Human Research Ethics Committee Conference

4th National HREC Conference

29 November – 1 December 2023

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Contents

Foreword

We are delighted to bring you the 4th National HREC Conference. The event has certainly grown in past years and last year we had 1,500 registrants which I believe demonstrates the value of providing the only opportunity for group HREC education as a free and online event. We hope to attract as many and more attendees this year and I believe that the program is strong, varied, and as inclusive as we have been able to make it, with talks ranging from marginalisation of research participants, to a proposal for HREC judicial review to a view from across the 'ditch'. All provocative, interesting and didactic.

I am once again indebted to the tireless efforts of Sara Gottliebsen from Health Translation Queensland for doing a lot of the organisation. She makes the job of myself and the Organising Committee so simple. To the Committee also, thank you once again for helping to put together a stellar array of talks which covers such a breadth of topics.

We continue to receive support from our sponsors: Bellberry Ltd, PRAXIS and AHRECS and are grateful to them for their continuing support. It is largely a truism that you get what you pay for, but the sponsorship that we receive engenders a significant return on investment of time for attendees and hopefully for our sponsors also.

We hope that you derive significant benefit, satisfaction, and most importantly knowledge from what I believe is our best program yet.

Best wishes for the conference,
Gordon McGurk PhD, JD, Grad Dip LP

Organising Committee

Gordon McGurk	QIMR Berghofer Medical Research Institute
Sara Gottliebsen	Health Translation Queensland
Hudson Birden	Townsville Hospital and Health Service HREC
Sophie Gatenby	The Royal Children's Hospital Melbourne
Sara Hubbard	Townsville Hospital and Health Service
Eleanor Milligan	Griffith University
Paula Swatman	Swinburne University of Technology
Ian Tindall	CALHN HREC at SA Health
Nik Zeps	Chrysalis Advisory

Day 1 – Wednesday 29 November 2023

All times in AEST (QLD)

08:30 – 08:40	**Welcome** Gordon McGurk, conference organiser
08:40 – 08:50	**Acknowledgement of Country** Geoff Binge, Principal Advisor, Aboriginal & Torres Strait Islander Program
08:50 - 09:00	**Opening remarks** Steve Wesselingh, NHMRC
09:00 – 10:00	**Plenary** *Chairperson: Gordon McGurk* Approving the approvers: The theory and practice of monitoring ethics committees Monique Jonas, Auckland, New Zealand
10:00 – 10:30	**Morning tea**
10:30 – 12:00	**Artificial intelligence and social media** *Chairperson: Gordon McGurk*
10:30 - 11:00	Revolutionising clinical trial recruitment: unleashing social media's power! Duncan Colyer, VCCC Alliance
11:00 - 11:30	View of apps as TGA regulatable in trials (issues to consider) Peter Keller
11:30 – 12:00	Development of guidelines for review of AI projects by HRECs Lukah Dykes, HeartAI
12:00 – 12:15	**Lunch**
12:15 – 13:45	**Effective use of data** *Chairperson: Paula Swatman*
12:15 – 12:45	Using 'synthetic data' to enable use of health information Jason Pole, The University of Queensland
12:45 - 13:15	ONDC Data Act update Gayle Milnes, National Data Commissioner
13:15 – 13:45	Secondary data in research: confusing ethics reviewers and applicants alike Paula Swatman, University of Swinburne
13:45 – 14:15	**Afternoon tea**
14:15 – 15:45	**Contemporary ethical considerations** *Chairperson: Hudson Birden*
14:15 – 14:45	HREC judicial review Rebekah McWhirter, Deakin University
14:45 – 15:15	The role and remit of the National Statement – guidance vs rulebook Rob Loblay, University of Sydney
15:15 – 15:45	Genomics, Human Research Ethics Committees and waivers of consent Lyndsay Newett, National Centre for Indigenous Genomics
15:45 – 16:00	**Afternoon break**
16:00 – 17:30	**The value of lived experience** *Chairperson: TBC*
16:00 – 16:20	Deterioration of health-related quality of life: the hidden health burden of informal caregiving Syed Alfroz Keramat, The University of Queensland

16:20 – 16:40	Advancing video-ethnographic research in health care: challenges, lessons learned and implications for practice Mila Obucina, Griffith University
16:40 – 17:00	Exploring the association between physical activity levels and healing outcomes among individuals with venous leg ulcers: a secondary analysis Shirley Qiu, University of Technology Sydney
17:00 – 17:20	Queer people, criminalisation, pathologisation, and ethics of health and medical research James Allen
17:20	**Close**

Day 2 – Thursday 30 November 2023

All times in AEST (QLD)

08:00 – 09:00	**Consumers** *Chairperson: Lisa Anemaat* Co-Chairperson: Natasha Roberts
08:00 - 08:20	What is the place of consumers in HRECs? Ian Tindall, Chair CALHN HREC at SA Health
08:20 – 08:40	Consumer and co-design considerations in research Ken Knight & Nyanhial Yang
08:40 – 09:00	Supporting Ethics Committees to amplify consumer and community involvement in health and medical research Brian Dalton & Carrie Hayter
09:00 – 09:15	**Morning break**
09:15 – 10:00	**PRAXIS Plenary** *Chairperson: Gordon McGurk* PRAXIS Australia – scholarship presentation Diversity in research: inclusion imperatives Jackie Leach Scully, University New South Wales
10:00 – 10:15	**Morning tea**
10:15 – 11:35	**Clinical Trials** *Chairperson: Roberta Littleford*
10:15 – 10:35	Psychedelic clinical trials prescription vs legislation – important things for HRECs to look for Ian Tindall, Chair CALHN HREC at SA Health
10:35 – 10:55	RCTs the gold standard – what do we need to know Kelvin Robertson, Townsville
10:55 – 11:15	Adaptive platform trials introducing PLATIPUS Clare Whitehead
11:15 – 11:35	A-CTEC: a national educational platform to professionalise the Australian clinical trials workforce Eman Nafea, Director, Australian Clinical Trials Education Centre (A-CTEC)
11:35 – 12:00	**Lunch**
12:00 – 13:00	**HREC Common Issues Workshop** *Chairperson: Ian Tindall & Gordon McGurk*
12:00 - 12:45	A panel discussion on HREC common issues. This session will consider contemporary barriers to effective committee review of research.
12:45 - 13:00	Research Ethics Committees in post-pandemic era: a call for a universal registration and accreditation platforms Ehsan Shami Gooshki, Monash University
13:00 – 13:10	**Afternoon break**
13:10 – 14:10	**External influences on HRECs** *Chairperson: TBA*

13:10 - 13:25	HeSANDA: HREC approval for data sharing Kristan Kang, Australian Research Data Commons
13:25 – 13:40	Authorised prescriber Robyn Langham
13:40 – 13:55	Authorised prescriber scheme and psychedelic medicine Hudson Birden & Kelly Parker
13:55 – 14:10	A nationally consistent approach to the accreditation of institutions and their HRECs Conor Brophy, Chair, Ethics Committee Advisor Group, Australian Commission on Safety and Quality in Health Care
14:10 - 14:20	**Afternoon tea**
14:20 – 15:20	**Consent** *Chairperson: Sophie Gatenby*
14:20 – 14:35	Ethical challenges to informed consent in aged care research Elspeth McInnes AM, HREC Chair University of South Australia
14:35 – 14:50	The use of multimedia aided consent in paediatric research Rebecca Doyle, Children's Health Queensland and The University of Queensland
14:50 – 15:05	Applying inclusive recruitment and consent practices to include people with aphasia in research: a case example Renee Clapham, Speech Pathology Dept, St Vincent's Hospital, Melbourne
15:05 – 15:20	Deferred consent in neonatology Amir Zayegh, Neonatologist, Women's Hospital
15:20 – 15:30	**Afternoon break**
15:30 – 17:00	**Privacy training** *Chairperson: Gordon McGurk* SalingerPrivacy
	Privacy essentials for HRECS Delivered by Andrea Calleia, Director of Learning, Salinger Privacy
17:00	**Close**

Day 3 – Friday 1 December 2023

All times in AEST (QLD)

08:00 – 09:45	**Inclusion and Diversity** *Chairperson: Natasha Roberts*
08:00 – 08:45	Inclusion, diversity and lived experience Philomena Horsley, PRAXIS Australia
08:45 – 09:15	TBC Maree Toombs, University of Sydney
09:15 – 09:45	Marginalisation in research Scott Walsberger, Manager Cancer Programs, ACON
09:45 – 10:00	**Morning break**
10:00 – 11:00	**Legislation (Stream 1)** *Chairperson: Gordon McGurk*
10:00 – 10:20	Researching traumatic experiences: vicarious trauma inside academia and the ethics of care Jennifer Smith, Central Queensland University
10:20 – 10:40	Navigating identity and integrity: exploring the intersection between gender diversity, research ethics and legislation Leonie Crosse, University of Tasmania Human Research Ethics Committee
10:40 – 11:00	Deciphering the complex interplay between voluntary assisted dying legislation and research ethics – a new tool for researchers Enna Stroli-Salama, QVAD Support and Pharmacy Service
	Parallel session
10:00 – 11:00	**Clinical trials (Stream 2)** *Chairperson: TBA*
10:00 – 10:20	Beyond the form: engaging with participants throughout clinical research Gudrun Wells, CT:IQ
10:20 – 10:40	Improving the capture and reporting of adverse events in clinical trials of non-pharmacological interventions: a PaCCSC/CST initiative Celia Marston & Ann-Marie Hoise
10:40 – 11:00	The Australian Teletrial Program – bringing clinical trials closer to home Sara Hubbard, Research Governance Officer, QRCCC
11:00-11:30	**Morning tea**
11:30-12:30	**Plenary** *Chairperson: Gordon McGurk*
	Artificial intelligence and HRECs – development of guidelines for review of artificial intelligence projects by HRECs Lyle Palmer, Professor of Genetic Epidemiology
12:30 – 13:00	**Lunch**
13:00 – 14:00	**Data and data sharing** *Chairperson: TBC*
13:00 – 13:20	'Caught in a loop': ethics and research governance of an interagency cross-jurisdictional suicide prevention data linkage study

	Carla Meurk, Queensland Centre for Mental Health Research
13:20 – 13:40	A national program set to accelerate research through data sharing Angela Webster, HeSANDA SHP-CTC Node
13:40 – 14:00	Ethical considerations are poorly reported in individual participant data meta-analyses (IPD-MA) Nigel Armfield, The University of Queensland
	Parallel session
13:00 – 14:30	**HREC coordinator session** For all HREC coordinators and administrators This year the session will include a presentation on indemnity and a workshopping session on translating the National Statement updates from Sections 2 and 5 into processes. This will focus on low risk and exempt from review applications. This session will be run concurrently with the Data and data sharing abstract session.
14:30	**Close**

Abstracts & biographies

09:00 – 10:00	Plenary session	Wednesday 29 November

Approving the approvers: the theory and practice of monitoring ethics committees

Monique Jonas

Associate Professor Health Systems

University of Auckland, New Zealand

Abstract

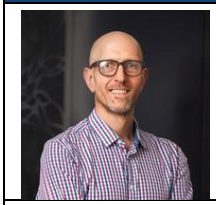
Norman Daniels and James Sabins' model of procedural justice, Accountability for Reasonableness, contains a requirement that decision-making processes, and the bodies that enact them, are subject to regulatory oversight. In Aotearoa New Zealand, the role of approving ethics committees has fallen to the Health Research Council Ethics Committee (HRCEC). It is a role that gives rise to challenging and important questions about how quality of ethics review ought to be judged, and how best to promote high standards of ethics review. In this session, Monique Jonas, the current chair of the HRCEC, will share experiences of undertaking this work and lead a discussion about how ethics committees should be regulated and audited.

Biography

Monique Jonas is an ethical theorist specialising in health care ethics; distributive justice in health; the relationship between the family and the state; and the ethics of advising and decision-making for children.

She studied English and Politics as an undergraduate and was drawn to political philosophy and ethical theory. That sparked her interest in moral status and decisions at the beginning of life. In 2005, she completed her PhD at Kings College London, exploring ethical aspects of decision-making for neonates under the supervision of Professor Jonathan Glover. Monique began her academic career working as a research assistant for Professor Søren Holm at Manchester University, and then as a lecturer at the Centre for Professional Ethics at Keele University. Since returning to the University of Auckland in 2010, Monique's research has focused on parental decision-making, the status of health advice, and the ethics of advice giving. She enjoys working in a multi-disciplinary environment in the School of Population Health.

10:30 – 11:00	AI and social media	Wednesday 29 November



Revolutionising clinical trial recruitment: unleashing social media's power

Duncan Colyer

VCCC Alliance

Abstract

Recruitment in clinical trials remains problematic. Social media has been heralded as an antidote to this problem, using its reach and power to counter the negative effect of lagging studies. However, its full utilisation has not lived up to the expectation. This project aimed to investigate the area and support researchers in realising and implementing the opportunities that social media can bring.

An initial scoping exercise was undertaken by the VCCC Alliance which demonstrated that current guidance on the use of social media in a research context failed to address the needs of both researchers and HRECs. Addressing this gap was key to providing confidence to researchers and streamlining HREC approvals.

Working with subject matter experts, the respective requirements were defined and resources developed. Guidance explained how to best create content appropriate for potential participants and acceptable for regulatory approval.
The resulting suite of guidance documents includes a dedicated webpage, an FAQ document, guidance procedures and resources that focus on both commercially sponsored and investigator initiated studies. These are freely available and have been promoted through various fora, with feedback requested. Updates will be provided at the time of the conference.

Biography

Duncan Colyer (BN, Grad Cert in Cancer Care) is a Senior Manager Clinical Research at the VCCC Alliance. Initially training as a nurse and working in Western Australia, he went to Oxford, UK, in 2007 where he commenced his career in clinical trials. Returning to Australia in 2010, he has worked at the Peter MacCallum Cancer Centre as a Senior Research Nurse and Team Leader before changing his career to Program Management at the VCCC Alliance, focusing on clinical research. Duncan currently oversees the Programs of Clinical Trial Innovations and Accelerating Novel Therapies.

11:00 – 11:30	AI and social media	Wednesday 29 November

View of apps as TGA regulate in trials (issues to consider)

Peter Keller

Research Manager, The Royal Victorian Eye and Ear Hospital

Biography

Peter is a clinical research professional with 35 years of experience across various and overlapping roles as a clinician, clinician-researcher, educator, clinical research organisation executive and government regulator. His expertise has been developed across private and public sectors, in academic, professional service organisation, government and industry settings.
Peter most recently developed and implemented the Good Clinical Practice (GCP) inspection program for the Therapeutic Goods Administration (TGA) and has a deep understanding and practical knowledge of clinical research, good clinical practice, the legislative framework for clinical trials, and research integrity. He has a long standing interest in research quality and integrity, and is an Honorary Principal Fellow at the University of Melbourne where he continues his research in evidence-based practice and research translation, as a founding member of a Cochrane Centre for Evidence-Based Vision Care.

11:30 – 12:00	AI and social media	Wednesday 29 November

Development of Guidelines for review of AI projects by HRECs

Lukah Dykes

Managing Director - HeartAI

Abstract

Contemporary approaches with digital systems, data processing and artificial intelligence are continuing to change the way that projects using these technologies should be assessed by HRECs. In many cases, potential access to large amounts of health data, high-throughput ways of processing data, and increasing use in clinical practice has necessitated a rethink of appropriate review and governance in these settings.

This presentation will explore this from 2 perspectives. First, how can HRECs assess these systems with consideration of the potential risks and benefits. This will include how complementary organisational policies may inform and be involved with these processes, such as digital systems, medical devices, IT, information security, and cybersecurity policies. Second, the technologies themselves will be discussed, considering key areas including AI system implementation, roles and responsibilities, secure use of data, management of (sub-)population biases, causal thinking, and ongoing logging, monitoring and auditing.
These approaches will be considered in the greater governance landscape with reference to state and national initiatives, together with guidance for how these could be introduced into HREC guidelines.

Biography

Lukah is an analyst, computer scientist and software engineer with a primary focus in artificial intelligence and integrated health systems. His current work explores digital systems implementations to support clinical care and service innovation through the operationalisation of health care data and information. These approaches utilise best practices in both high-performance analytics and computational systems engineering.
Through his role as Managing Director of HeartAI Pty Ltd he has developed a modern data and analytics platform that is currently operational within the South Australian health system. This platform provides data integration across many primary health data sources and consolidates these resources for data and analytics use-cases. The microservices data mesh capabilities of this environment can support high-throughput data streaming, reconciliation across varied data sources, and operational reliance in mission-critical contexts. These abilities are further extended with state-of-the-art artificial intelligence methodology including probabilistic modelling and variational methods.
HeartAI has been deployed to support SA Health initiatives including CALHN Critical Care Informatics System and the SA Virtual Care Service, providing real-time data and information, situational awareness, and modern predictive analytics. The HeartAI team hopes to develop as core service providers in partnership with the health care system, academia, industry and the greater community.

12:15 – 12:45	Effective use of data	Wednesday 29 November

Using ‘synthetic data’ to enable use of health information

Jason Pole
The University of Queensland

Biography

Jason D. Pole is the Deputy Director of the Queensland Digital Health Centre (QDHeC) and a Professor in the Centre for Health Services Research (CHSR) within the Faculty of Medicine. Jason provides academic and research leadership within QDHeC. Relocating from Toronto, Canada in early 2020, Jason's program of research utilises clinical and surveillance data linked with real-world administrative data to answer health questions in several areas.
Jason has a background in epidemiology, health services research and digital health with an emphasis in the use of real-world data and complex survey instruments.

12:45 – 13:15	Effective use of data	Wednesday 29 November

ONDC Data Act update

Gayle Milnes
National Data Commissioner

Biography

As National Data Commissioner, Gayle is responsible for overseeing a new, best practice scheme for sharing Australian Government data and fostering best practice data handling and sharing.
Gayle has held a range of senior leadership positions across the Australian Public Service with the Departments of Infrastructure, Transport, Regional Development and Communications, the Environment, and Foreign Affairs and Trade; and as CEO of the Climate Change Authority. In these roles she has driven nationally significant reforms, strengthened enterprise data governance and management and been an avid data user across a range of sectors.

13:15 – 13:45	Effective use of data	Wednesday 29 November

Secondary data in research: confusing ethics reviewers and applicants alike

Paula Swatman
University of Swinburne

Abstract

While the National Statement provides what appear to be very clear guidance on handling secondary data in ethics applications, this area is one which leads to confusion and frustration for both applicants and reviewers, for multiple reasons including:

- Applicants who requested only ‘specific’ data use for their study cannot understand why they must now submit an application for a waiver of consent to re-use their ‘very own data’.
- Applicants who have a consent form from participants in a prior study can become very frustrated when HREC points out the consent provided is not broad enough (or, worse, is too broad – as with many social media apps) to support a secondary data application.
- Applicants (and some reviewers) become confused over the distinction between a ‘waiver of consent’ and ‘exemption from ethical review’.

This presentation will attempt to clarify some of the tangled issues associated with secondary data studies, using anonymised examples of real questions from both applicants and reviewers – but is really an open forum for conference attendees to discuss the problems associated with reviewing secondary data applications. Attendees are therefore encouraged to bring along their own examples of such queries for discussion and enlightenment.

Biography

Professor Paula Swatman has been an Information Systems academic since 1988 and has worked in ICT and e-Business for 25 years, holding Chairs in both Australia and Germany. After retiring from full-time academic life at the end of 2009, Paula and her husband moved to Tasmania’s Huon Valley, where they now breed Santa Gertrudis cattle on their small farm.

14:15 – 15:45	Contemporary ethical considerations	Wednesday 29 November

HREC judicial review

Rebekah McWhirter

Senior Lecturer, Deakin University

Biography

Dr Rebekah McWhirter is a senior lecturer in health law and ethics at the School of Medicine at Deakin University. Her research interests include ethical and legal issues in health and health research, Indigenous genetics, and empirical research methods in ethical and legal research. She completed her PhD at the University of Tasmania on the history of compulsory vaccination legislation, and has a MSc in Public Health Research from the University of Edinburgh, investigating genetic risk factors for multiple sclerosis in the Orkney and Shetland Islands.After working at the Menzies School of Health Research in Darwin and the Menzies Institute for Medical Research on a range of cancer genetics projects, Rebekah joined the Centre for Law and Genetics, and retrained in law at the University of Melbourne and the ANU. Her work now brings together her multi-disciplinary experiences to focus on how the law can be used to improve public health and health research.

14:45 – 15:15	Contemporary ethical considerations	Wednesday 29 November

The role and remit of the National Statement – guidebook vs rulebook

Rob Loblay

University of Sydney

Biography

Dr Loblay is a clinical senior lecturer in the Central Clinical School at the University of Sydney.

15:15 – 15:45	Contemporary ethical considerations	Wednesday 29 November

Genomics, Human Research Ethics Committees and waivers of consent

Lindsay Newett

Research Fellow, National Centre for Indigenous Genomics

Abstract

Genomics is a field of research that centres on the study of the genome. It is facilitated by technological advancement and a culture of data sharing. While genomics presents opportunities to improve our knowledge and treatment of health conditions and diseases, it also presents new challenges. One such challenge pertains to how decisions regarding this type of research are made. Within the Australian context, HRECs have a key role in determining whether, and how, genomic studies are undertaken. As part of this, HRECs often need to decide if genomic data can be obtained, and used by researchers without the express consent of donors. When making decisions of this nature, HRECs are guided by criteria set by the National Health and Medical Research Council (NHMRC) in the

National Statement on the Ethical Conduct in Human Research (National Statement) (2007, updated 2018).
The circumstances in which a HREC may authorise a waiver of consent in relation to genomic research are provided in chapter 3.3. of the National Statement. These differ to the criteria provided in chapter 2.3, which are utilised by HRECs to grant waivers in relation to projects that fall outside of genomics. We were interested in exploring how members of the Australian public felt about these latter criteria, within the context of genomic data sharing. Specifically, we sought to explore the extent to which Australians would trust HRECs to make decisions on their behalf, when these criteria were employed, and when research involved genomic data. This presentation will outline results from the survey (N = 3013) we undertook to do this, and show that some circumstances – not currently considered by HRECs – appear to be conducive to public trust within the context of genomic data sharing.

Biography

Lyndsay Newett is a former Research Fellow at the University of Tasmania's Centre for Law and Genetics. She contributed to projects concerning technology, public health, ethics, and genomics at this institution while completing her PhD in sociology. She is now a Research Fellow at the National Centre for Indigenous Genomics, located at the Australian National University.

16:00 – 16:20	The value of lived experience	Wednesday 29 November

Deterioration of health-related quality of life: The hidden health burden of informal caregiving

Syed Afroz Keramat
The University of Queensland

Abstract

Objectives: Informal carers are individuals who provide unpaid informal care to a sick or disabled person within the context of an existing relationship. Informal caregiving is often physically and mentally demanding and may lead to poor health and impaired wellbeing. This study aims to check the impact of informal caregiving on health-related quality of life.
Methods: We utilised longitudinal data from the most recent 16 waves of the Household, Income and Labour Dynamics in Australia (HILDA) survey. This study measured health-related quality of life (HRQoL) through the physical component summary (PCS), the mental component summary (MCS), and the short-form six-dimension utility index (SF-6D). The primary exposure variable is informal caregiving. The variable was categorised into no caregiving, lighter (<5 hours/week), moderate (5-19 hours/week), and intensive caregiving (≥ 20 hours/week) based on the hours of providing care per week. We fitted longitudinal fixed-effects regression models to estimate the effects of informal caregiving on health-related quality of life (HRQoL).
Results: We have found that informal caregiving negatively affects HRQoL. More specifically, lighter (β = -0.003, 95% CI: -0.005 - -0.001), moderate (β = -0.005, 95% CI: -0.007 - -0.002), and intensive caregiving (β = -0.010, 95% CI: -0.014 - -0.006) significantly reduced SF-6D utility value. Our results also showed that moderate (β = -0.61, 95% CI: -0.86 - -0.36) and intensive (β = -1.75, 95% CI: -2.15 - -1.35) caregiving lowered MCS score after adjusting covariates.
Conclusion: Our study findings have significant policy implications for enhancing the HRQoL and wellbeing of the carers. Some ways to protect the health and wellbeing of informal carers include helping them balance caregiving with work and personal life, providing financial support and social security, giving access to community-

based services, giving access to information and training, and provision of respite care.

Biography

Dr Syed Afroz Keramat is a Research Fellow (health economist) at the Centre for Health Services Research (CHSR), The University of Queensland. He holds a PhD in health economics from the University of Southern Queensland and master's degrees in economics from the University of Warwick (UK), Lund University (Sweden), and Pavia University (Italy). Dr Afroz's primary fields of research encompass health economics, public health, health services research, and health technology assessment. He possesses significant expertise in utilising longitudinal data to provide an evidence base for research and to inform health policy. He has published over 40 peer-reviewed journal articles (including 17 first-authored) over the last 5 years. Several awards, such as the 2022 and 2021 UniSQ HDR Publication Excellence Awards, demonstrate his capacity to undertake high-quality research. His research works have received international media attention. For example, his research findings were featured in The Chronicle and PharmacoEconomics & outcome news. At present, he holds the position of Associate Editor for the esteemed academic journals BMC Public Health and PLoS ONE.

16:20 – 16:40	The value of lived experience	Wednesday 29 November

Advancing video-ethnographic research in health care: challenges, lessons learned and implications for practice

Mila Obucina

Griffith University

Abstract

Researchers studying organisational and cultural practices often use qualitative methods to answer the 'why' and 'how' of some of the most persistent health care issues today (Hayre et al., 2022). While different types of qualitative designs exist (Renjith et al., 2021), there has been renewed interest in the use of ethnographic research in health, recognised for its potential to 'capture context-specific phenomena, understand insiders' perspectives and study complex interactions' (Gertner et al., 2021).

Ethnographic observations are real-world orientated, explicitly considerate of context, nonlinear, iterative and emergent (Faro et al., 2022). They focus on understanding how people make sense of their surroundings, and how this in turn shapes their behaviour and actions (Asan & Montague, 2014; Atkinson, 2007; Dixon-Woods, 2010). Ethnography often deploys multiple data collection methods, including collecting fieldnotes, conducting in depth interviews, performing document analysis and doing video observations (Marshall & Rossman, 2016). One more recent extension to ethnographic research in health care practice has been the use of video-reflexive ethnography, a 'specific approach focused on observing and reflecting on unspoken, informal and tacit knowledge that exists in care delivery' (Pope & Mays, 2020).

In this presentation, we briefly describe a recent video-reflexive ethnographic study conducted at Gold Coast Health. This study explored the implementation of an antibiotic prescribing app in the Emergency Department and the clinical communication in the process. We detail some of the challenges faced, and lessons learned.

Acknowledging the intricate process involved in obtaining ethical approvals for video-based research, we discuss some common obstacles from both researcher and institutional perspectives and provide recommendations for future research

endeavours. Striving to showcase a potential for an equilibrium, we continue to call for broader acceptance and integration of such methodologies in medical research.

Biography

Mila is an early career researcher with background in health services management and qualifications in economics, applied management, innovation, and most recently, implementation science. Her current research focuses on program evaluation using implementation science frameworks and models, an area which is rapidly becoming complex. Additionally, she has particular interest in developing communities of practice, implementation practitioner role competencies and studying the quality of research practice in health care organisations. Her PhD examined the use of video-observational methods to evaluate implementation fidelity of an antibiotic prescribing app in hospital emergency departments. Mila contributes to several committees, including being a co-chair of the Emerging Researcher Alliance (ERA) at Gold Coast Health that she helped establish, as a member of the Diversity and Inclusion Committee at Griffith University Business School, and internationally as a founding member of the Standards Committee of the Global Implementation Society.

16:40 – 17:00	The value of lived experience	Wednesday 29 November

Exploring the association between physical activity levels and healing outcomes among individuals with venous leg ulcers: a secondary analysis

Shirley Qiu

University of Technology Sydney

Abstract

At the time of the COVID-19 pandemic, secondary data analysis has emerged as a compelling methodology. In contrast to traditional primary data collection, which demands substantial resources and time investments, secondary data analysis offers a strategic avenue for researchers to extract novel insights from pre-existing datasets. This proves especially advantageous for researchers planning to conduct investigations at the time of a pandemic, when research funds are limited and health care facilities impose restrictions on the number of primary studies.

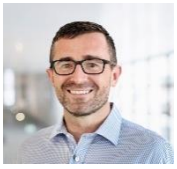
However, the utility of secondary data analysis is not without its complexities. Researchers need to navigate issues pertaining to ethics, context, and potential biases inherent in the original data collection process. Ethical approval must be obtained from the primary investigation site, and researchers also need to ensure that the consent obtained from study participants aligns appropriately with the future research utilisation of the data.

Our prior comprehensive review revealed a notable gap in the existing research literature, specifically the lack of exploration into whether characteristics of physical activity (e.g. intensity and level etc.) impact venous leg ulcer healing. This information is vital for the development of an effective exercise programme. However, due to the impact of the COVID-19 pandemic, the originally planned pilot randomised controlled trial became unfeasible. To explore the correlation between physical activity levels and outcomes related to venous leg ulcer healing, we conducted a secondary analysis of data from the multicentre observational cohort study that explored factors influencing venous leg ulcer healing and recurrence. This cohort study employed self-reported questionnaires to gather information on the participants' nutrition, medication usage, sleeping pattern and physical activity. The results of our study indicate that individuals with venous leg ulcers who engage in higher levels of physical activity experience shorter periods of ulcer healing and have an improved quality of life.

Biography

Dr Shirley Qiu is a Lecturer at the University of Technology Sydney (UTS). She earned her PhD from Monash University in 2023, with a research focus on venous leg ulcers and physical activity interventions. Her current research projects investigate the potential benefits of physical activity as an adjunct treatment for managing venous leg ulcers alongside compression therapy. In addition to her academic work, Dr Qiu has worked as a registered nurse in various health care settings, including acute medical, palliative care, and operating suites, for over 9 years in Victoria, Queensland and Tasmania.

17:00 – 17:20	The value of lived experience	Wednesday 29 November



Queer people, criminalisation, pathologisation and the ethics of health and medical research

James Allen

Biography

James Allen completed the combined bachelor's degrees in medicine, surgery and law at Monash University. He is a Fellow of the Australasian College of Legal Medicine; an Associated Fellow of the Australasian College of Health Services Managers; a Fellow of the Royal Australian College of General Practitioners and a Council Member for AMA Queensland. James is a director of the Orbona Foundation – an NGO preventing harm to LGBTIQASB+ children and youth. In Roman mythology, Orbona was the goddess of abandoned children. For the past 19 years he has worked across Kimberley, Pilbara and remote Queensland supporting some of the most marginalised and invisible populations. In 2021, 2 of his young gay male patients died from suicide within 2 months of each other. He advocates that identifying and addressing unconscious bias in research, and understanding the unique ethical consideration relevant to Queer People, is fundamental to addressing disparate health outcomes. He is extremely grateful to have the opportunity to raise awareness and build understanding of this important health equity matter.

08:00 – 08:20	Consumers	Thursday 30 November

What is the place of consumers in HRECs

Ian Tindall

Chair CALHN HREC at SA Health

Abstract

Until recently, consumer voices and those with lived experience of the health system have not been heard in human research. Now guidance from the NHMRC outlines how these voices should be heard. Consumers of research are not the only voices though. What should HRECs consider in relation to the consumer voice?

Biography

Ian Tindall is currently the Chair of the Central Adelaide Local Health Network HREC at SA Health. This is a professional Chair position and encompasses a large part of the human research effort in South Australia. Ian is a qualified pharmacist by profession and has been involved in all aspects of pharmaceutical clinical trials for more than 30 years. Ian was first was involved in the Ashford Hospital HREC in the early 1990s and then was the inaugural Deputy Chair of Bellberry in the early 2000s. He has also been a RAAF Reservist for 25 years and was the Chair of the Defence and Veterans HREC for 7 years.

08:40 – 09:00	Consumers	Thursday 30 November

Supporting Ethics Committees to amplify consumer and community involvement in health and medical research

Brian Dalton & Carrie Hayter

Sydney Local Health District (SLHD) Ethics Committee Consumer (Lay Person)Consumer Engagement Manager, Health and Medical Research Health Consumers NSW

Abstract

Consumer and Community Involvement (CCI) in health and medical research (HMR) improves the design, recruitment, conduct and translation of research outcomes for consumers and the health system. CCI should be an active partnership between consumers and researchers where consumers are involved in all phases of the research process. The National Health and Medical Research Council's (NHMRC) 'Statement on consumer and community involvement in HMR' recognises that appropriate consumer involvement in research should be encouraged and facilitated by researchers and research organisations. Furthermore, it is a key requirement of HMR grant funding through the NHRMC, the Medical Research Futures Fund (MRFF) and the National Clinical Trials Governance Framework.

While there is this recognition for the importance of CCI in HMR, ethics committees have essentially been left alone to determine how to assess CCI in research. The workshop will provide some effective and practical tips and resources for ethics committees and also highlight the work of Health Consumers NSW in supporting CCI in HMR. In this workshop we will explore:

- What should an ethics committee be looking for in a clinical trial research proposal that demonstrates good CCI practices?
- What infrastructure is needed to support ethics committees in supporting good CCI in HMR?

Biography

Brian brings a diverse and complementary set of skills and competencies built up over more than 30 years fostering the consumer in the health, for purpose (social/community services) and for profit sectors. He has 'lived experience' of the health and aged care systems, as well as experience as a consumer representative member of advisory committees in public/private health care settings, HRECs, tertiary institutes and with NSW Health. Brian is passionate about championing the consumer voice to foster a cultural shift that elevates consumer involvement from basic consultation to consumer-leadership (empowerment), opening the way for more collaborative practice, co-design and integration into decision-making that results in better patient-centred health care models.

Carrie has over 30 years of experience working alongside older people, people with disabilities, and health consumers to improve their involvement in research and the design of services. Carrie has degrees in social work and economics. Before joining Health Consumers NSW, she worked with a diverse range of consumer organisations, and not-for-profit and government organisations across health, aged care and disability services in Australia. Carrie's vision is for consumers, researchers and practitioners to work collaboratively to improve the involvement of consumers and the community in all health and medical research in Australia.

09:20 – 10:00	PRAXIS Plenary	Thursday 30 November

Diversity in research: Inclusion imperatives

Jackie Leach Scully

University New South Wales

Abstract

The language of greater diversity and inclusion is now ubiquitous in health research, but actually putting these principles into practice is still novel and often problematic. The inclusion of anything beyond the notional 'ideal subject/participant' will often require modification of long established practices, especially related to consent. In this talk I'll start by considering how the National Statement attempts to approach diversity through its current Section 4, before focusing more on research with people with disability, including intellectual disability, and the issues that inclusive and co-produced research present for HRECs.

Biography

Jackie Leach Scully is Professor of Bioethics and Director of the Disability Innovation Institute at the University of New South Wales. After some years in biomedical research she helped establish the first interdisciplinary bioethics unit at the University of Basel, Switzerland, before returning to the UK to join the Policy, Ethics and Life Sciences Research Centre at Newcastle University. She joined UNSW in late 2019, just in time for bushfires, floods and COVID. Among other activities she is a member of the Australian Health Ethics Committee, chairs the New South Wales Health Ethics Advisory Panel, and is on the Board of the National Disability Research Partnership.

10:15 – 10:35	Clinical trials	Thursday 30 November

Psychedelic clinical trials: prescription vs legislation – Important things for HRECs to look for

Ian Tindall

Chair CALHN HREC at SA Health

Abstract

From 1 July this year, medicines containing the psychedelic substances psilocybin and MDMA (3,4-methylenedioxy-methamphetamine) can be prescribed by specifically authorised psychiatrists for the treatment of certain mental health conditions. To prescribe, psychiatrists will need to be approved under the Authorised Prescriber Scheme of the TGA following approval by a HREC. How should a HREC deal with the responsibility and risk that this TGA decision places upon it?

Biography

Ian Tindall is currently the Chair of the Central Adelaide Local Health Network HREC at SA Health. This is a professional Chair position and encompasses a large part of the human research effort in South Australia. Ian is a qualified pharmacist by profession and has been involved in all aspects of pharmaceutical clinical trials for more than 30 years. Ian was first was involved in the Ashford Hospital HREC in the early 1990s and then was the inaugural Deputy Chair of Bellberry in the early 2000s. He has also been a RAAF Reservist for 25 years and was the Chair of the Defence and Veterans HREC for 7 years.

10:35 – 10:55	Clinical trials	Thursday 30 November

RCTs the gold standard: what do we need to know

Kelvin Robertson

Pharmacy Director, Townsville Hospital and Health Service

Abstract

The presentation aims to provide a comprehensive understanding of RCTs, with a focus on FIH trials, and will discuss randomisation, control group, and blinding. Ethical concerns in RCTs, such as ensuring voluntary participation and minimising harm, will also be addressed as will common challenges in conducting RCTs, such as patient recruitment and follow-up.

In addition, the session will explain the role of the ethics committee in reviewing RCT protocols, including assessing ethical considerations.

The presentation will also cover defining FIH trials, including safety assessment, dose determination and initial efficacy; and adaptive ethics in FIH trials.

Biography

Dr Robertson is a distinguished professional in the field of health care and pharmaceuticals. With a solid educational background, including a Bachelor of Pharmacy, a Masters in Clinical Trials Research, and a PhD in Pain Medicine, Dr Robertson has demonstrated a commitment to advancing medical knowledge recognised and is a fellow of the Society of Hospital Pharmacists and Consultant of the Australian and New Zealand College of Advanced Pharmacists.

Dr Robertson's contributions extend beyond academia. Serving as a current Director of Pharmacy and having previously chaired the Townsville Ethics Committee, Dr Robertson has played pivotal roles in health care management and ethics. Furthermore, Dr Robertson's dedication to research is evident through numerous peer-reviewed publications, including Randomized Controlled Trials (RCTs). As a mentor, Dr Robertson nurtures the next generation of scholars, supervising PhD, Masters and Honours students.

10:55 – 11:15	Clinical trials	Thursday 30 November

Adaptive platform trials: introducing PLATIPUS

Clare Whitehead

The Royal Women’s Hospital, Melbourne

Biography

Clare is an obstetrician combining subspecialty Maternal Fetal Medicine training with translational research at the Royal Women’s Hospital. She is also a Senior Research Fellow, in the University of Melbourne Department of Obstetrics & Gynaecology. Her research combines bench side development of protein and genetic markers to monitor placental function with their evaluation in the clinic in combination with clinical, ultrasound and novel MRI techniques. Another current research focus is the Impact of COVID-19 on pregnancy. Her research career has been supported by a NHMRC Neil Hamilton Fairley Clinical Research Fellowship.

11:15 – 11:35	Clinical trials	Thursday 30 November

A-CTEC: a national educational platform to professionalise the Australian clinical trials workforce

Eman Nafea, MPharmSci, MHM, PhD

Director, Australian Clinical Trials Education Centre (A-CTEC)

Abstract

The need for high-quality and easy to access clinical trials education is crucial for the Australian workforce, supporting the requirements of the National Clinical Trials Governance Framework and growth of the clinical trial sector. Current trials education offerings vary in quality, accessibility and cost.

Supported by the Victorian Research Translation Centres, the Australian Clinical Trials Education Centre (A-CTEC) was established to address this need for the clinical trial site workforce and build capacity, particularly in regional areas. A-CTEC is a not for profit, Australia-wide education centre with a dedicated Learning Management System (LMS) hosting a suite of evidence-based, interactive education opportunities, enabling all clinical trial professionals to access high-quality, world-class training at no cost.

Working towards professionalisation of the Australian clinical trials workforce, A-CTEC has collaboratively developed national competency frameworks customised to essential roles involved in running and overseeing clinical trials including research office staff (ethics and governance) and clinical research operations teams.

A-CTEC's multi-modal offerings cater to the various levels of experience and role competency of the clinical trials workforce and are relevant to the needs of different trials settings across metropolitan, regional, and rural Australia. A-CTEC aims to address the education and training needs of all site staff (e.g. research coordinators and nurses, investigators, pharmacists, ethics and governance officers, clinical and non-clinical research staff) involved in clinical trials from hospital, community health and university settings, and any location where clinical trial research is undertaken.

With more than 3,200 current users (and still expanding), it is envisioned that A-CTEC will advance clinical trials education rapidly in Australia, meeting the needs of staff and sites into the future. The long-term aim is for A-CTEC to become recognised globally as a leader in clinical trials education and training.

Biography

With nearly 20-year experience in academia, translational research, and clinical research education, Eman's current focus is on enhancing clinical research quality through competency-based education and training. Her projects aim to build workforce capacity and capability in the clinical research industry in Australia. Eman has been leading clinical trials education and training in Victoria before establishing the first Australian Clinical Trials Education Centre (A-CTEC) with the support of the Victorian Research Translation Centres Collaborative.

12:45 – 13:00	Workshop	Thursday 30 November

Research ethics committees in post-pandemic era: A call for a universal registration and accreditation platforms

Ehsan Shami Gooshki

Monash University / Member of WHO ethics review committee

Abstract

Post World War II, Research Ethics Committees (RECs) emerged following the Declaration of Helsinki. Influenced by the US National Research Act, the Belmont Report, scientific journals and international entities like WHO, RECs became an integral global research fixture. However, REC efficacy has faced enduring critique

over effectiveness, consistency, workflow efficiency and real-world impact. The COVID-19 pandemic stress-tested biomedical research systems, including RECs. Despite post-Ebola calls for ethical preparedness and streamlined facilitated review, it's evident that the present research ethics setup is insufficient for swift responses to global health emergencies, particularly in conducting widespread global and multi-country clinical trials as stressed in the recent World Medical Assembly resolution. Challenges in conducting such trials and widespread research misconduct in reporting outcomes accentuate the pressing need for novel problem-solving mechanisms.

Building upon the precedent experience of implementing global platforms for registering human clinical trials on platforms like clinicaltrials.gov and ICTRP registries, my study advocates for the creation of parallel global platforms to register and accredit RECs. This platform would also index their approvals which could be connected to the global scientific publishing system. I highlight a comparable system implemented in a specific country. This approach aims to enable comprehensive tracking of research from its inception, enhancing REC accountability. This proposed system not only lays the foundation for global research ethics oversight and REC governance but also streamlines the execution of international clinical trials. The basis for my endorsement of this system rests on the premise that, unlike contentious medical ethics dilemmas like abortion and euthanasia, the majority of research ethics standards enjoy widespread acceptance and consensus within the scientific community.

Biography

Dr Ehsan Shamsi Gooshki, a certified medical doctor, made a significant shift in his career toward biomedical ethics. Over the course of 2 decades in the field of bioethics, he embarked on a remarkable journey, engaging in the realms of education, research, and governance at local, national, regional, and global echelons.

His professional trajectory includes a succession of roles: a policymaker in health and research ethics, an associate professor, a clinical ethics consultant, and a dedicated member of research and clinical ethics committees. Throughout these roles, he has diligently applied the principles of bioethics across various facets of the health care system. His endeavours have earned him international recognition for pioneering innovative platforms aimed at implementing bioethics, yielding measurable positive impacts on the healthcare landscape. Notably, he spearheaded the establishment of novel national frameworks for research, clinical practice, professional conduct, and public health ethics in Iran before embarking on his journey as a lecturer at the Monash Bioethics Centre.

The onset of the COVID-19 pandemic presented a unique juncture in which he assumed the role of an ‘insider ethicist’, playing a pivotal role in shaping the national response to this unprecedented crisis.

Ehsan’s global perspective in bioethics germinated during his international forays in 2010 at Monash University. His global footprint continued to expand through lecturing engagements at numerous national and international workshops and conferences. He made substantial contributions to UNESCO and WHO programs and furthered his expertise with visiting research fellowships at the Institute of Biomedical Ethics at the University of Zurich and the Kennedy Institute of Ethics at Georgetown University in Washington D.C.

Since 2018, Dr Shamsi Gooshki has been appointed by the Director-General of UNESCO as a distinguished member of the International Bioethics Committee (IBC), where he was subsequently elected as Vice-Chair in 2023. In 2020, his stature in the field was further affirmed when the Director-General of WHO appointed him as a member of the WHO Ethics Review Committee. He has actively participated in

several WHO working groups, notably the Ethics and COVID-19 Working Group. Notably, he is the lead author of the inaugural WHO guideline on clinical ethics, a pioneering document currently under development.

13:10 – 13:25	External influences on HRECs	Thursday 30 November

HeSANDA – HREC approval for data sharing

Kristan Kang

Australian Research Data Commons

Abstract

As part of its Health Studies Australian National Data Asset (HeSANDA) program, the Australian Research Data Commons (ARDC) has been working with the Australian clinical trials community to develop national standards and infrastructure for sharing data for secondary research. In partnership with 72 Australian organisations, it launched the Health Data Australia in July - an online platform for researchers to find and request access to clinical trials data. The platform makes it easier for researchers to connect and collaborate using existing trial participant data while leaving the governance and ethical management of data at the control of the chief investigator. Despite the platform not holding any data itself, the increased researcher interest in data sharing, collaboration, and the technologies that support them has implications for HRECs. In this talk you will hear about this national initiative and its progress to date - including its partnership with CT:IQ's InFORMed project to develop a PICF template and user guide to help researchers obtain consent for data sharing. You will also hear about planned work to develop guidance for ethical approval for data sharing.

Biography

Dr Kristan Kang is the Senior Research Data Specialist (Health & Medical) at the Australian Research Data Commons (ARDC) and the manager of the Health Australian National Data Asset (HeSANDA) program. Kristan's expertise is built on 2 decades experience working in academic research and teaching, health research management, data management, and infrastructure development. At ARDC, Kristan oversees the design and delivery of the infrastructure programs, manages stakeholder and partner engagement, and provides strategic advice to ARDC regarding the direction of the HeSANDA program and other investments into health and medical research infrastructure.

13:25 – 13:40	External influences on HRECs	Thursday 30 November

Authorised prescriber

Robyn Langham

Nephrologist

Biography

Professor Langham is Head of School of Rural Health at Monash University, a nephrologist and medical researcher. A clinician researcher, she has worked on the area of fibrosis in human renal disease, translating basic research findings into drug development opportunities. Professor Langham has had a distinguished career as a medical specialist, and is recognised nationally and internationally for her leadership capabilities, as past President of the ANZSN and also through roles with the

Australian Medical Association, Kidney Health Australia and the International Society of Nephrology.

13:40 – 13:55	External influences on HRECs	Thursday 30 November

Authorised prescriber scheme and psychedelic medicine

Hudson Birden and Kelly Parker

Abstract

Effective July 2023, the Therapeutic Goods Administration (TGA) permits psychiatrists to engage in therapies using MDMA (3,4-methylenedioxy-methamphetamine) for the treatment of post-traumatic stress disorder, and psilocybin for people with treatment-resistant depression where first-line therapies have failed. TGA requires that a HREC approve each therapist's application. The Townsville University Hospital and Health Service HREC has received several applications for psychedelic prescription and has been in the process of developing criteria by which to review such applications. This presentation will report on progress so far in developing these criteria, and for formalising the review process.

13:55 – 14:10	External influences on HRECs	Thursday 30 November

A nationally consistent approach to the accreditation of institutions and their HRECs

Conor Brophy

Adjunct Professor; Chair, Ethics Committee Advisory Group, Australian Commission on Safety and Quality in Health Care

Abstract

In 2006, the NHMRC commenced the Harmonisation of Multi-centre Ethical Review (HoMER) project to minimise unnecessary duplication of ethics review. This national approach to single ethical review resulted in the NHMRC HREC Certification Scheme and the National Mutual Acceptance Scheme (NMA). Concerns around acceptance by one institution of another's ethics review remain however. To address these issues, the Australian Government Department of Health and Aged Care is working with the Australian Commission on Safety and Quality in Health Care (Commission) to develop national quality standards for the operation and activities of HRECs. A key outcome of this project is to enable participation of HRECs and their institutions, accredited by the Commission, in the NMA Scheme. This talk will describe the current status of this national work.

Biography

Conor holds the following qualifications: MBBS; MD; Master of Bioethics; FRCP; AFRACMA. She has experience as a UK hospital-based clinician and researcher, in Pharma R&D, with development of research and clinical governance systems in an NHS Hospital Trust and, since 2006 in Australia, with a variety of research governance and ethics activities, including participating in the development of the NHMRC National Certification Scheme. From 1997, she served on HRECs in the UK and Australia. She also served 14 years as chairperson of the Queensland Hospital HRECs, and from 2017 of the Queensland University of Technology HREC. In February 2022, she was appointed as Chair of the Ethics Committee Advisory Group advising on the accreditation scheme for HRECs and their institutions to further national mutual acceptance of research ethics approvals.

14:20 – 14:35	Consent	Thursday 30 November

Ethical challenges to informed consent in aged care research

Elspeth McInnes AM

HREC Chair of South Australia

Abstract

HRECs have a key role in ensuring that aged care residents are able to participate in research. Excluding vulnerable populations, such as those living with dementia, can constrain research seeking advances in their care needs. People living in aged care residential services are dependent on aged care staff and vulnerable to coercion when care providers undertake research to evaluate standards of care. Residents may feel obligated to participate and to provide positive assessments of care. Other possible dimensions of vulnerability include aged care residents with impaired cognitive function arising from neurodegenerative conditions such as dementia, or psychotic illness, brain injury or other physical condition affecting cognitive function, medications negatively impacting cognitive function, and high dependency on medical care. Aged care residents with degenerative conditions may experience declining cognition over time, such that they had been able to give informed consent prior to data collection but may decline over the time of data collection.

Key strategies supporting ethical research participation include ensuring researchers use appropriate processes to determine the participant's capacity to consent, consulting with care providers and family members regarding potential participants' cognitive and language needs, and regularly re-visiting consent over time to ensure the participant is willing and able to consent to the data collection activities.

Biography

Professor Elspeth McInnes AM is professor of Sociology in Education and Chair of the Human Research Ethics Committee at the University of South Australia since 2018, having previously served on HREC since 2013. She also serves as a Layperson representative on the Adelaide Women's and Children's Hospital Patient Care Ethics Committee. Elspeth's research and teaching engages with trauma and wellbeing strategies involving vulnerable populations.

14:35 – 14:50	Consent	Thursday 30 November

The use of multimedia aided consent in paediatric research

Rebecca Doyle

Nurse researcher, Queensland Specialist immunisation Service

Project Manager, PATCH Trial

Abstract

Background: An integral principle of good clinical practice is to obtain prospective, informed consent. In pediatric research, consent is obtained from a parent or legal guardian. The consent process is intended to protect the rights of potential participants and their families, but it should be considered a process, not a tick-box. For participants to decide to enter research voluntarily they need: sufficient information; comprehension of processes and activities of the project; knowledge of risks and benefits of the research; and an understanding of the implications of their participation. They also need to be able to decide on participation without coercion or pressure and within a reasonable time to consider the information and ask any questions that arise.

Problem: There are some barriers to informed consent that exist in paediatric research. Parental distress can impact decision-making capability.

The comprehension of written information sheets may be dependent on factors such as literacy, health literacy and language spoken. Many trials provide excessive information which may be overwhelming and difficult to effectively understand. Proposed solution: One potential solution is the use of digital multimedia as an adjunct to the consent process. Digital multimedia has several advantages including promoting comprehension, standardising information and flexibility. Some collaborative trials being conducted by UQ and Children's Health Queensland have developed a short information video for participants intended for use in conjunction with written information sheets. The transcript for the video is approved by the HREC and the result is a short clip using voice, simple text, photos, and diagrams to explain the research.
Next steps: The way consumers learn and gather information is changing and consent resources need to reflect this change. Digital media does this by supporting accessibility and inclusivity with the potential for language translation and adaption to suit cultural groups and specific cohorts.

14:50 – 15:05	Consent	Thursday 30 November

Applying inclusive recruitment and consent practices to include people with aphasia in research: a case example

Renee Clapham

Speech Pathology Department, St Vincent's Hospital Melbourne

Abstract

With the increasing recognition of the systematic (intentional or unintentional) exclusion of groups and sub-groups from research, there is a corresponding call for ethics committees and researchers to challenge this systematic exclusion. One area where there appears to be a changing attitude to the exclusion of participant groups is the area of stroke research, specifically to include people with aphasia in stroke research. Aphasia is an acquired communication impairment, often the result of stroke, that can impact a person's ability to express themselves, understand others, to read and/or to write. For researchers who want to include people with aphasia in research, it can be a challenge to develop recruitment and consent processes that are both inclusive *and* supported by an ethics committee.
Our research group, which includes people with lived experience of aphasia, recently applied inclusive research practices to develop materials and consent processes that supported including people with aphasia in research. This included development of aphasia-friendly participant facing materials, using supported communication techniques to discuss the research, building an understanding check in the consent process to demonstrate informed decision-making and including consent by proxy where informed decision-making could be established. To date, all people with aphasia who expressed an interest in participating in the research completed the consent process and there have been no withdrawals.

Biography

Dr Renee Clapham (PhD University of Amsterdam) is qualified Speech Pathologist and experienced researcher and research manager in the health sector. With a focus on supporting research that improves health outcomes for people, Renee is experienced in developing and leading research projects, research governance, and research ethics and integrity. Her current affiliations are with St Vincent's Hospital Melbourne and Cancer Council Victoria. Renee is also a volunteer on a Human Research Ethics Committee and mentors emerging clinician-researchers.

15:05 – 15:20	Consent	Thursday 30 November

Deferred consent in neonatology

Amir Zayegh
Neonatologist, Women's Hospital

Abstract

Clinical research to improve care in critically ill infants and children is fraught with ethical and logistical challenges. Traditionally, researchers have been ethicolegally required to obtain informed consent from parents prior to the child's enrolment in a clinical trial. However, obtaining prospective and truly informed consent can be particularly challenging in the delivery room, emergency department or intensive care setting. Parents may often be unavailable or incapacitated, and the additional decision-making burden at a time of intense parental stress may make it impossible or inappropriate to seek true informed consent. Additionally, trials which use prospective consent only often miss out on recruiting the sickest patients, making their results less relevant and applicable in the real world. This may lead to inadvertent detrimental effects when the intervention is applied to clinical practice. Deferred or complete waivers of consent have been proposed and are being increasingly utilised in clinical trials in these contexts. However, doubts remain as to their acceptability by clinicians and parents, and the risks of damaging trust in research by conducting research without prior consent.

Biography

Amir is a consultant neonatologist who trained in Melbourne and Oxford. He has completed a Masters in Practical Ethics at the University of Oxford, and a Certificate in Clinician Performed Ultrasound. He is co-chair of the ethics working group of the PLATIPUS adaptive platform trial. His clinical and research interests include ethical issues in the neonatal intensive care, and functional echocardiography in the neonate.

15:30 – 17:00	Privacy training	Thursday 30 November

Privacy essentials for HRECs

Andrea Calleia
Salinger Privacy

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 Salinger Privacy, 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 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.

08:00 – 08:45	Workshop	Friday 1 December

PRAXIS presented – Inclusion. Risk. Agency. What are the challenges for HRECs

Philomena Horsley

PRAXIS Australia

Abstract

Recent changes to Section 5 of the National Statement Diversity reflect an increased awareness of the need for more diversity in HREC membership. An assumption is that this will assist with the important task of ensuring greater inclusivity of under-represented groups in Australian research.

However, broader modes of thinking - the 'cognitive diversity' of a committee – are also essential to ensure a reduction in the systemic exclusion of some participant groups. How risk averse should HRECs be? Do HRECs sufficiently recognise the agency of 'vulnerable populations'? What is lost if research fails to capture the data and voices of such groups?

This workshop is a discussion about the ways we can encourage more diversity in the collective decision-making of HRECs.

Biography

Philomena Horsley is a Medical Anthropologist who has been a Chair of HRECs for over 20 years in the fields of health, disability and the justice system. She also served on the NHMRC's National Statement Section 4 Review Working Committee from 2018-2020. Since 2005, Philomena has been engaged in teaching ethical thinking to HREC members, researchers and students. She is particularly focussed on the inclusion of diverse and marginalised populations, and the importance of engaging relevant communities in the design of research. Her expertise includes gender and health, family and sexual violence, disability services, LGBTQ health and wellbeing, genetics and cancer, medical autopsies, and death and dying.

09:05 – 09:25	Workshop	Friday 1 December

Marginalisation in research

Scott Walsberger

Manager, Cancer Programs, ACON

Abstract

Key messages:

- LGBTQ+ people have higher rates of risk factors and experience barriers to accessing health services due to discrimination and stigma

- gender and sexuality are often not collected or reported in health/medical research making it difficult to identify and understand inequities in health
- there are recommended indicators to use in research to collect gender and sexuality data and LGBTQ+ HREC to review and guide research with LGBTQ+ communities
- inclusive community-led research and interventions are effective in informing and addressing health inequities experienced by LGBTQ+ people.

Biography

Scott Walsberger (he/him) is Cancer Programs Manager at ACON. He leads programs to raise awareness of cancer risks and screening among LGBTQ communities and improve inclusivity among health services. Scott has nearly 15 years of experience in cancer control. He was the Tobacco Control Unit Manager and Lead Prevention Manager at Cancer Council NSW. Prior to that he managed the Skin Cancer Prevention portfolio at Cancer Institute NSW as well as worked on breast, cervical and bowel cancer screening campaigns. Scott has partnered with several researchers on smoking cessation trials in alcohol and other drug and community managed mental health services, as well as tobacco control policy research projects. He has a Master of Public Health from UNSW in Sydney and a Bachelor of Arts in Economics and Management and International Relations from Beloit College in the USA. He lives in Sydney with his husband, their 12 year old daughter and their Sheepadoodle puppy.

10:00 – 10:20	Stream 1 – Legislation	Friday 1 December

Researching traumatic experiences: vicarious trauma inside academia and the ethics of care

Jennifer Smith

Associate Professor, Queensland Centre for Domestic and Family Violence Research
Central Queensland University

Abstract

Traumatic experiences are sadly a fact of life for many who chose to research the issues that have impacted on their own lives and/or the lives of vulnerable groups. Many challenges may arise for researchers when their research centres on traumatic topics. They may find themselves interrogating their past or present traumatic experiences or be triggered by the experiences recounted by research participants. Amongst inexperienced and/or unsupported researchers who attempt to mask symptoms of trauma to appear 'objective', there can be the additional risk of inadvertently doing harm to participants, assistants and transcribers. COVID-19 further exacerbated the negative effects for some trauma researchers due to the need to work with distressing material in personal spaces instead of a work office. As the process of researching trauma histories can be psychologically harmful, it warrants careful consideration of the ethics of care. This paper will contribute to discussion about researcher trauma debriefing and trauma-informed supervision and consider how research institutions can implement improved systems to ensure research is psychologically safe for the researcher as well as participants. It will argue that an ethics of care approach requires that adequate time and support is needed to allow researchers to practice reflexivity and obtain access to appropriate support.

Biography

Jennifer is currently employed as an Associate Professor in the Queensland Centre for Domestic and Family Violence Research. She has been a practitioner/academic social worker for 40 years. Her experience includes 17 years university teaching (at

QUT, UQ, ACU and UNE) and 23 years as a practitioner in the government (Child Health and Child Safety) and community sectors (Lifeline and UnitingCare Community). Jennifer's teaching and publications have been in the areas of domestic and family violence, child protection, social work, child and family practice, counselling, and group work. Her social work masters and doctorial research focused on the impact of domestic violence on children and their mothers' parenting, as well as children's perceptions of domestic violence and was the earliest Australian research in this field.
Jennifer is passionate about child advocacy, early intervention, family support and public health approaches to family violence as well as trauma-informed and narrative approaches to practice. Her interests also include professional supervision and the 'use of self' and the 'wounded healer' in professional practice. In 2002, while employed as the Director of the Child Advocacy service at the Royal Children's Hospital, Jennifer was a successful recipient of a Creswick Fellowship in Family Relations and Child Development which enabled her to undertake further studies at the Kempe Centre, Denver Children's Hospital and Primary Children's Hospital, Salt Lake City.

10:20 – 10:40	Stream 1 – Legislation	Friday 1 December

Navigating identity and integrity: exploring the intersection between gender diversity, research ethics and legislation

Leonie Crosse

Member of University of Tasmania Human Research Ethics Committee

Member THS-RHH Diversity, Equity, Inclusion and Belonging Working Group

Abstract

The National Statement is a guiding document that places fundamental principles of ethical conduct, such as integrity, before all else. For research to be conducted with integrity, it must be designed to ensure that respect for the participants is not compromised by the way it is carried out. The National Statement covers a broad range of participant considerations, including protecting those that are considered more at risk of harm. Within all cohorts, including those specifically identified, transgender and gender diverse (TGD) people vulnerably exist. TGD people disproportionately experience disparate social and health outcomes compared to cisgender peers, and it can be argued this starts with research participation. Many researchers design their study with limited understanding of the concerns of the TGD community, therefore these individuals are often not afforded the regard they should be as potential participants of research projects. It is not uncommon for applications to be presented to HRECs with errors related to TGD inclusion or gender-inclusive language. This lack of recognition and respect can create a barrier for TGD people to engage with research. Consequently, they may be intentionally or unintentionally excluded from research, and the subsequent improvements to their social welfare and individual wellbeing.
The National Statement provides little direction to applicants or HRECs on how to be appropriately gender inclusive. It is incumbent upon HRECs to develop an understanding of the consequences of anticipated gender experiences and of gendered language within the context of each application. To achieve this, they should refer to legislation that can inform their deliberations and decisions for requesting any TGD-related amendments. Legislation that prevents gender discrimination and promotes a standardised, respectful management of gender-related information can protect this highly marginalised, at-risk community from

harm. An educated, focussed, and collaborative effort would improve gender inclusion and promote greater integrity within research.

Biography

Leonie Crosse (she/her) graduated from hospital-based nursing in 1990. After completing a bachelor and master's in nursing she is now a youth health nurse supporting young, often underprivileged people of southern Lutruwita (Tasmania). She is also a senior staff member at the Royal Hobart Hospital – Neonatal and Paediatric Intensive Care Unit. She gained a particular interest in ethics and gender diversity while studying for a master's degree in bioethics at Monash University and has subsequently published work regarding ethical considerations of gender-affirming care in adolescents. She is a member of the HREC at the University of Tasmania.

10:40 – 11:00	Stream 1 – Legislation	Friday 1 December

Deciphering the complex interplay between voluntary assisted dying legislation and research ethics – a new tool for researchers

Enna Stroil-Salama

Operations Manager, QVAD Support and Pharmacy Service, Queensland Health

Abstract

Aim: To help researchers navigate the convergence of voluntary assisted dying (VAD) practice, recent Queensland legislation and research ethics.

Background: VAD, a subject of frequent moral and social discourse, involves the provision of medical assistance to eligible adults seeking to choose the timing and circumstances of their death. In this nascent area of clinical practice there is a need to:

- research and implement evidence-based, best practice in VAD
- alleviate challenges for researchers
- contextualise research practice within the framework of Queensland VAD legislation
- underscore the need for a conscientious approach that prioritises compassion, empathy, and patient-centred care.

Methodology: Safeguards and protections outlined in Queensland VAD legislation were examined considering their influence on research integrity and clinical practice. Guidance was sought from research ethics experts, VAD practitioners, consumers, lawyers and a senior VAD psychologist to create a comprehensive tool to guide researchers in navigating VAD research.

Results: A VAD Research Guide was developed to address multifaceted ethical, clinical and legal challenges researchers are likely to encounter in conducting VAD-related research in Queensland. It considers core principles of autonomy, beneficence, non-maleficence, and justice underpinning research ethics in this sensitive context. The guide scrutinises the impact of Queensland legislation on research methodologies, data collection and reporting, and how that shapes the ethical responsibilities of researchers. It also encourages transparency, respect for individual rights, and adherence to the National Statement on Ethical Conduct in Human Research.

Discussion: The VAD Research Guide outlines the intricate interplay between Queensland legislation, VAD practice and research ethics. It underscores the pivotal role of researchers in shaping VAD discourse and practice, while helping them to

navigate the ethical terrain with diligence and sensitivity. It forms a novel ethical framework to guide research conduct in this evolving field, promoting transparency, compassion, and the highest standards of integrity.

Biography

Enna Stroil-Salama is the Operations Manager at the Queensland Voluntary Assisted Dying Support and Pharmacy Service (QVAD SPS). She is a member of the Metro South Health HREC and has worked in palliative care prior to joining QVAD SPS. Enna has an implementation science background, with an interest in health care improvement and change management.

10:00 – 10:20	Stream 2 – Clinical trials	Friday 1 December

Beyond the form: engaging with participants throughout clinical research

Gudrun Wells

Research Officer CT:IQ / Bellberry Limited

Abstract

There is increasing recognition of the importance of ongoing communication between research personnel and participants throughout the duration of clinical research studies. Enhanced communication strategies may increase research merit and integrity by increasing participant retention. They also may promote feelings of respect and engagement, including by communicating findings or results of interest to participants. However, innovation in research review and design is needed to optimise ongoing communication practices for clinical research.

CT:IQ and the VCCC Alliance have established a project to assess current initiatives used to facilitate ongoing communication between research personnel and participants during a clinical research study. The final output will be recommendations and guidance for designing future studies, as valued by both researchers and study participants. The project is adopting desktop and qualitative research methodologies to better understand the current Australian landscape and participant preferences.

This presentation will report on results from the first project output – a rapid review white paper – which found that few studies publish the communication strategies used during the study. Those strategies that have been published include diversifying the modes of communication and embedding community members in the study team either as co-designers of engagement interventions or employed as study personnel. Preliminary results from interviews with research professionals reveal the pivotal role of appropriate protocol design at the time of initial HREC review. In addition, the need for ethical approval of communication strategies has been cited as a barrier to tailoring communication strategies around participant needs.

Further qualitative research components of the project are underway, with preliminary results expected to be available in late 2023, including participant engagement preferences.

The National HREC Conference provides an ideal opportunity to introduce the HREC community to the communication factors that should be considered both at the time of initial protocol review and in protocol amendments.

Biography

Gudrun Wells' work with CT:IQ aims to make it easier for researchers to create trials that deliver great results and are respectful of their participants. She has worked at the University of Tasmania in clinical research and research governance over the

last 8 years. In her role as a clinical trial coordinator and senior project officer Gudrun has worked on a range of projects with both commercial and investigator-led trials in disease areas including musculoskeletal, public health, cardiovascular and behaviour change. In her role as a Research Governance Officer she has worked to redesign the way the university supports both researchers designing and conducting trials, and staff reviewing and approving those trials, to achieve high-quality research. In combination, these roles have given Gudrun a broad understanding of the issues faced by sites and academic sponsors in conducting and monitoring clinical research.

10:20 – 10:40	Stream 2 – Clinical trials	Friday 1 December

Improving the capture and reporting of adverse events in clinical trials of non-pharmacological interventions: a PaCCSC/CST initiative

Celia Marston and Ann-Marie Holse

Abstract

Accurate capture and reporting of adverse events (Aes) in clinical trials is critical to understand the potential harms of prospective interventions. A series of collaborative discussions with consumers, interdisciplinary clinical trialists and case study analysis, identified that clinical trials investigating non-pharmacological interventions rarely incorporate systematic capture of Aes and often report no harms. This has the potential for under-reporting, which could impact the safety of such interventions when implemented in clinical practice. Current AE-reporting frameworks (e.g. International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Guideline for Good Clinical Practice and the National Cancer Institute's Common Terminology Criteria for Adverse Events) are structured to capture Aes that occur in pharmacological trials. Adaptation of pharmacological AE-reporting frameworks imparts a risk of excluding Aes unique to non-pharmacological interventions that have not yet been defined, for example, capturing a participants' feeling of failure associated with an inability to complete a mindfulness-based intervention. Furthermore, there can be study setting-dependant AE-reporting disparities in non-pharmacological trials, with a risk of Aes not being captured when conducted in a community setting compared to a hospital clinic, due to rigid reporting frameworks and inadequate participant self-reporting. In addition, clinical trials focus primarily on the participant receiving the intervention, with current AE-reporting frameworks failing to recognise potential harms to participants' families, carers, clinical and research staff. For example, the risk of harm to research nurses from participants presenting with unpredictable behaviour. This initiative aims to: (i) increase the awareness for the potential under-reporting of Aes, particularly in non-pharmacological trials; and (ii) explore appropriate AE-reporting frameworks to aid the systematic capture and reporting of Aes experienced by all individuals, either directly or indirectly, participating in clinical trials. Addressing this gap will enable a comprehensive and accurate understanding of the potential harms of all types of prospective interventions.

Biography

Celia is the Clinical Lead for Occupational Therapy at Peter MacCallum Cancer Centre and has specialised in oncology and palliative care for more than 15 years. She is also Research Lead for Occupational Therapy at The Royal Melbourne Hospital and Adjunct Lecturer at Monash University. Celia is completing her PhD at the University of Technology Sydney. Her PhD aims to produce a model of care that can best support carers and patients with advanced cancer when returning home

from hospital. Celia is involved with research in palliative care, cancer rehabilitation, and health services research. She isa member of the Cancer Symptoms Trials Scientific Committee; and Palliative Care Clinical Studies Collaborative; has authored 19 peer reviewed publications, three book chapters and presented at several national and international conferences.

10:40 – 11:00	Stream 2 – Clinical trials	Friday 1 December

The Australian Teletrial Program – Bringing clinical trials closer to home

Sara Hubbard
Research Governance Officer, QRCCC

Abstract

At the centre of every clinical trial is a patient waiting for a treatment to arrive safely and on time. With at least one third of Australia's population living outside the metropolitan areas, many patients in regional, rural, remote communities do not have localised access to clinical trials. Traditionally, patients from these areas must travel to metro centres if they wish to participate in a clinical trial.

The Australian Teletrial Model (ATM) is an innovative solution to address this disparity in access to clinical trials. Primary clinical trial sites set up satellite sites to deliver all or part of a clinical trial, enabling patients from non-metro postcodes to access clinical trials closer to home. Ethics review of a clinical trial that will be conducted as a teletrial is largely unchanged, but there are some additional points that HRECs should be aware of, to ensure the review is compliant with the guidance in the National Statement. This presentation aims to:

- provide HREC members with an understanding of the Australian Teletrial Model
- identify specific elements in the National Statement that may be impacted by use of the teletrial model
- introduce new and specific documentation used for teletrials.

Biography

Sara Hubbard is an experienced advisor and educator in human rights, research ethics and governance, consent and research conduct. Sara brings over 10 years experience in health and research sectors, and is currently engaged with the Australian Teletrial Program as a Principal Policy Officer.

11:30 – 12:30	Plenary	Friday 1 December

AI and HRECs: Development of guidelines for review of AI projects by HRECs

Lyle Palmer PhD FRSS
Professor of Genetic Epidemiology, Senior Research Fellow
Australian Institute for Machine Learning, University of Adelaide

Abstract

AI research in health care is rapidly growing in momentum and impacts. There has been a concomitant growing focus on the responsible, safe, and ethical conduct of AI research and its application to clinical contexts. This seminar discusses the current status of responsible medical AI.

Biography

Professor Palmer relocated to Adelaide from Toronto in 2014 to take up a new opportunity as Professor of Genetic Epidemiology at the University of Adelaide. He is currently leading the creation of several new resources in Adelaide, including the South Australian Family Connections Project. Before moving to Adelaide, Professor Palmer was a Senior Principal Investigator and Program Director at the Ontario Institute for Cancer Research, and a Professor of Biostatistics, Epidemiology, and Obstetrics & Gynaecology at the University of Toronto. Together with many partner organisations across Ontario, Professor Palmer led a large-scale expansion of the provincial capacity in translational epidemiology. From 2010 to 2014, he was the founding Executive Scientific Director of the Ontario Health Study, the largest population-based cohort study (n=230,000) ever undertaken in Canada.
Prior to moving to Canada, Professor Palmer was the foundation Winthrop Chair in Genetic Epidemiology and the founding Director of the Centre for Genetic Epidemiology & Biostatistics at the University of Western Australia, where he was also a Professor in the Schools of Medicine & Pharmacology and Population Health. Whilst in Perth, he was responsible for establishing over 10 major clinical and general population-based cohorts, including the WA Twins Register, in addition to national research programs in glioma and mesothelioma. Until 2003, he was an Assistant Professor of Medicine at Harvard Medical School and the Director of Statistical Genomics at the Channing Laboratory, Boston. His background includes training in clinical epidemiology, human genetics, bioinformatics, and biostatistics. He has a particular interest in the areas of life-course genetic epidemiology, the developmental origins of health and disease (DoHAD), and chronic disease clinical and genetic epidemiology.
Professor Palmer has been recognised for his leadership role in biomedical research by numerous awards, including Fulbright and Churchill Fellowships. He has chaired and/or given invited symposia at over 60 international scientific meetings, has delivered over 300 invited lectures, has produced over 300 publications, and has co-edited a commercially successful encyclopedia of genetic epidemiology that has become a standard reference work.
Professor Palmer has extensive experience in constructing and using ‘big data’, particularly linked health data, for translation-oriented research. His research team in Adelaide is focused on applying deep learning methods to clinical problems and is active in producing new software and methods for data analysis and visualisation.

13:00 – 13:20 **Data and data sharing** **Friday 1 December**

‘Caught in a loop’: ethics and research governance of an interagency cross-jurisdictional suicide prevention data linkage study

Carla Muerk

Forensic Mental Health Group and Military and Veterans’ Mental Health Collaborative, Queensland Centre for Mental Health

Abstract

Ethics and research governance processes are a necessary yet increasingly complex terrain to navigate, particularly where the study design includes access, linkage and use of routinely collected administrative data. The aim of this presentation is to describe challenges and possible pathways through ethics and governance processes, in reference to the Partners in Prevention study on first responses to suicide crisis situations – a case study of creating a large, multi-agency, multi-jurisdictional dataset, including health and non-health administrative datasets. To date, over 50 separate pieces of documentation have been required to receive and maintain approval of this study, including more than 10 initial application documents and legislative approval requests, more than 20 amendments, and more

than 15 annual progress reports. These requirements have resulted in 4 interlinked protocols being generated. Beyond the substantial resource implications in managing these processes, for both investigators and ethics and research governance officers, there is evidence that the complexity of the processes can start to generate their own complexity and risks to be managed. Additionally, lack of clarity and knowledge among potential data custodians, particularly those in agencies outside of the health sector, around how the Privacy Act exemption for a waiver of consent operates in relation to other legislation under which they operate, can raise concerns and may cause blockages or prevent research proceeding.
In sum, these issues not only delay research, create grant funding and feasibility risks, and consume scarce research resources, but they can begin to limit as well as undermine the rigour of the research itself. Engagement with organisational research committees and creation and dissemination of informational resources for institutional stakeholders outside of the health sector, regarding the application of the Privacy Act to waivers of consent, and automating some elements of amendment requests, are among suggestions for improvement that will be discussed.

13:20 – 13:40 **Data and data sharing** **Friday 1 December**

A national program set to accelerate research through data sharing

Angela Webster
HeSANDA SHP-CTC Node

Abstract
Background: Health Studies Australian National Data Asset (HeSANDA) is a national data sharing program that aims to increase the benefits of investment in health research by reusing health data for new research. This program is led by the Australian Research Data Commons and facilitated by 9 local nodes (representing 72 research organisations across Australia) including the Sydney Health Partners (SHP) and NHMRC Clinical Trials Centre (SHP-CTC) Node.
Methodology: HeSANDA's platform (Health Data Australia or HDA) was co-designed with the nodes over a 2-year period, with an initial focus on clinical trial data. In parallel, individual nodes, including our SHP-CTC Node, developed technological, administrative and research processes to facilitate sharing of data through HeSANDA. We also developed data sharing procedures and policies to support alignment of processes across partner institutions. Metadata – information about each data collection and not the dataset itself – was harvested from the Australian and New Zealand Clinical Trial Registry and affiliated researchers.
Results: HDA was launched with 114 registered clinical trials including 10 from our Node, and more trials will be added. During our collection of metadata, ethical issues were raised by researchers when data sharing had not been approved before study start-up. They were reluctant to provide the metadata from completed trials and unsure about seeking ethical approval for future use.
Conclusion: A national platform to support the sharing and reuse of clinical trial data is ready for the research community to use. Further communication activities are underway and user guidelines are being developed. HeSANDA, in partnership with CT:IQ, have developed a data sharing statement for use in participant information and consent forms for future research. However, targeted strategies to engage researchers including further guidance on how and when to obtain ethical approval to share and reuse research data are required.

13:40 – 14:00	Data and data sharing	Friday 1 December

Ethical considerations are poorly reported in individual participant data meta-analysis (IPD-MA)

Nigel Armfield

The University of Queensland

Abstract

Background: Unlike conventional meta-analyses, which use aggregate data from published works, individual participant data meta-analyses (IPD-MA) rely on the sharing and secondary use of raw *participant-level* data from primary studies. Internationally, the value of data sharing to science and society is well recognised. Within health and medical research specifically, many government research funding agencies have developed policies to foster the sharing of data (and corresponding metadata) arising from publicly-funded research. While the benefits of data reuse are clear, it may only occur within legal and ethical constraints, which vary by jurisdiction and project. Here, we aimed to summarise how ethical considerations are described in published IPD-MA studies.

Methods: A recent systematic review by Wang et al assessed the methodological quality of 323 IPD- MAs; their review used a comprehensive search strategy to identify IPD-MA studies developed from a previous systematic review by Nevitt et al relating to data retrieval in IPD-MA. Here we re-use the list of IPD MA studies identified by Wang et al in their supplementary material. For each study we extracted descriptions of ethical considerations and then summarised the results descriptively.

Results: We extracted statements from 315/323 (97.5%) of studies (1 not IPD, 6 unavailable to us, 1 duplicate); 14/315 (4.4%) had ethics committee approval, while 8/315 (2.5%) had exceptions or waivers. 258/315 (81.9%) had no ethics statements; 32/315 (10.2%) declared that ethics approval was not required, of which 19 provided supporting justifications, most commonly that the data were de-identified and/or participants consented to the primary studies from which the data were drawn. 3/315 (1%) were unclear. Only one study indicated that the deidentified IPD were used according to the purpose originally collected.

Conclusion: Overall, reporting of ethical considerations is poor and attitudes towards ethical requirements for IPD-MA studies vary. Further guidance for researchers may be beneficial.

13:00 – 14:30	HREC coordinators	Friday 1 December

For all HREC coordinators and administrators

This year the session will include a presentation on indemnity and a workshop session on translating the National Statement updates from Sections 2 and 5 into processes. This will focus on low risk and exempt from review applications.

healthtranslationqld.org.au/hrec-conference-2023