BOND UNIVERSITY

SEQ Combined Human ResearchEthics TrainingDay | 11 October 2019

Clinical trials as a model for best practice

9.30am – 10.00am | Welcome and Introduction
Dr Mark Bahr

I am very pleased to welcome you to our ninth year of the South-East Queensland combined human research ethics training days. Each year we identify a theme to reflect upon. These themes allow us to reflect on our role. This year is no different, in fact we will start with a variation of that very question what is the role of the HREC in clinical trials? Why are we framing this year's discussion around clinical trial as best practice? Clinical trials are a vital part of the development of new procedures and the development of improved clinical outcomes for patients. I don't think that is in dispute, what is perhaps of more concern is the perpetual claim that new treatments in clinical trial necessarily provide better patient outcomes than traditional treatments. This line is often presented in trial recruitment and it presents an ethical concern, especially if the trial precludes the patient of the opportunity to avail themselves of a well understood effective treatment.

Once again, we have been fortunate to have brought together well-respected speakers with expertise in the clinical trial ethics and research. Together they constitute a program of international standard. As always, the speakers provide us with insight into their experiences of working with these groups. Two recent reviews of scientific development provided contrasting views of our current state, one indicated that our knowledgebase was continuing to increase exponentially and that we were in a period of flowering of knowledge, whereas the other suggested that development had plateaued from a technological perspective. Research in clinical trials tend to suggest the former is true as trials increasingly approach very subtle mechanisms to achieve their aims. On the other hand, the emergent issue of antibiotic resistance without a commensurate replacement with new compounds suggests the plateau view is also accurate at some levels. Clearly clinical trials of new compounds provide hope for patients where existing treatments are becoming less effective or where no effective treatment exists, a serious ethics concern arises when a false hope is promoted, or hope is exaggerated for a participant population which may be desperate for hope.

As always my hope is that in exploring these issues with our fellow attendees it will enable us to better identify strategies to engage with clinical trials research and indeed ethics review in general to enable the important research to proceed with respect to the participants in such a way that they better understand the benefits and risks associated with their participation in the study. One of the great benefits of these seminars is that they provide an opportunity for attendees to engage in conversations with others and to reflect on one's own experiences and to learn from others.

It is in this spirit of cooperating that I have the pleasure to welcome you to the South-East Queensland combined human research ethics training day.

Clinical Trials – Schedule of events

9.00 am - 9.30 am	Registration
9.30am – 10.00am	**Welcome and Introduction** - *Dr Mark Bahr, Chair Bond University HREC*
10.00am – 10.45am	**The HREC role in Clinical trials** - *Dr Gordon McGurk, Chairperson, Royal Brisbane and Women's Hospital HREC*
10.45am – 11.30am	**Reproducibility in Research** - *Dr Alexandra Bannach-Brown, Postdoctoral Research Fellow, Institute for Evidence-Based Healthcare*
11.30am – 12.00pm	**Morning Tea**
12.00pm – 12.45pm	**Honest equipoise and what it will mean for patients** - *Dr Lewis Campbell, Intensive care physician, Royal Darwin Hospital*
12.45pm – 1.30pm	**Therapeutic Misconceptions** - *Dr Ian Pieper, Director, Research Strategy, Centre for Health and Medical Research, ACT Health*
1.30pm – 2.15pm	**Lunch**
2.15pm – 3.00pm	**Clinical Trials governance** - *Dr Bernadette Aliprandi-Costa, Manager, Safety and Quality Improvement Systems and Intergovernmental Relations at the Australian Commission on Safety and Quality in Health Care*
3.00pm – 3.45pm	**Patient outcomes, lessons from trial failures** – *Dr Mark Bahr*
3.45pm	**Close**

10.00am – 10.45am | Dr Gordon McGurk
The HREC role in Clinical Trials

Gordon has been the Chairperson of the Royal Brisbane and Women's Hospital Human Research Ethics Committee (HREC) since Feb 2018, the UQ HREC 'A' since Feb 2019, and is a member of the Townsville Hospital and Health Service HREC.

Prior to working in the area of Human Research Ethics, Gordon was a Director in the National Health and Medical Research Council and conducted work in the areas of human and animal ethics, academic integrity, research misconduct, research governance and improving clinical trials in Australia.

He is the Director of OmniAdvisory Consulting, specialising in the relevant areas of clinical trials strategy development:

- human and animal ethics
- research governance
- corporate governance
- research integrity

He is also a Fellow of the Governance Institute of Australia and Graduate of the Australian Institute of Company Directors

Metro North
Hospital and Health Service

Queensland
Government

10.45am – 11.30am | Dr Alexandra Bannach-Brown
Reproducibility in Research

Alex is a post-doctoral research fellow at the Centre for Evidence-Based Practice, Bond University, with expertise and interests in evidence synthesis, open science and the automation of systematic reviews.

Her research involves developing and implementing automation tools to reduce waste in healthcare and biomedical research and improve research quality.

INSTITUTE FOR
Evidence-Based Healthcare

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11.30am – 12.00pm| Morning Tea

12.00pm – 12.45pm | Dr Lewis Campbell
Honest equipoise and what it will mean for patients.

Lewis is an Intensive Care physician at the Royal Darwin Hospital, NT.

He is also Chair of the HREC of the NT Department of Health and Menzies School of Health Research, with some jurisdictional responsibilities attached to those jobs.

He finds this most rewarding due to how much there is to learn and how many cultures come together to agree on difficult things.

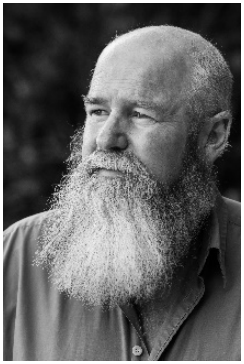
Lewis has research interests in computational biology and adaptive clinical trials, which he feels should make Therapeutic less of a Misconception, and equipoise easier to agree. For the time being, these big moral issues, along with consumer engagement, are what keep him awake at night.

NORTHERN TERRITORY GOVERNMENT

menzies school of health research

12.45pm – 1.30pm | Dr Ian Pieper, Therapeutic Misconceptions

Ian Pieper Director, Research Strategy, Centre for Health and Medical Research, ACT Health – ORCiD: https://orcid.org/0000-0003-4838-224X



Ian has supported the ethical conduct of health and medical research for more than a decade. He has supported researchers, students and human research ethics committees (HRECs) within universities, health services, and as a consultant. Ian has organised and conducted HREC and research ethics training across a wide range of institutions. Ian helped to develop the combined training seminar for the HRECs based in South East Qld and Northern NSW and has presented on several occasions. He has been instrumental in establishing a similar training program for the ACT-based HRECs.

Ian was appointed to the expert advisor panel to advise Australian Commission on Safety and Quality in Health Care (ACSQHC) during the development of the national Clinical Trials Governance Framework as an expert in both human research ethics and governance processes.

He has developed and conducted the induction and general training for several HRECs and at AEN conferences, with a focus in ensuring compliance with research governance frameworks.

Ian is based in the ACT, where he is currently the Director of Research Strategy for ACT Health and is in the process of completing his PhD through the QUT Australian Centre for Health Law Research. He has completed formal qualifications – Bachelor of IT, Grad. Cert. HRM, Grad. Cert. Research Ethics and a Masters of Ethics and Legal Studies.

ACT Government | ACT Health

1.30pm – 2.15pm| Lunch

2.15pm – 3.00pm | Dr Bernadette Aliprandi-Costa, Clinical Trials governance

Bernadette is the Manager, Safety and Quality Improvement Systems and Intergovernmental Relations at the Australian Commission on Safety and Quality in Health Care (the Commission).

The Commission is an Australian government agency funded by the Council of Australian Governments (COAG) and all states and territories. It leads and coordinates national improvements in safety & quality of health care based on best available evidence. The Commission works in partnership with the Australian Government, state and territory governments, private sector, patients, clinicians, managers and health care organisations.

Bernadette holds a PhD in health outcomes research from the University of Sydney and has lead programs of work in the hospital setting:

- developing quality reporting frameworks
- designing and implementing system performance reporting programs designing and managing clinical quality registries
- designing and implementing government funding models in the health and vocational education and training sectors

Currently, Bernadette is leading the revision of the Australian Framework for Clinical Quality Registries and the development and implementation of the National Clinical Trials Governance Framework which is a key element of the COAG Health Council's revitalised clinical trials agenda.

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

3.00pm – 3.45pm| Dr Mark Bahr, Chair of Research Ethics Committee, Bond University

Dr Mark Bahr BA, G.Dip Psych, Ph.D. is a cognitive psychologist and research methodologist.

During the last 20 years he has taught experimental psychology, statistics and methodology courses at Griffith University, The University of Queensland and since 2004 at Bond University.

He has been Chair of the Bond University Human Research Ethics committee since 2005. As Chair of the ethics committee he has been involved in the adoption of the 2007 National Statement on Ethical Conduct in Human Research and experienced the evolution of ethics review in the Australian context in the intervening years.

Following the decline of NHMRC sponsored ethics training days, Mark, along with a group of like-minded colleagues from across South-East Queensland hosted the first South East Queensland Ethics Training day in February of 2011. In 2012 he served on the organising committee of the first Australian Ethics Network Conference hosted by QUT in 2012. He has had the opportunity to work on very large research projects with Education Queensland and other Queensland government and national bodies.

He has more than 60 publications in book chapters, journals and conference publications. He has supervised numerous 4th year and Master level student projects as well as 13 PhD projects.

Mark has presented at the AEN conferences as well as being an active contributor to the South-East Queensland Annual Ethics training day and regularly provides training to academic staff and students on ethics matters at Bond University.

He has also had a role in drafting institutional polices at Bond University regarding ethics, bioethics, animal ethics, research integrity and academic misconduct.

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3.45pm – 4pm| Dr Mark Bahr, Chair of Research Ethics Committee, Bond University

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Acknowledgement and closure

of 2019 Research Ethics Training Day

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