V6

Human Research Ethics Committee Conference

3rd National HREC Conference

23 – 25 November 2022

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Health Translation Queensland

AHRECS

PRAXIS AUSTRALIA
Promoting Ethics and Education in Research

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Contents

Foreword

Friends, colleagues, HREC members, Coordinators, researchers, and other interested parties, we come this year to the 3rd National HREC Conference, the only conference that is free, virtual and designed to provide insightful information to HREC members, to challenge paradigms and to recognise the large community of HREC practice that exists across Australia.

In putting together this year's conference, we have considered feedback from the last 2 years to develop a mixed-methods approach that comprises plenaries, talks, workshops and which culminates in a debate on the *Future of HRECs in Australia*. It is, in my view, the most diverse content we have included to date, with a focus on the value of lived experience and an international perspective.

We are again including a Privacy workshop, combined with workshops on getting your HREC fit for purpose and the secondary use of data. This year, we are also raising the profile of HREC Coordinators as an essential part of the HREC process. It promises to be a very informative and useful conference and one unrivalled in Australia.

I have been fortunate for the support from Ms Sara Gottliebsen and Health Translation Queensland, as well as a dynamic organising committee. We have also received some tangible or in-kind support from Australasian Human Research Ethics Consultancy Services, PRAXIS, and Bellberry Limited. Each of these sponsors will be able to share their message with you, which I'm sure will resonate with the purpose of this conference - to foster a community of practice in human research ethics in Australia.

We hope this conference is of significant value for you. We are always looking to improve this product, so please complete the survey forms at the end of the sessions. Finally, using this forum allows us to reach a much greater number of interested people than would otherwise be possible. We hope that you are supportive of this approach.

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

Organising Committee

Dr Gordon McGurk	QIMR Berghofer Medical Research Institute
Ms Sara Gottliebsen	Health Translation Queensland
Dr Hudson Birden	Townsville Hospital and Health Service HREC
Ms Sophie Gatenby	The Royal Children's Hospital Melbourne
Ms Sara Hubbard	Townsville Hospital and Health Service
Ms Roberta Littleford	University of Queensland
A/Prof Fiona MacDonald	Queensland University of Technology
Prof Eleanor Milligan	Griffith University
Prof Paula Swatman	Swinburne University of Technology
A/Prof Nik Zeps	Chrysalis Advisory

Day 1 – Wednesday 23 November 2022

All times in AEST (QLD)

08:30 – 08:40	**Welcome** Dr Gordon McGurk, Conference organiser
08:40 – 08:50	**Acknowledgement of Country** Professor Gregg Pratt, QIMR Berghofer
08:50 - 09:00	**Opening remarks** Professor Ingrid Winship, NHMRC
09:00 – 10:00	**Plenary** ***Chairperson: Dr Gordon McGurk*** *Conflict of interest in medical research: new thinking, new processes* Professor Wendy Lipworth, Macquarie University
10:00 – 10:30	Morning Tea Break
10:30 – 12:00	**Ethics and Genetics** ***Chairperson: Dr Hudson Birden***
10:30 - 11:00	*Ethical challenges and opportunities in rare disease research* Professor Tiong Tan, Victorian Clinical Genetics Services, Murdoch Children's Research Institute, University of Melbourne
11:00 - 11:30	*Public trust and genomic data sharing: uncertainty, control, and waivers of consent* Ms Vanessa Warren, University of Tasmania
11:30 – 12:00	*First Nations Leadership and the Evolution of Ethical Genomics Research* Mr Greg Pratt, QIMR Berghofer
12:00 – 12:30	Lunch Break
12:30 – 14:10	**Consent** ***Chairperson: Dr Gordon McGurk***
12:30 – 12:50	*Ethics and Older Adults: Moving with the Times* Professor Nancy Pachana, University of Queensland
12:50 - 13:10	*Relational Considerations in Consent in Clinical Research* Mr Ian Pieper, University of Canberra
13:10 – 13:30	*Navigating the pitfalls of using a waiver of the requirement for consent: practical approaches based on real world applications* Professor Nik Zeps, Chrysalis Advisory
13:30 – 13:50	*Assessing a young person's maturity and capacity to consent via social media* Professor Sonia Grover & Dr Courtney Munro, Murdoch Children's Research Institute
13:50 – 14:10	*Development of a consumer-centred participant information and consent form in Australia: The inFORMed Project* Dr Lisa Eckstein & Dr Tanya Symons, CT:IQ
14:10 – 15:00	Afternoon Tea Break
15:00 – 16:30	**Workshop** ***Chaired by Dr Paula Swatman & Ms Sophie Gatenby*** *Use of Secondary Data*
15:00 – 15:30	*Facilitating reuse of LifeCourse data to benefit child and adolescent health* Dr Meredith O'Connor, Murdoch Children's Research Institute
15:30 – 16:00	*Setting up clinical registries* Professor Susan Rossell, Swinburn University of Technology
16:00 – 16:30	Discussion

Day 2 – Thursday 24 November 2022

All times in AEST (QLD)

09:00 – 10:00	**Plenary** ***Chairperson: Dr Hudson Birden*** *Global Research Ethics* Professor Paul Komesaroff, Monash University
10:00 – 10:30	Morning Tea Break
10:30 – 11:30	**Workshop** ***Chaired by Philomena Horsley, PRAXIS Facilitator and HREC Consultant*** *Lay People on HRECs* Panel: Francis Colley Kate Henderson Peter Gourlay
11:30 – 12:30	Lunch Break
12:30 – 13:50	**The value of lived experience** ***Chairperson: Dr Tim Dyke***
12:30 - 12:50	*The involvement of consumers in the development of guidelines* Mr Vidar Enebakk, Director at The National Committee for Research Ethics in the Social Sciences and the Humanities, Norway
12:50 - 13:10	*Ethical considerations of patient-reported outcomes in clinical research: The PRO ethics guidelines* Dr Jessica Roydhouse, University of Tasmania
13:10 – 13:30	*Partnering with consumers in research* Dr Natasha Roberts, The University of Queensland
13:30 – 13:50	*Involvement in cancer trials groups* Ms Leonie Young, Wesley Hospital Choices Cancer Support Centre
13:50 – 15:00	Afternoon Tea Break
15:00 – 16:30	**International Perspectives** ***Chairperson: Dr Roberta Littleford***
15:00 - 15:30	*BRIDGE Guidelines: development and use of guidelines for good epidemiological practice in global health* Dr Sandra Alba, KIT Royal Tropical Institute, The Netherlands
15:30 - 16:00	*The intersection of ethics and integrity in Human Subjects Research* Dr Jake Earl, Walter Reed Army Institute of Research, USA
16:00 – 16:30	Discussion

Day 3 – Friday 25 November 2022

All times in AEST (QLD)

08:00 – 09:00	**Plenary** ***Chairperson: Dr Gordon McGurk*** *How research ethics committees can contribute to equitable research partnerships* Professor Doris Schroeder *University of Central Lancashire, School of Sport and Health Sciences, UK and UCLan Cyprus, School of Law*
09:00 – 10:30	**Privacy Training Chairperson: Dr Paula Swatman** SalingerPrivacy Delivered by Andrea Calleia, Director of Learning, Salinger Privacy
10:30 – 11:00	Morning Tea Break
11:00 – 12:00	**Workshop** ***Chaired by Dr Gordon McGurk and Dr Ian Tindall*** *Making your HREC fit for purpose*
12:00 – 12:30	Lunch Break
12:30 – 13:30	**Abstract Session – Stream 1** ***Chairperson: Dr Paula Swatman***
12:30-12:50	*The ethics of evaluating co-parenting smartphone apps: Cussing for science* Professor Bruce Smyth & Professor Jason Payne, ANU & University of Wollongong
12:50-13:10	*HRECs as resource versus obstruction: the vexed relationships between Human Research Ethics Committees and Researchers* Dr Susan Hemer, University of Adelaide
13:10-13:30	*Do HRECs have a role in cyber security?* Mr Geoff Vass, Lay member, Women's and Children's Hospital, Adelaide
	Parallel session
12:30 – 13:30	**Abstract Session – Stream 2** ***Chairperson: Dr Tam Nguyen***
12:30-12:50	*Do HRECs need a decision-making framework when considering research applications requesting deferred consent? Experiences of a paediatric HREC* Ms Rebecca Doyle, Children's Health Queensland Human Research Ethics Committee & University of Queensland
12:50-13:10	*Ethics Review-Disruption, Innovation and Advancement* Ms Sashika Naidoo, QIMR Berghofer
13:10-13:30	*Human research ethics application pathways: Implementing an online decision support tool for researchers and higher researcher degree students* Dr Karen Olave-Encina, University of Queensland
12:30 – 14:00	**HREC Coordinator Session** *In this session you will hear from Norther Territory and Victorian HRECs on how they induct and onboard HREC members, and a panel discussion with the NHMRC on member induction and education* This session will be run concurrently with the abstract sessions

13:30 – 14:00	Afternoon Tea Break
14:00 – 16:00	**Panel Discussion** ***Chairperson: Dr Gordon McGurk*** *The future of HRECs in Australia* Panel: **Professor Cindy Shannon**, PVC- Research (Indigenous) – Griffith University, former Council members NHMRC; Expert on Indigenous Health and Policy **Professor Michael James**, University of Adelaide, Medical Scientist, Rheumatology, Bellberry HREC Chair since 2009 **Dr Hudson Birden**, Townsville HHS HREC Chair
14:00-14:30	*The only way is ethics – Lessons learned from the UK* Ms Charlotte Allen, HRA UK
14:30-15:00	*When HRECs reach their limit of competence* Ms Kylie Sproston, Bellberry Limited
15:00-1600	Discussion

Abstracts & Biographies

09:00 – 10:00	Plenary Session	Wednesday 23 November

Conflict of interest in medical research: new thinking, new processes

Professor Wendy Lipworth

Professor of Bioethics, Department of Philosophy Macquarie University and PRAXIS Member Representative on AEHA

Bio

Professor Wendy Lipworth is a medically-trained bioethicist and health social scientist. Her approach to research might be referred to as “translational bioethics” in that it is deliberately oriented towards finding pragmatic solutions to morally complex and controversial real-world problems. Wendy's work aims to assist decision-makers in all spheres of practice (clinicians, researchers, policymakers, industry and educators) to manage uncertainty and moral complexity and to act in the face of disagreement. Her research focuses on four intersecting areas:

1. Commercial influences, conflict of interest and corruption in healthcare and biomedicine
2. The development, regulation and funding of medicines and medical devices
3. Evidence-based medicine and clinical innovation
4. Research using biobanks, big data and "real world data"

Wendy's work draws on a variety of methods—both empirical (qualitative and quantitative) and theoretical. It is also interdisciplinary and synthesises insights from ethics, law, sociology, policy, economics, epidemiology and other disciplines and involves engagement with all stakeholders to elicit the full range of perspectives and ensure legitimacy.

With regards to grant funding Wendy has received over $5 million in research funding from the NHMRC, ARC and Medical Research Future Fund.

10:30 – 11:00	Ethics and Genetics	Wednesday 23 November

Ethical challenges and opportunities in rare disease research

Professor Tiong Tan

Victorian Clinical Genetics Services, Murdoch Children's Research Institute, University of Melbourne

Bio

Tiong is a clinical geneticist with a PhD in developmental biology. He sees children and families affected by genetic conditions and has particular interests in craniofacial disorders, genodermatoses, and genomics for gene discovery research and clinical diagnostics. As a clinician-scientist, his research focuses on understanding the cause of rare conditions in order to help affected patients.

11:00 – 11:30	Ethics and Genetics	Wednesday 23 November

Public trust and genomic data sharing: uncertainty, control, and waivers of consent

Ms Vanessa Warren

University of Tasmania

Abstract

Genomic data sharing occupies a challenging regulatory and ethical space, frequently characterised by the twin goals of facilitating innovation and efficiencies in research, while also maintaining ongoing social acceptance through appropriate participant protections. This presentation shares early findings from a qualitative investigation into how trust in genomic data sharing is constructed by members of the Australian public, including how the possibility of genomic data sharing being facilitated by HRECs through a waiver of consent might support or undermine perceived trustworthiness in this space.

Bio

Vanessa Warren (she/her) is a PhD candidate in the Centre for Law and Genetics at the University of Tasmania. With a background in sociology and information management, her research concerns the interactions between the social and legal norms surrounding data, power, and uncertain futures.

11:30 – 12:00	Ethics and Genetics	Wednesday 23 November

First Nations Leadership and the Evolution of Ethical Genomics Research

Mr Greg Pratt

QIMR Berghofer Medical Research Institute

Bio

Greg is an Aboriginal man and descendant of the Brown family of the Noonucal tribe of the Quandamooka people of Stradbroke Island. He is a family man, a husband and father to four (three boys and one girl). He spent much of his childhood years with the Ghughuyalanghi people of Cape York, growing up in the township of Laura. With the support of his community and his family, Greg undertook study at the University of Southern Queensland, where he later graduated with a degree in psychology.

With an interest in people, mental health and social and emotional wellbeing, Greg spent his post graduate years working in rural New South Wales as an Indigenous mental health practitioner.

Since then, Greg has worked in both community and government sectors, in policy development, service delivery and project management. Before commencing with the QIMR Berghofer in December 2012, Greg was with the Centre for Rural and Remote Mental Health in Cairns and the Health Quality and Complaints Commission in Brisbane. Greg is passionate about community empowerment, emphasising strength-based approaches to change motivation and the ability of Indigenous Australia to lead the way with respect to better health and wellbeing.

12:30 – 12:50	Consent	Wednesday 23 December

Ethics and older adults: Moving with the times

Professor Nancy Pachana

School of Psychology, University of Queensland

Abstract

The WHO has declared 2021-2030 the Decade of Healthy Ageing, a global effort aligned with the Sustainable Development Goals, including Good Health and Wellbeing, and Reduced Inequalities. Global efforts to improve the inclusion and participation of older adults in society often come undone with respect to ethics applications and their review, with ageist and paternalistic stances persisting. This presentation will review global studies on both consumer and researcher views of enablers and barriers to fuller participation of older persons in research, with findings linked to the Australian context. It will also include the presenter's own research on capacity, consent and the ethics review process with respect to research focusing on older people. A case example of a community participant research pool will be discussed. Finally, practical steps that researchers (including student and early career researchers) and ethics committees can take to be more inclusive, informed, and encouraging of older adults participating in research, and of research with older persons as consumers and co-researchers, will be presented.

Bio

Dr Nancy A. Pachana is a clinical geropsychologist, neuropsychologist and professor in the School of Psychology at The University of Queensland. She is Director, Healthy Ageing Initiative in the Health & Behavioural Sciences Faculty, and Program Lead of the Age Friendly University Initiative, at UQ. She is also co-director of the UQ Ageing Mind Initiative, providing a focal point for clinical, translational ageing-related research at UQ. She has an international reputation in the area of geriatric mental health, particularly with her research on late-life anxiety disorders. She is co-developer of the Geriatric Anxiety Inventory, a published brief self-report inventory in wide clinical and research use globally, translated into over two dozen languages. She has published over 300 peer-reviewed articles, book chapters and books on various topics in the field of ageing, and has been awarded more than $24 million in competitive research funding, primarily in the areas of dementia and mental health in later life. Her research is well-cited cited and she maintains a clear international focus in her collaborations and research interests, which include anxiety in later life, psychological interventions for those with Parkinson's Disease, nursing home interventions, use of assistance animals in later life, older adults and environmental sustainability, strategies for healthy ageing, driving safety and dementia, teaching and learning in psychogeriatrics and mental health policy and ageing.

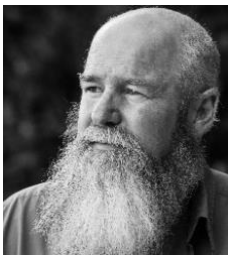
12:50 – 13:10	Consent	Wednesday 23 November

Relational Considerations in Consent in Clinical Research

Mr Ian Pieper

University of Canberra

Abstract



There are a number of constructs used to explain autonomy. This presentation frames autonomy as a relational concept. Relational theories see autonomy as inseparable from history, culture, relationships, and community. Under a relational autonomy model of consent, the engagement is individualised to ensure that the information and the process are relevant to each participant's personal circumstances. Individual agency is forged through social relationships and contextualised by intersecting social determinants, such as race, class, gender, and ethnicity. Individual agency within relational autonomy acknowledges that individuals make choices which are affected by relationships and by context. A relational approach to consent is, therefore, more reflective of the way people make decisions in the culturally-diverse society of modern Australia.

Bio

Ian Pieper became involved with health and medical research in 2001 working as a data manager for Quintiles in Europe, supervising the blinding of drug trials.
He has worked in research ethics and governance for industry, universities, governments, and as a consultant. He has lectured in health law and ethics and has multiple peer reviewed publications.

He is a subject matter expert advising the Commonwealth Department of Health's clinical trial reform agenda and currently holds appointments on committees advising the Australian Commission on Safety and Quality in Health Care, including on the development of the National One Stop and strengthening mutual acceptance of ethical review.

Ian is Chair of the University of Canberra Human Research Ethics Committee, a member of the Australasian Ethics Network Advisory Group, and of the QUT Australian Centre for Health Law Research.

His latest publication is a PhD thesis - Relational autonomy in clinical research: Relational considerations of adult participation in clinical research – which promotes the idea that participants in research must be afforded respect as individuals.

https://orcid.org/0000-0003-4838-224X

13:10 – 13:30	Consent	Wednesday 23 November

Navigating the pitfalls of using a waiver of the requirement for consent: practical approaches based on real world applications

Professor Nik Zeps

Chrysalis Advisory

Bio

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

Nik retains an academic role through the Eastern Health Clinical School of Monash University where he is an adjunct Professor and is Clinical Research Lead of Monash Partners through engagement with Chrysalis. He is a current Chief Investigator on grants of over $5 million and still co-supervises post graduate students and publishes academic papers.

13:30 – 13:50	Consent	Wednesday 23 November

Assessing a young person's maturity and capacity to consent via social media

Professor Sonia Grover & Dr Courtney Munro

Murdoch Children's Research Institute (MCRI)

Abstract

Acknowledging the importance of ascertaining capacity to consent and the difficulties of assessing an adolescent's competency for the survey for those recruited via social media, the LongSTEPPP study adopted a simple set of 8 questions to assess maturity and capacity to consent. These questions were administered in a secure online platform, REDCap.

The study successfully screened 2,362 individuals and recruited 1,811 adolescents in six weeks between September and October of 2021.

Bio

Professor Sonia Grover has extensive experience in paediatric and adolescent gynaecology having worked in this field for over 20 years. She has been instrumental in establishing this subspecialty in Australia as well as an Asia and internationally with teaching, providing clinical support and mentoring. As a gynaecologist, Sonia has the skills and expertise to undertake surgery on the reproductive and genital tract.

Dr Courtney Munro is the project coordinator for LongSTEPPP and a Senior Research Officer at MCRI. She has extensive experience in paediatrics having worked as a clinical pharmacist at Mercy Hospital for Women and The Royal Children's Hospital. She completed her PhD in the field of early detection of predictive indicators, or biomarkers, of aminoglycoside nephrotoxicity and ototoxicity in cystic fibrosis. Courtney has worked in a variety of healthcare settings, in academia, and more recently in a not-for-profit organisation in policy and advocacy – before returning to clinical research at MCRI in mid-2021. She holds an interest in the early detection and treatment of disease in paediatrics.

13:50 – 14:10	Consent	Wednesday 23 November

Development of a consumer-centred participant information and consent form in Australia: The inFORMed Project

Dr Lisa Eckstein & Dr Tanya Symons

CT:IQ

Abstract

The CT:IQ InFORMed project is developing a simplified and consumer- centred participant information and consent form (PICF) for the use of the Australian research sector, with the goal of replacing the current templates on the NHMRC website. A project team, including over 35 representatives of CT:IQ member organisations and consumer representatives, have developed a draft template. The layout is based on the premise of tiered information provision, with key information being provided upfront and (if necessary) more detailed information accessible through a second layer if a potential participant wants further information. The template has been informed by best practice, the scholarly literature and two separate surveys, one with consumers and another with other stakeholders (researchers, sites, sponsors, contract research organisations, HREC members and executive officers and governance officers). An overarching theme from the 715 survey respondents was the need for shorter, simpler, and less legalistic wording to make PICF's easier to understand.

In the second half of 2022, three studies are being selected as the basis for consumer consultation. For each study, a PICF will be developed with assistance from the study team, based on the inFORMed template. A representative group of consumers will be recruited to assess whether the PICF meets their needs. Is there enough information? Too much information? What kinds of visual and other cues are helpful to promote understanding?

The National HREC Conference provides an ideal opportunity to introduce the broader HREC community to the draft inFORMed template. The session will use live polling and other interactive strategies to ascertain attendee views on the template's compatibility with the National Statement on Ethical Conduct in Human Research and other regulatory requirements. This will feed into the next stage of the development process.

Bio

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

15:00 – 15:30	Use of Secondary Data	Wednesday 23 November

Facilitating reuse of LifeCourse data to benefit child and adolescent health

Dr Meredith O'Connor

Murdoch Children's Research Institute

Bio

Dr Meredith O'Connor is an educational and developmental psychologist. Her research investigates the development of optimal mental health over the life course. This includes both mental health challenges, and the mental health strengths and assets that allow people to thrive. To investigate this, she uses data from major Australian and international longitudinal cohorts.

15:30 – 16:00	Use of Secondary Data	Wednesday 23 November

Setting up clinical registries

Professor Susan Rossell

Swinburn University of Technology

Bio

Professor Susan Rossell is a cognitive neuropsychologist and Professorial Research Fellow at Swinburne's Centre for Mental Health. She also holds adjunct positions at Monash Alfred Psychiatry Research Centre and at St Vincent's Health.

Professor Rossell's research focuses on understanding the cognitive and neurobiological processes involved in psychosis and related disorders. She has published extensively and received both the International and European award for Young Investigator into Schizophrenia Research.

Prior to coming to Australia, Professor Rossell studied at the University of Manchester, the Institute of Psychiatry (part of King's College London) and Oxford University. She gained extensive experience in neuroimaging while undertaking a position at London's world-renowned Functional Imaging Lab. In 2000 Professor Rossell was awarded a prestigious International Wellcome Post-doctoral Fellowship during which she spent time at Macquarie University. Before joining Swinburne, she also held roles as Head of the Cognitive Neuropsychiatry Department at the Mental Health Research Institute of Victoria and at Monash Alfred Psychiatry Research Centre.

09:00 – 10:00	Plenary	Thursday 24 November

Global Research Ethics

Professor Paul Komesaroff

physician, medical researcher, and philosopher - Monash University, Director and Board Member of PRAXIS Australia

Bio

Paul Komesaroff is a practising physician and Professor of Medicine, and Executive Director of the international NGO Global Reconciliation. He has a PhD in philosophy and an international reputation in health care ethics, and has made a major impact on the field of clinical ethics in Australia. He has developed expertise in both qualitative and quantitative investigations of the social and cultural dimensions of health and health care.

As a physician, Paul's field of speciality is endocrinology. He is Director of the international ethics centre, the Centre for Ethics in Medicine and Society. He believes that one of the objectives of medical research is to contribute to the improvement of clinical practice and the development of new, more effective social policies.

12:30 – 12:50	The value of lived experience	Thursday 24 November

The involvement of consumers in the development of guidelines

Mr Vidar Enebakk, *Director*

The National Committee for Research Ethics in the Social Sciences and the Humanities, Norway

Bio

Vidar Enebakk is head of the secretariat of the National Committee for Research Ethics in the Social Sciences and the Humanities (NESH). He has a master's degree in the history of ideas and a PhD in philosophy of science and science studies from UiO. EN: Director of The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH).

12:50 – 13:10	The value of lived experience	Thursday 24 November

Ethical considerations for the inclusion of patient-reported outcomes in clinical research: The PRO ethics guidelines

Dr Jessica Roydhouse

University of Tasmania

Abstract

Background - Patient-reported outcomes (PROs) are used in clinical research to provide evidence of the benefits and risk of therapies from a patient perspective. PRO trial data have the potential to inform regulatory approvals, health policy and clinical practice. In observational studies and routine clinical care, PRO data provides information on disease burden and real-world evidence of treatment safety and effectiveness. However, ethical concerns have been raised regarding PRO use.

Bio

Prior to her PhD, Jessica worked at the University of Sydney, where she coordinated a community-based randomised controlled trial and worked on health services research projects in cancer care. She completed her PhD at Brown University, focusing on proxy reporting for patient-reported outcomes in cancer, and then spent over two years at the FDA working on methodological research in cancer trials.

13:10 – 13:30	The value of lived experience	Thursday 24 November

Partnering with consumers in research

Dr Natasha Roberts

University of Queensland

Bio

Natasha Roberts is a Specialist Nurse, Clinical Research Fellow with Metro North Health and Nursing Conjoint with the STARS Alliance in Brisbane Queensland. Natasha has an interest in clinical implementation, with an emphasis on co-design with clinical teams, patients, families and communities. Presently she is the Chair Elect for the International Society for Quality of Life Patient Engagement Special Interest Group, and also a member of the Royal Brisbane and Women's Hospital human research ethics committee.

13:30 – 13:50	The value of lived experience	Thursday 24 November

Involvement in cancer trials groups

Ms Leonie Young, *Peer Support Coordinator*

Wesley Hospital Choices for Cancer Support Centre

Abstract

There are some key principles of engaging well with people with a lived experience in all aspects of research, decision making, policy, and support initiatives and when these are applied, the overall result will be far more successful and satisfying for all. The consistent message is that people with a lived experience of their disease bring a unique perspective, something that is distinctive to them. They also bring a wealth of diversity, knowledge, and capabilities. Above all, they bring motivation for improving outcomes and the ability to ground research in the lived reality. When the person matches the role in these areas, then their contributions can be enormous and invaluable, however, achieving this can be a challenge.

Bio

Leonie Young DUniv lives in Brisbane, Australia. She was diagnosed with breast cancer in 1987 and since her diagnosis, she has been involved with many aspects of cancer consumer advocacy, support, training, and mentoring. As an advocate of clinical trials research, she is also involved as an experienced consumer member and investigator on numerous research initiatives engaging with both national and international cancer organisations and institutions.

Leonie is a member of several committees and cancer focused organisations including - the Australia & New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) Consumer Advisory Panel; Breast Cancer Trials (BCT) (and is immediate past Chair and an inaugural member of the BCT Consumer Advisory Panel); International Society for Quality of Life Research (ISOQOL); ABC Global Alliance; the National Breast Cancer Foundation Grant Review Committee; the Cochrane Collaboration; the breast tumour steam for the Centre for Personalised Analysis of Cancers (CPAC); the Queensland Cancer Clinical Network Executive Committee (Queensland Health); and the Clinical Oncology Society of Australia (COSA) Council.

In addition, she is the Peer Support Coordinator for the Wesley Hospital Choices Cancer Support Centre, Brisbane; a co-founder and co-facilitator of *EveryCloud* Consumer Advocacy Training Programs; President of Reach to Recovery International; and she holds a position as Honorary Research Fellow with Wesley Medical Research.

Leonie is a regular presenter at national and international conferences, presenting from the consumer perspective on topics relating to research, survivorship, communication, sexuality and intimacy, advocacy, and leadership.

Leonie is the recipient of an Honorary Degree of Doctor of the University, Griffith University, Brisbane, Australia and the Reach to Recovery International Terese Lasser Award both in recognition of distinguished service to the community, particularly as an advocate for women diagnosed with breast cancer.

15:00 – 15:30	International Perspectives	Thursday 24 November

BRIDGE Guidelines: development and use of guidelines for good epidemiological practice in global health

***Dr Sandra Alba**, Senior Epidemiologist*

KIT Royal Tropical Institute, The Netherlands

Abstract

Research integrity and research fairness have gained considerable momentum in the past decade and have direct implications for global health epidemiology. Research integrity and research fairness principles should be equally nurtured to produce high-quality impactful research—but bridging the two can lead to practical and ethical dilemmas. In order to provide practical guidance to researchers and epidemiologist, we set out to develop good epidemiological practice guidelines specifically for global health epidemiology, targeted at stakeholders involved in the commissioning, conduct, appraisal and publication of global health research.

Bio

Sandra Alba, MSc, PhD, is an epidemiologist with a background in medical statistics. She has 15 years' experience in the application of statistical and epidemiological methods to evaluate global health programmes.

She obtained an MSc in Medical Statistics at the London School of Hygiene and Tropical Medicine in 2006, and soon after joined the Swiss Tropical and Public Health Institute to evaluate a programme aimed at improving access to malaria treatment in rural Tanzania. After completing her PhD in 2010, she spent two years working as a clinical trial statistician in Switzerland. At the end of 2012 she joined the KIT, in the Netherlands, as an epidemiologist. She has ample experience in designing studies, developing data collection tools, coordinating fieldwork and data management, analyzing data, reporting on study results, and formulating public policy recommendations.

Sandra's responsibilities at KIT include coordinating epidemiology and statistics courses for the KIT Masters courses in International and Public Health, and she also supervises students' final year theses.

15:30 – 16:00	International Perspectives	Thursday 24 November

The intersection of ethics and integrity in Human Subjects Research

Dr Jake Earl, *Bioethicist*

Walter Reed Army, Institute of Research, USA

Abstract

Despite widespread agreement about the importance of "research integrity" and "research ethics," there is pervasive disagreement and lack of clarity about what these terms mean. Various international scholarly, legal, regulatory, educational, and organizational sources offer conflicting or confusing definitions, which can cause uncertainty about the responsibilities of different stakeholders in the research enterprise. This talk provides a new conceptual analysis on which "ethics" and "integrity" refer to two different types of norms that apply to scientific research, which often but do not always align. Using real-world examples, this talk illustrates how this conceptualization of ethics and integrity norms can be applied to research with human subjects.

Bio

Jake Earl is a bioethicist with the Walter Reed Army Institute of Research in Silver Spring, Maryland, USA. Prior to his current position, he completed a postdoctoral fellowship in bioethics at the National Institutes of Health Clinical Centre and worked as a hospital ethicist. He holds a PhD in philosophy from Georgetown University, and his research interests include topics such as procreation and parenthood, biomedical research and innovation, population and climate change, and infectious disease.

08:00 – 09:00	Plenary	Friday 25 November

How research ethics committees can contribute to equitable research partnerships

Professor Doris Schroeder, *Director of Centre for Professional Ethics*

University of Central Lancashire, School of Sport and Health Sciences, UK and UCLan Cyprus, School of Law

Abstract

Our research has shown that *equitable* research partnerships are governed by fairness, respect, care and honesty. They are best established prior to the research agenda setting and ideally involve all stakeholders from the start. That's an ambitious task. How can research ethics committees (RECs) contribute to it? The session will discuss *pro-active* REC contributions such as the encouragement of local research partners to avoid helicopter research practices or the use of the *Global Code of Conduct for Research in Resource-Poor Settings*. And it will discuss the potential harm of *top-down* REC decisions, which may exclude vulnerable populations from research they could benefit from instead of trying to reduce the risks involved.

This session will be in two parts. The first part will be a video clip where Prof. Schroeder will be joined by the Editor-in-Chief of Research Ethics, the research director of seven clinics looking after 40,000 sex workers in Nairobi, the main lawyer of the San people in South Africa, a community HIV champion from Nairobi and the Director of the South African San Council. Together, the group will try to convey what to RECs can do to promote equitable research partnerships. In the second part, Prof. Schroeder will join the conference live to answer questions and get involved in the debate.

Bio

Doris was educated in Germany and the UK at postgraduate level in business / economics and philosophy / politics. Her first career was in management, as a budget planner for Time Warner. She has given invited presentations on all continents and in 28 countries. Previous employers include the University of Melbourne (Professorial Fellow), the University of Oslo and the University of Witwatersrand in Johannesburg.

Doris has a research-only post at the University of Central Lancashire, which includes doctoral supervision. She has led a considerable number of competitive funding projects, including from the European Commission and the Wellcome Trust. Doris is the leading academic on 'ethics dumping', the export of unethical research practices from high to lower income regions. Her co-edited ethics dumping case studies (Springer, 2018) have been downloaded over 160,000 times. She is also the Lead Author of the Global Code of Conduct for Research in Resource-Poor Settings, which is being used in at least 40 countries.

09:00 – 10:30	Privacy Training	Friday 25 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

Bio

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 our e-learning privacy training program, and delivers most of our face to face training. She has developed and delivered customised privacy training on behalf of clients including QANTAS, Sage Software, the Office of the Australian Information Commissioner, and PRAXIS Australia.

12:30 – 12:50	Abstracts – Stream A	Friday 25 November

The ethics of evaluating co-parenting smartphone apps: Cussing for science

Professor Bruce Smyth

Australian National University

Abstract

An ever-increasing number of post-separation parenting smartphone apps are available in Australia. These apps seek to help parents manage their post-separating parenting arrangements, and typically comprise a messaging tool, shared calendar, expense tracker, and a means to retain documents for legal purposes. A challenge for separated parents, as well as family law professionals, is knowing which apps work for different family contexts and situations. In spite of a lack of evidence for their efficacy, family courts are mandating the use of apps, and divorce mediators are recommending them to separated parents. In this presentation, we set out key ethical challenges of our Linkage Project in which we evaluate co-parenting apps. The need for burner phones, Gmail aliases, consent for mediators to swear and menace each other in role plays as high-conflict parents, and staying at arm's length to app developers, stretched the team in ways not anticipated. This novel project is funded by the Australian Research Council (LP200100413) in partnership with the Australian National University, the University of Wollongong, and Relationships Australia (Canberra and Victoria).

Bio

Bruce is a family sociologist, with a background in psychology and research methods. He has been at the ANU for almost a decade. Previous appointments include Senior Research Fellow at the Australian Institute of Family Studies; and member of the Ministerial Taskforce on Child Support. He recently completed an ARC Future Fellowship. Bruce has published widely in the area of divorce and post-separation parenting, and currently serves on the editorial boards of Family Court Review; Journal of Family Studies; Australian Journal of Family Law; and Family Law Review.

HRECs as resource versus obstruction: the vexed relationships between Human Research Ethics Committees and Researchers

Dr Susan R. Hemer

University of Adelaide

Abstract

This paper examines the sometimes-difficult relationships between researchers and Human Research Ethics Committees. The literature has characterised these relationships as ranging from HRECS seen as a resource for researchers, to them being obstructive, disconnected or having poor communication with researchers. Quite often the literature demonstrates a slippage between the relative roles of the National Statement, the HRECs and the institutions that host HRECs, with accusations, for example, of HRECs as protecting the institution's reputation or being overly individualist or positivist. Having been on both sides of this relationship, I reflect on my experience as both a social science researcher, and a HREC member at a major Australian University. The paper suggests that despite calls for better communication between researchers and HRECs at least fifteen years ago (Gillam et al 2007), relationships between HRECs and researchers continue to be problematic, and this potentially undermines the integrity of ethics and review processes as researchers may practice ethics avoidance (Gorman 2011: 14.6). It ends with some reflections on potential ways to broach the gulf between researchers and HRECS.

Gillam, L., M. Guillemin, D. Rosenthal. 2007. â€˜Obstructive and power hungry: the Austraian human research ethics process. Monash Bioethics Review 25 (2)30-8.
Gorman, S. M. 2011. Ethics Creep or Governance Creep: Challenges for Australian Human Research Ethics Committees. Monash Bioethics Review 29 (4): 14.1-14.16.

Bio

Dr Susan Hemer is a Senior Lecturer in Anthropology & Development Studies. Dr Hemer's research interests include the social, health and gendered impacts of mining and development projects in Melanesia; socio-cultural, gendered, historical and political aspects of access to health care; health care issues including HIV/AIDS, Tuberculosis, gendered violence and maternal health care in Papua New Guinea; emotions, death, grief and mourning. Dr Hemer publishes in medical and psychological anthropology, and development studies. She holds a long-standing interest in the ethics of research, and is currently a member of the University of Adelaide HREC. Her research expertise includes ethnography, interviews, qualitative surveys and archival research. Her book, Tracing the Melanesian Person, was published in 2013. She lectures in the areas of medical and psychological anthropology, and development studies. She gained her PhD in Anthropology from the University of Melbourne.

13:10 – 13:30	Abstracts – Stream A	Friday 25 November

Do HRECs have a role in cyber security?

Geoff Vass

Lay member, Women's and Children's Hospital, Adelaide

Profession: IT Professional, Cadzow TECH Pty Ltd

Abstract

How many protocols have you read that promised documents would be kept in a locked filing cabinet in the researcher's office? And yet how many have you read where the researchers detailed all their security practices?

Like everything else, research is now conducted largely online - email, file storage, cloud compute, data sharing in bulk; the papers in someone's office are no longer the main risk. The risk is online - ransomware, weak security, privacy breaches. HRECs may think of those as operational problems unrelated to whether research satisfies the National Statement. Yet the author will argue HRECs should play a role in cyber security practices across the researcher/institution/industry ecosystem.

NB This talk will be closer to an editorial than an academic paper as the author is not an academic

Do HRECs need a decision-making framework when considering research applications requesting deferred consent? Experiences of a paediatric HREC

Ms Rebecca Doyle

Children's Health Queensland Human Research Ethics Committee

University of Queensland

Abstract

Background:

The National Statement on Ethical Conduct in Human Research (The National Statement) provides ethical guidance for potentially vulnerable research participants. However, some sections of The National Statement are ambiguous and equivocal, particularly when considering consent for potential research participants undergoing treatment in emergency and intensive care. Researchers conducting studies focused on critically ill children face an ethical dilemma in that many life-saving interventions do not allow time for informed, prospective consent to be obtained from parents or legal guardians. One course of action is for researchers to request the use of 'deferred consent', whereby a patient is enrolled in a trial and treated according to trial protocols before explanatory discussion or request for consent has occurred.

Challenges for HRECs:

Twenty-two research projects were submitted to a paediatric HREC between 2013 and 2022 that specifically requested the use of deferred consent. Eighty-two percent (n=18) were granted approval to use deferred consent while the remainder of projects were approved but restricted to the use of prospective informed consent. Consideration of these projects elicited robust discussion amongst committee members and the National Statement provided little clarity during the decision-making process.

Development of a criteria for deferred consent:

The committee developed a Position Paper as a reference point for researchers and HREC members. This document outlined specific criteria projects should meet if requesting deferred consent, and the conditions of approval of deferred consent. Whilst it has provided some guidance, HRECs may benefit further from clear and concise guidance sanctioned by The National Statement. What is needed is a pragmatic decision-making framework that considers the urgency of the intervention; examines the equipoise of proposed treatments; and provides some scaffolding around mitigating risk to patients and families.

Authors:

Ms Rebecca Doyle [1,2]; Dr Helen Petsky [1,3]; Ms Amanda Smith [1]; Prof Alan Isles [1], A/Prof Craig McBride [1,2,3]

1 Children's Health Queensland Human Research Ethics Committee
2 University of Queensland
3 Griffith University

12:50 – 13:10	Abstracts – Stream B	Friday 25 November

Ethics Review-Disruption, Innovation and Advancement

Ms Sashika Naidoo

QIMR Berghofer Medical Research Institute

Abstract

The COVID-19 pandemic has led to extraordinary global responses to manage the challenges posed by this upheaval. It has affected every facet of society. This presentation deals with efforts of pandemic proportions: the collapse of order, as we know it; the disruption of systems and an ethical re-orientation.

13:10 – 13:30	Abstracts – Stream B	Friday 25 November

Human research ethics application pathways: Implementing an online decision support tool for researchers and higher researcher degree students

Dr Karen Olave-Encina

The University of Queensland

Abstract

Conducting ethical research with humans is a foundation to the generation of reliable and high-quality research and innovation. Fostering a culture of responsible and ethical research while simultaneously responding to the specific obligations prior to starting the research work are priorities for higher education institutions. The review of human research ethics application depends on the characteristics of the research projects. For many new researchers especially HDR students selecting the appropriate application review pathway can be a time consuming and confusing. Researchers and HDR students are hesitant about the pathway they need to choose relying only on the information provided on the institution's website. Data collected from over a dozen human ethics training events indicated that 30 percent of questions asked were related to human ethics review pathways. We designed and developed an online decision support tool in Articulate, storyline to support them in this decision. This support tool was implemented at an Australian university with over 22,000 postgraduate students and researchers. A collaborative approach was adopted to develop the tool and constructive feedback loops were used to make improvements. Over a period of three months, we piloted the decision support tool with review panel and HREC chairs, researchers and HDR students. Participants reported that it was easy to use and allowed them to get a fast response about the human ethics review pathway. This initiative will contribute to the education and training of researchers on human research ethics in higher education.

14:00 – 14:30	The future of HRECs in Australia	Friday 25 November

The only way is Ethics – Lessons learned in the UK

Ms Charlotte Allen

Health Research Authority UK

Abstract

This presentation will cover the UK HREC model with insights into what works and why. You will be provided with an overview of the HRAUK's quality assurance program and standards. Even well-established programs have their challenges, find out what challenges the HRAUK are facing and finally what is their vision for the future!

14:30 – 15:00	The future of HRECs in Australia	Friday 25 November

When HRECs reach their limit of competence

Ms Kylie Sproston

Bellberry Limited

Bio

Kylie is an experienced Chief Executive Officer with a demonstrated history of working across the pharmaceutical/biotech life cycle. She is a chartered professional Engineer, Fellow of the Australian Academy of Technological Sciences and Engineering. Skilled in Manufacturing, Regulatory Strategy, Research and Development, Engineering Project Management and Change Control, Corporate Management and Business Development. She has experience in both for profit and profit for purpose sectors.

healthtranslationqld.org.au/hrec-conference-2022