related sub-studies, describing 36 unique treatments. Ten trials included 'adaptive' or 'platform' in their title and most trials

were investigating cancer treatments (50%) followed by COVID-19 (16%).

Discussions with the WHO trial registry network covered: (a) ensuring new treatment arms can be prospectively registered by capturing trial recruitment dates in new or existing records, (b) improving identification of trials and related sub-studies within and across trial registries through secondary IDs, (c) recommendations from ClinicalTrials.gov around 'separate registrations for each sub-study within one master protocol (with potential exceptions noted)'; and (d) taking into account any pre-specified synthesis of results across sub-studies when deciding on the registration format (e.g. one registration record may suffice in some cases).

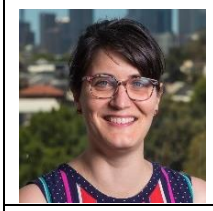
Conclusions: The approach for registering adaptive trials needs to balance research transparency while minimising trial administrative burden. Currently, the ANZCTR asks that study investigators contact us before registering an adaptive trial. Where feasible, discussions on HREC requirements and any potential areas of harmonisation across HREC and ANZCTR would be of benefit and could help inform the design process in the new national trial infrastructure.

Biography

Peta Skeers is a Project Officer with the Australian New Zealand Clinical Trials Registry (ANZCTR) and an Information Specialist with the Cochrane Breast Cancer Group at the NHMRC Clinical Trials Centre (CTC), University of Sydney.

Melina Willson is the manager of the Australian New Zealand Clinical Trials Registry (ANZCTR) and Cochrane Breast Cancer Group at the NHMRC Clinical Trials Centre (CTC), University of Sydney.

08:45–09:00	Professionalisation – Zoom stream 1	Friday 29 November



Facilitating up-to-date information on clinical trials: A case for collaboration between ethics committees and the Australian New Zealand Clinical Trials Registry (ANZCTR)

Angie Barba ***(presented by Ava Grace Tan-Koay and Melina Willson)***
The University of Sydney

Abstract

Aim: Registration of clinical trials in a primary registry, such as the ANZCTR, is an ethical standard to enable research transparency and promote dissemination of trial results. During the trial life cycle, it is recommended to update trial registrations regularly after initial registration, in addition to providing regular updates to ethics committees. This project aims to identify 1) what information is commonly updated in the ANZCTR, and 2) overlapping sections between the ANZCTR and the Human Research Ethics Application (HREA).

Method: Part 1: We downloaded ANZCTR data for interventional trials registered from 1 January 2015 to the 31 May 2024. Data included registration year, ethics information, recruitment dates, study design data, funding, sponsor and collaborator information. We obtained update data (i.e. what information was updated and when) up to the 31 May 2024 from the ANZCTR technical team.
Part 2: We reviewed data fields collected in the ANZCTR and HREA as part of the initial ethics application, annual updates and final report. Fields were categorised as 'matching' when definitions were identical, while 'similar' fields indicated different definitions or level of detail required.

Results: 63% of total eligible trials have updated trial registry information at least once (8,150/13,018 trials). Majority of updates involve trial recruitment: 96% of these complete updates to recruitment dates, 88% provide updates to recruitment status, and 89% provide updates to sample size, including both updates to the target sample size and the number currently enrolled in the trial (figure 1). 41% provide updates regarding study results, 36% provide updates regarding ethics committee details and 31% provide updates to ethics status. For these, the largest proportion (25%) of updates occurred at 11-13 months since registration or last update. When looking at information collected by the HREA, information on recruitment status and sites, sample size (target, current and final), and details on the funder, sponsor or contacts were considered 'matching'. Information for the description of intervention or phase of trial were considered 'similar'.

Conclusion: Most trials that updated their records on the ANZCTR provide information also collected by ethics or regarding ethics committees themselves, and these occur on an annual basis, consistent with ethics updates. Collaboration between the 2 is likely to benefit the ANZCTR, ethics committees and researchers currently providing identical information across the systems. Proposed next steps include comparison of definitions and requirements of similar data collected, with a view to harmonise these.

Biography

Ava Grace Tan-Koay is a Senior Project Officer at the NHMRC Clinical Trials Centre (CTC), The University of Sydney. At the CTC, she works primarily on the Australian New Zealand Clinical Trials Registry (ANZCTR) and Cochrane Breast Cancer. She is involved in reviewing trial submissions and research on clinical trial activity on the ANZCTR and involved in the management and development of systematic reviews and providing author support with Cochrane Breast Cancer. Ava has a PhD in cataract epidemiology and has a keen interest in research study designs, systematic review development and big data.

Melina Willson is the manager of the Australian New Zealand Clinical Trials Registry (ANZCTR) and Cochrane Breast Cancer Group at the NHMRC Clinical Trials Centre (CTC), University of Sydney.

09:00–09:15	Professionalisation – Zoom stream 1	Friday 29 November

What is the national prevalence of statisticians as full members of human research ethics committees in Australia?

Adrian Barnett

Queensland University of Technology

Abstract

Much health and medical research is wasted because of study design and analysis errors. Preventable errors regularly occur when planned studies are not reviewed by a qualified statistician. Badly designed studies waste the time of enrolled patients, and potentially expose them to unnecessary risks.

We attempted to contact the chair of every Australian HREC registered with the NHMRC to ascertain if a qualified statistician was involved in the review process. We currently have responses from 117 out of 187 committees (63%). 26% of committees stated they have a statistician as a full member, but 27% of these members had no formal qualifications in Statistics or their qualifications were

unknown. 27% of committees stated they had non-members who can be consulted on statistical issues, but 53% of these non-members had no formal qualifications in Statistics or their qualifications were unknown. Participants frequently commented that statistical expertise could be provided by researchers from other fields, most often medicine, epidemiology and psychology, for example, “A number of committee members have statistical expertise, although they are not statisticians per se”. Some committees saw a statistical member as crucial for ensuring that the proposed study had merit, and some committees had access to multiple qualified statisticians.

Statistical practice is often poor in published health and medical papers, even for simple study designs. The ongoing shortage of statisticians has contributed to the field being marginalised, with echo-chambers of poor practice developing in some fields. The ethical review process is a key opportunity to improve flawed designs, maximise research impact and reduce research waste. However, our results suggest many Australian HRECs do not have adequate statistical expertise. Worryingly, results indicate that the expertise of a qualified statistician is understood as comparable to people with “some experience in statistics”. This could well be causing harm. As the eminent statisticians Bland and Altman wrote: “Bad statistics makes bad research, bad research may lead to bad medicine, and bad medicine may cost lives”.

We will discuss some potential ways to improve practice, including methods review panels that are separate to the HREC review, which some Australian HRECs already use.

Biography

Adrian Barnett is a Professor of Statistics who has worked for over 29 years in health and medical research. He was the president of the Statistical Society of Australia from 2018 to 2020. His current research concerns improving statistical practice to reduce research waste. He is the President of the Association for Interdisciplinary Meta-Research and Open Science, whose mission is to improve research quality.

08:30–08:45	Specific participant groups – Zoom stream 2	Friday 29 November

Geographies of ethics, rural communities and education research: A struggle for ethical research

Dipane Hlalele

University of Kwazulu-Natal, South Africa

Abstract

Researchers conducting research with vulnerable populations in rural African settings are confronted with distinctive ethical and cultural challenges due to the community context of their research, their methods of investigation, and the implications of their findings.

The current study explores the struggles in respect of research ethics and integrity in research with and about rural people and communities. The problematic crystallises itself on the premise that dynamism imbues the ethics of research since no 2 rural spaces are identical and researchers may not necessarily be expected to be monolithic in their research approach. Assuming that ethical judgements by their very nature ponder a variety of realities (relative or actual) and are therefore diverse,

diversity foregrounds plurality, fluidity, and a multiplicity of rural communities. For the purpose of the research, the concept geography is understood as a space in a psycho-, socio-political and recursively constructed sense. Geographies include exceptionism, situationism, subjectivism and absolutism mapped across relativism and idealism as dimensions. Drawing from diverse international literature (189 peer reviewed articles and book chapters) published in the last 10 years on rural education, and using PRISMA as an analytical tool, this scoping review finds that almost half of publications make no reference, even in the tacit sense, to ethical issues.

We conclude with an observation that varying ethical geographies may create conflicting, competing, or crosscutting ethical obligations and ramifications, reflecting both the relative vulnerabilities of rural communities, power implicit in these scholarly relationships, and the diverse ethical frameworks. Due to the uniqueness of different rural contexts, we argue for a differentiated and context-sensitive approach regarding the application of ethical issues in research. We further argue that there is a need for a monitoring mechanism tool to enhance compliance and promote the protection of vulnerable people in rural settings.

Biography

Dipane Hlalele is a full Professor of Education at the University of KwaZulu-Natal and a C2 National Research Foundation rated researcher (2022-2027) who appears in the World Top 100 Education Scientists in South Africa (2022, no. 92), (2024. no. 61) and Africa (2024, no. 87) according to the AD Scientific Index. He is currently Ethics Chair: Human and Social Sciences Research Ethics Committee at the University of KwaZulu-Natal, South Africa, and a Principal Investigator in the *Geographies of ethics in rural humanities research (2024-2026)* National Research Foundation funded project.

08:45–09:00	Specific participant groups – Zoom stream 2	Friday 29 November

Visual consent tools for participant information and consent in health research with First Nations peoples

Mina Kinghorn

The University of Queensland

Abstract

Introduction: Informed consent in research is crucial for meeting ethical standards, transparency, and voluntary participation. However, current institutional research consent processes often rely on text-heavy documents filled with complex academic jargon. This approach can lead to misunderstandings and disengagement, posing a significant challenge to obtaining genuinely informed consent. This study outlines the process of developing visual tools to improve the informed consent process in sleep health research with First Nations peoples.

Methods: Through a collaborative process engaging First Nations visual communication experts and First Nations community researchers, visual consent tools were redesigned to prioritise participant engagement. Iterative feedback was provided regarding accessibility, cultural responsiveness, and suitability for First Nations communities, whilst balancing consumer-centric information and the rigour of the informed consent process. Subsequently, the Lets Yarn About Sleep First Nations Data Governance team (including First Nations academics, and community

researchers) assessed the work for cultural responsiveness and suitability for First Nations sleep health research. The final stage involved obtaining institutional ethics committee approval for consumers to test and evaluate the visual tools.

Results: Initial feedback from First Nations community researchers and the First Nations Data Governance team highlights the potential of the visual consent tools to enhance the informed consent process. Further testing and evaluation will confirm the impact of these tools on participant comprehension and engagement.

Discussion: This study documented the initial steps in the First Nations led development of culturally responsive visual tools for seeking informed consent in sleep health research. Future work must evaluate the broader acceptability of culturally grounded visual consent approaches, to reform institutional research ethics processes.

Biography

Mina Kinghorn is a non-Indigenous public health professional with a strong commitment to supporting First Nations health research and education-based advocacy. Her expertise lies in research translation, where she focuses on transforming complex health data into accessible resources for communities. Mina is deeply passionate about the role of education in supporting health equity, and she has worked alongside First Nations leaders to integrate their knowledges into health-related programs at The University of Queensland, including the Bachelor of Environmental Science, Master of Public Health, Master of Epidemiology, and Doctor of Medicine programs.

09:00–09:15	Specific participant groups – Zoom stream 2	Friday 29 November

Ethical issues in conducting health research with people in prison: Results of a deliberative research project conducted with people in Australian prisons

Paul Simpson

University of New South Wales

Abstract

Introduction: Planning health research involving people in prison raises concerns based on past abuses of this population amongst other factors. Despite the development of guidelines for the ethical conduct of research in prisons, researchers and advocates have questioned whether current approaches aimed at ‘protecting’ incarcerated persons from unethical research unfairly excludes them from participating in and benefitting from research. Discussion of these issues comes mostly from expert opinion and court proceedings. The voices of people in prison are absent in these debates.

Aim: In this paper we identify key ethical issues according to people in prison for research involving the health of people in prison.

Method: Using a deliberative research approach, citizens’ juries were conducted in 2019 within 6 Australian prisons (3 men’s and 3 women’s; 4 in New South Wales and 2 in Queensland). Participants were selected following submissions of expression of interest forms that were distributed within the prisons. Pre-recorded information by experts in research ethics and research with incarcerated populations

was shown to participants who subsequently deliberated for almost 4 hours before collectively agreeing on 5 key ethical issues regarded as important when conducting health research in prisons.

Finding: Key ethical issues selected by participants were: 1) Feedback results to participants; 2) Involving the lived experience voice in assessing what research happens; 3) Equal research access to those in community; 4) Recruitment bias regarding prison staff selecting participants; 5) Confidentiality of responses; 6) Recognizing the capacity and ability of informed consent by those in prison; and 7) Conflict of interest regarding the censoring of research findings by prison health services or corrective services.

Discussion/takeaway message: We propose that deliberative methods are a responsive way that allows the voices of those with lived experience to be heard regarding the design and conduct of research. Focal points identified within our findings suggest that if we are to genuinely consider the voices of people in prison, then it may be time to incorporate ways for research participation to be more accessible to incarcerated citizens.

Biography

Dr Paul Leslie Simpson (he/him), PhD, is a research fellow of the Justice Health Research Program at the School of Population Health, University of NSW, Associate of the Australian Human Rights Institute, and Associate of the Centre of Research Excellence in Violence Perpetration Prevention. His research centres on health and marginalisation among justice system involved populations with a focus on sexuality and gender diversity, and Aboriginal and Torres Strait Islander peoples using diverse methodologies. He has developed deliberative research methods to involve and give voice to diverse stakeholder including those with lived experience of incarceration in the coproduction of research outcomes. He has been a member on ethics panels and committees for almost 10 years and is current Co-Chair of the NSW Justice Health and Forensic Mental Health Network Human Research Ethics Committee.

09:15–09:30	Specific participant groups – Zoom stream 2	Friday 29 November

Ethical barriers and opportunities to facilitate effective involvement of people with a living experience of dementia in research

Sarah Jay

Dementia Australia

Abstract

Internationally, it is recognised that involving people with a living or lived experience of a condition or situation in research strengthens the research and the increases the likelihood that outcomes will be useful.

In the field of dementia in Australia, initiatives have largely focused on capacity building of researchers and people with a living experience of dementia to ensure effective, meaningful involvement in the decision-making aspects of research. Unsurprisingly, involvement is strengthened when both researchers and people with a living experience are informed and supported. For researchers, institutional processes, including human research ethics protocols, are influential and can either facilitate or hinder research efforts.

Insights from researchers and dementia ‘advocates’ (people living with dementia and those involved in their care) as part of in-house scoping work by Dementia Australia and Dementia Australia Research Foundation, highlighted systemic ethical constraints on the involvement of advocates in the design and development of research projects. Further, building collaborative capacity with ethics committees was ranked in the top 5 of 25 projects proposed to both Advocates and researchers highlighting it as a priority issue.

Common barriers encountered by dementia researchers in relation to ethics will be summarised with the focus of the presentation on the following key areas of opportunity: 1) Importance of involving people living with dementia in research; 2) Inclusion of people with a living experience of dementia on ethics committees; 3) Approaches for assessing research projects that focus on support rather than exclusion based on assumptions of incapacity – a ‘dignity of risk’ approach, including insights from dementia advocates; and 4) Shared solutions and ways of working that will support the building of trust and respect between for academic and non-academic partners.

Biography

Sarah Jay is the Consumer Engagement Coordinator (Research) in the Consumer Engagement team at Dementia Australia. The role is centred around supporting advocates engaged in research projects, liaising with researchers, developing projects to build capacity for meaningful engagement of people with lived experience in research. Previously, Sarah worked as both a research administrator (for the Dementia Australia Research Foundation and in the university sector) and a researcher where her PhD and the work that followed, focused on understanding the impact of shift work for sleep, health, safety, and wellbeing.

09:30–10:00	Plenary	Friday 29 November

Positioning positionality

Mandy Downing
Curtin University

Biography

Associate Professor Mandy Downing is identified through maternal lineage to the Ngarluma and Yindjibarndi people of the Lerrumugudu (Roebourne) area. However, as the granddaughter of a Stolen Generation survivor, she was raised off-Country on Wadjuk Noongar Boodjar. Mandy is the Dean of Indigenous Futures, responsible for ensuring Australia’s Indigenous futures across the nation’s culture and economy are supported and considered in the learning, research, and partnership activities of the Faculty of Humanities at Curtin University. Mandy is an applied scientist in Indigenous Australian research with research interests in institutional racism and the first Aboriginal person appointed as a Dean in the Faculty of Humanities at Curtin University.

Nationally, Mandy is the Senior Indigenous Facilitator for the National Environmental Science Program Sustainable Communities and Waste Research Hub and is the Co-Chair of the Australian Institute of Aboriginal and Torres Strait Islander Studies National Research Ethics Committee.

In the community, Mandy co-designed an emerging leadership program through the Western Australian Aboriginal Leadership Institute for Aboriginal and Torres Strait Islander youth and has voluntarily facilitated this since its inception in 2019. Associate Professor Mandy Downing is a 2023 inductee into the Western Australian Women's Hall of Fame for her contributions to education for more than 20 years. Most recently, Mandy is a co-editor of the newly published book The Routledge Handbook of Human Research Ethics and Integrity in Australia.

12:45–13:00	Consent	Friday 29 November

What constitutes 'informed' in informed consent?

Ian Pieper

Chair of The University of Canberra Human Research Ethics Committee

Abstract

The requirement for consent to be both informed and voluntary is a keystone of contemporary bioethics and is supported by law and regulation. Consent is not lawful unless each of the elements of valid consent are satisfied:

1. The decision is made voluntarily; and
2. The person providing the consent must be informed in broad terms about the activity; and
3. The person must be provided with any specific information relevant to them as an individual making a decision about participation and any alternatives; and
4. The person must have the legal authority and the capacity to make the decision.

This presentation will focus on information provided to research participants that must be relevant to them as the individuals making a decision about participation.

The National Statement requires that researchers provide sufficient information about potential risks and benefits to enable an informed decision about participation. This requirement is intended to support the decision-making ability of each participant and to respect that person's dignity.

There is a growing tension between genuine engagement with participants as individuals and the commodification of cohorts for research purposes. How researchers ensure that participants are informed in ways that meet their specific circumstances is often a matter of trust. How ethics committees assess the validity of consent processes is often a matter of debate. However, ensuring that individuals have the information that they need, in a way that they can comprehend and make sense of, is not just a nicety – it is a legal requirement.

Biography

Ian has 2 decades of experience across all aspects of the administration and regulation of medical and health research in Australia and in the UK, including industry, university, and government sectors. He has made significant contributions to the Australian clinical trials reform agenda as a subject matter expert advising the

Commonwealth Department of Health and Aged Care and the Australian Commission on Safety and Quality in Health Care.

The objective of Ian's PhD thesis was to reframe the narrative around how autonomy is conceptualised by researchers and decision-makers within clinical research. The thesis highlighted that the current perception of autonomy is based on a rational consideration whereas a relational consideration of autonomy can lead to a greater understanding of participant self-governance and create opportunities to promote greater respect for autonomy.

Ian is currently Chair of the University of Canberra Human Research Ethics Committee.

13:00–13:15	Consent	Friday 29 November

Determining decision-making abilities of people with intellectual disability consenting to participate in qualitative research: Moving from substitutes to supporters

Rhonda Beggs

Logan and Beaudesert Hospital

Abstract

Introduction: The purpose of this presentation is to discuss the nuances between Substitute Decision Making (SDM) and decision-making support for people with intellectual disabilities consenting to participate in qualitative research.

Background: People with intellectual disabilities are a vulnerable population and are afforded special protections within research consenting processes[1]. Often researchers are utilising SDM or proxy consenters to engage people with intellectual disability in research. Moves towards recognition of the rights for self-determination are increasingly supporting the notion of decision-making ability frameworks[2]. Decision-making ability frameworks are considered the least restrictive options to afford persons with disability their own agency.

Aims: To outline decision-making support frameworks that facilitate the participation of people with an intellectual disability in qualitative research.

Discussion: Formalised processes for decision-making and capacity exist within Queensland[3]. Unless a formalised framework exists, a person with intellectual disability is deemed to have capacity for their own decisions. People with intellectual disability have a range of difficulties pertaining to cognitive processes, however, these difficulties may be subject to alternative communication strategies to enable decision-making to occur. The Public Advocate [Qld] has suggested that the time has come for decision-making *abilities* of people with intellectual disabilities to be recognised[2]. Assent pathways are one way to recognise an individual's inherent right to have their say. Assent pathways require a different way to view consent processes, with consideration given to flexible consenting structures, alternative communication pathways and recognition of supports to assist researchers to understand the individual's will. Currently, if there is a doubt in a person's ability to consent, the decision-making falls to a SDM or exclusion from the study. The act of engaging a SDM contravenes the notion of supporting self-determination. Implementing rolling consent processes alongside a decision-making support model would enable greater self-nomination and determination practices to assist people with intellectual disabilities to engage in qualitative research.

Conclusion: Substitute decision-making should be the last resort of consent for people with an intellectual disability to engage in qualitative research. Combining decision making ability frameworks with rolling consent practices offers qualitative researchers an opportunity to engage with a vulnerable group about their health care needs.

1. National Health and Medical Research Council, Australian Research Council and Universities Australia. National Statement on Ethical Conduct in Human Research, 2023. [Internet] [cited 2024 Jun 10]. Available from https://www.nhmrc.gov.au
1. 2.Public Advocate [Qld]. Expanding Horizons: Examples of Supported Decision Making in Queensland, 2024 [Internet] [cited 2024 Jun 10]. Available from https://www.justice.qld.gov.au
2. Queensland Government. Queensland Assessment Capacity Guidelines 2020 Version 2. [Internet] [cited 2024 Jun 10]. Available from https://www.publication.qld.gov.au/dataset/capacity-assessment-guidelines/resource/23e5bde1-40d7-4115-a15d-c15165422020

Biography

Rhonda completed her nurse training in the UK specialising in intellectual disability nursing, with a later addition of a postgraduate mental health nursing registration. Rhonda has worked in a variety of settings including hospital, community (paediatric and adult), sexual health and drug and alcohol services, with a focus on intellectual disability and/or mental health nursing. Rhonda has worked as a lecturer in the UK and in Australia, and currently holds an adjunct position with Griffith University School of Nursing and Midwifery. Rhonda is a member of the Professional Association of Nurses in Developmental Disability Australia (PANDDA). Rhonda is currently employed as Disability Nurse Navigator within Metro South Health (MSH) and as Project Officer on a joint research project between Griffith University and MSH. Starting work in the early 1990's, Rhonda has seen significant change from institution-based care, but many barriers still exist, and Rhonda is committed to create positive environments for people with intellectual disabilities to have their health and psychosocial needs met.

13:15–13:30 | **Consent** | **Friday 29 November**

Inclusive consent practices: Learnings from Generation Victoria

Libby Hughes

Murdoch Children's Research Institute

Abstract

Despite greater recognition of the need to include diverse and under-represented populations, child research continues to be skewed to participation by white, English-speaking, well-educated mothers living in metropolitan areas. Too often, researchers neglect to consider inclusive practices when designing studies, or dismiss them as too costly, complex, or unnecessary.

Generation Victoria (GenV) is a large birth and parent cohort (>120,000 participants) led from the Murdoch Children's Research Institute. From its inception, we set ourselves the challenge to be a truly inclusive cohort representative of the whole state and of the full range of social, educational, cultural and linguistic diversity. In this presentation, we will describe how GenV achieved inclusivity through our design (open to all children born in a 2-year window and living in Victoria, and all their parent/guardians), consent (tiered multi-modal information, in 26 languages, plus interpreters for further languages), recruitment (face-to-face at 58 birthing services across Victoria supplemented with phone and online), and ongoing engagement and data collection (remote digital collection and linkage to existing data and samples).

GenV has shown that, given the right conditions, typically under-represented groups are in fact as likely to enter research as others. We will describe how GenV worked to overcome challenges faced in achieving an inclusive design, and how our learnings can be applied in future research. We will explore the role of HRECs and Research Governance Offices in setting expectations and enabling inclusive designs including eligibility criteria, consent materials and processes, and supporting multi-site research governance.

Biography

Dr Libby Hughes is a Senior Research Fellow and Design Lead for Generation Victoria (GenV), Australia's largest child and parent cohort study led from the Murdoch Children's Research Institute. She has a PhD in psychology and over 20 years experience in clinical and population health research. Dr Hughes has held a variety of research roles at the University of Melbourne, Monash University, Centre for Community Child Health, Centre for Adolescent Health, and Australian Institute of Family Studies. Her role on GenV includes leading the design of participant recruitment, retention, and consent management; overseeing ethics, governance, and privacy compliance; and conducting research to improve the scientific quality, ethical integrity, and longevity of the cohort.

13:30–13:45	Consent	Friday 29 November

Health Information and bundled consent in primary care

Helen Deuchar

University of Auckland, New Zealand

Abstract

Consent is commonly viewed as the touchstone of ethical healthcare and research, and its core elements are well documented in the literature. However, there remains a lack of shared language around what 'consent' is, and its parameters in practice. New variations of consent such as integrated or bundled consent are largely undiscussed in the literature despite becoming increasingly common. Bundled consent is often regarded as having the same validity as usual explicit consent practices, despite posing unique ethical issues in an increasingly datafied world.

This talk will explore the key elements of consent and bundled consent to illustrate how bundled consent differs from a lack of consent. A case study of Primary Care and health information, which was conducted as part of my Masters thesis, will be discussed to explore some of the ethical issues of bundled consent and potential challenges in theorising an 'unbundled' alternative.

Currently, in Aotearoa New Zealand, consent for accessing Primary Care is bundled with consent for data collection and (re)use. General Practice enrolment forms require individuals to have 'read and agree the Health Information Sheet', which outlines that their health information (including patient notes, lab results and imaging) will be collected and shared with other organisations including researchers. It may be difficult for service users to opt out of their data being collected and (re)used if they wish to still access Primary Care services.

Biography

Helen Deuchar is a Masters candidate at the University of Auckland, in Aotearoa New Zealand. Her areas of focus are data justice, data ethics and data harms from a decolonial standpoint. As a South African (tauiwi) woman living in Aotearoa, she is particularly interested in how settler colonialism is embedded in and perpetuated by our data practices.

Helen's Masters explores the ethics of consent, particularly new iterations of consent such as bundled and integrated consent. Prior to her Masters, Helen worked on a project exploring the ethical issues of publishing identifiable coroners' reports online.

healthtranslationqld.org.au/hrec-conference-2024