

Dealing with Vulnerability

SEQ Combined Human Research Ethics Training Day

Program of Events
Wednesday, 11 October, 2017



Welcome



I am very pleased to welcome you to our sixth year of the South-East Queensland Combined Human Research Ethics Training Day. Many of the reviews we conduct in our ethics review role deal with the general population and often our thinking around ethical review of those populations is influenced by the notion of greater good and individual freedoms. In most instances, the ethics committee has a role as a voice for the community in these matters but we assume that the participants are capable of speaking for themselves. However, there are a range of studies that we come across where the participant's voice may not be as strong as we are used to and where the balance of our assessments may need to account for other factors such as our own biases. This year's theme addresses the issues associated with working with vulnerable populations.

As in the past we have invited well-respected speakers who work with, research or speak for vulnerable populations, and together they constitute a program of international standard. As always, the speakers provide us with insight into the problems associated with working with vulnerable populations - usually this raises more questions than answers. In the discussion of these questions with our fellow attendees we broaden our understanding of the issues, have an opportunity to expose our presumptions, and learn about different approaches to common problems. 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.

Following the format of previous seminars, the day will consist of a mix of formal presentations and informal case study discussions. The purpose of these training days is not simply to passively learn but also to actively engage in respectful debate and discussion, and to learn from the experiences of others and see the same problems from another perspective.

It is in this spirit of cooperation that I have the pleasure to welcome you to the South-East Queensland Combined Human Research Ethics Training Day.

Dr Mark Bahr

Bond University Human Research Ethics Committee

Note from the Organiser



Ian Pieper has been organising these seminars since the first event in 2012. For him, these days are about ideas, opinions, and philosophical debate with practical outcomes. Ian has had a wide range of experience in all aspects of human research ethics, from the administration of human research ethics committees and the development and conduct of training packages. He has several qualifications in the field of ethics and is currently working on his PhD, studying the considerations given to autonomy within consenting process for clinical research. Ian has worked for several universities and government departments and is currently with the Department of Health in Canberra. The work he does in organising this seminar is not related to the work he does for the Commonwealth.

Mr Ian Pieper

Ethical Futures

Dealing with Vulnerability

SCHEDULE OF EVENTS

9.15am - 9.45am	Registration
9.45am - 10am	Welcome
10am - 10.45am	Research by Government Reform Bodies Involving Vulnerable People and Populations
10.45am - 11.30am	Addressing Vulnerability in Research Ethics
11.30am - 12 noon	Morning tea
12 noon - 12.45pm	Researching Incarcerated Populations
12.45pm - 1.30pm	Researching Suicide
1.30pm - 2.15pm	Lunch
2.15pm - 3pm	Ethical Complexities of Child Co-Research
3pm - 3.45pm	Identifying Vulnerability
3.45pm	Close, followed by informal afternoon tea



10AM - 10.45AM

RESEARCH BY GOVERNMENT REFORM BODIES INVOLVING VULNERABLE PEOPLE AND POPULATIONS

The Australian Human Rights Commission works extensively with people and communities who constitute 'vulnerable populations' in the human research ethics context. For example, the National Children's Commissioner is currently exploring the issues faced by young parents aged 19 years and under, the Sex Discrimination Commissioner has just completed a landmark project on the nature and extent of sexual assault and sexual harassment at Australian universities and the Human Rights Commissioner has recently commenced a project to determine how best to protect the human rights of people with

intersex variations in the context of medical interventions.

The content and conduct of this research necessarily raises important human rights and ethical considerations. In this session, Human Rights Commissioner Edward Santow will reflect on some of the particular ethical challenges encountered by the Commission in its work with vulnerable populations and the strategies it has adopted to meet these challenges within a human rights-based framework.

Mr Edward Santow Human Rights Commissioner, Australian Human Rights Commission



Ed commenced his five-year term as Human Rights Commissioner at the Australian Human Rights Commission in August 2016.

Prior to joining the Commission, Ed was Chief Executive of the Public

Interest Advocacy Centre, a leading non-profit organisation that promotes human rights through strategic litigation, policy development and education.

Ed was previously a Senior Lecturer at UNSW Law School and a research director at the Gilbert + Tobin Centre of Public Law. His areas of expertise include human rights, administrative and constitutional law, discrimination and freedom of information.

As Human Rights Commissioner, Ed leads the Commission's work on marriage equality and other human rights issues affecting LGBTI Australians. Ed also leads the Commission's work on the Optional Protocol to the Convention Against Torture (OPCAT) and he has primary responsibility for the Commission's work on freedom of expression, freedom of association and freedom of religion.

Ed is a Senior Visiting Fellow at the University of New South Wales (UNSW), and serves on a number of boards and committees, including the Australia Pro Bono Centre. In 2009, Ed was presented with an Australian Leadership Award, and in 2017, he was recognised as a Young Global Leader by the World Economic Forum.

10.45AM - 11.30AM

ADDRESSING VULNERABILITY IN RESEARCH ETHICS

Section 4 of the *National Statement on Ethical Conduct in Human Research (NS)* concerns 'Ethical considerations specific to participants'. Each chapter identifies a potentially vulnerable research population such as pregnant women, people highly dependent on medical care and Aboriginal and Torres Strait Islander Peoples. The *NS* requires full HREC review of any research proposals for most of these identified populations.

This approach is based on the idea that identified vulnerable groups of participants require protections over and above the usual considerations for all research participants. However, 'labelling' some groups or individuals as vulnerable and requiring specific protections is problematic. This approach assumes that all members in the designated group are equally vulnerable and that all research with them requires extra scrutiny. But this does not seem right - not all research with pregnant women is high risk.

Professor Wendy Rogers Professor of Clinical Ethics, Macquarie University



Wendy holds a joint appointment between the Department of Philosophy and Department of Clinical Medicine at Macquarie University. She has qualifications in medicine (BM.BS, Flinders University; MRCP, UK; FRACGP) and in philosophy

and bioethics (BA Hons and PhD, Flinders University).

Wendy has twice been a member of the Australian Health Ethics Committee. In the 2003 - 2006 triennium she was a member of the working party responsible for the 2007 version of the *National Statement on Ethical Conduct in*

In addition, labelling can lead to stereotyping and / or paternalism, such as the requirement that all research involving Aboriginal and Torres Strait Islander Peoples be subject to full HREC review.

In this presentation, Professor Wendy Rogers presents a way of thinking about vulnerability that identifies specific sources of vulnerability relevant to participation in research. Three main 'ethical considerations specific to participants' will be identified and are relevant to reviewing research with participants who may be vulnerable in one or more ways. These are:

- Capacity for decision making regarding participation in research;
- The potential for exploitation of participants (e.g. arising from their role in a relationship, such as student or patient) or other inequalities; and
- Other sources of vulnerability or unique sensibilities regarding specific participants.

Human Research. In the 2012 - 2015 triennium, she was appointed to lead the rolling review of the *National Statement*, and she currently remains chair of the NHMRC s39 working group continuing with that review.

Wendy has research interests across a wide range of topics in bioethics. Her current project, funded by an Australian Research Council Future Fellowship, investigates conceptual and practical issues to do with overdiagnosis. Her previous research has engaged with many areas of bioethics including research ethics; the ethics of surgical practice and innovation; public health ethics; organ donation; conflicts of interest; and a project investigating the nature of vulnerability and duties owed to the vulnerable.

11.30AM - 12 NOON MORNING TEA

12 NOON - 12.45PM RESEARCHING INCARCERATED POPULATIONS

Research with incarcerated populations involves collecting data from special groups who are more vulnerable than the general population, minors; prisoners; Aboriginal and Torres Strait Islanders; and intellectual, mentally or physically impaired individuals. This requires consideration of privacy in obtaining identifying details of incarcerated individuals, potential for power-dependency when custodial staff are involved in recruitment and the potential for disclosure of illegal behaviour.

Obtaining consent from incarcerated samples requires consideration of high rates of cognitive impairment, potential impairment of capacity to provide informed consent and cultural

considerations. Incarcerated samples have high rates of trauma, heightened risk for suicide and self-harm and potential for harm toward researchers, necessitating precautions and safety plans.

Data collection within prisons requires corrective personnel to collect and transfer prisoners, imposing costs upon external organisations. Further, the use of incentives can pose a challenge, whereby offending youth have potential to misuse such resources. Each of these considerations are detailed while describing previous research completed with both juvenile and adult offenders.

Dr Bruce Watt Assistant Professor in Psychology, Bond University



Bruce is a Forensic and Clinical Psychologist who commenced his career researching interventions with incarcerated violent offenders. He has subsequently investigated family based interventions for antisocial youth, predictors of juvenile

violent recidivism, community correlates of violence and psychopathy, evaluation of a return to work assist program, animal cruelty and fire-setting among juvenile offenders, and juvenile fitness for trial.

Currently, Bruce is investigating arson-related homicides, high risk psychotic phenomena and juvenile threats of harm to others.

12.45PM - 1.30PM

THE PSYCHOLOGICAL AUTOPSY AND STUDIES IN SUICIDE RESEARCH - WHAT ABOUT THEIR ETHICS?

The Psychological Autopsy (PA) is a valuable tool both for determining the manner or mode of equivocal deaths and eliciting information from important sources, including medical and police reports, personal documents, the clinical opinions of health professionals, as well as interviews with next-of-kin. This method has been used to study suicide, but also considered as an appropriate method to study the

bereavement of suicide and other types of death.

The aim of the presentation is to look more deeply into ethics of conducting psychological autopsy and other types of studies in the field of suicide research.

Dr Kairi Kõlves

**Principal Research Fellow and Course Convener,
Australian Institute for Suicide Research and Prevention (AISRAP)**

Co-director

**WHO Collaborating Centre for Research and Training in Suicide Prevention
Griffith University**



Kairi has been working in suicide research and prevention since 1998. Between 1999 and 2008, she worked at the Estonian-Swedish Mental Health and Suicidology Institute and joined AISRAP in 2008. Kairi has been involved in several

committees including the Commonwealth Department of Health's Expert Panel on Suicide Prevention, the Queensland Advisory Group on Suicide, the Advisory Board of 'Lifeline Research Foundation' and others.

Her work has been published in over 80 peer-reviewed papers, a number of book chapters and numerous reports.

Australian, Estonian and international projects. She is a member of a number of advisory

1.30PM - 2.15PM

LUNCH

2.15PM - 3PM

ETHICAL COMPLEXITIES OF CHILD CO-RESEARCH

Using research participants as co-researchers is a growing trend in social research in a range of research methodologies and research types. Child co-research has become popular in social research involving children. This is attributed to the emphasis on children's rights and is seen as a way to promote children's agency and voice. It is a way of putting into practice the philosophy, common amongst childhood researchers, that children are experts on childhood. Advocates of this approach claim it is a positive experience for child co-researchers and that it produces better quality outcomes. There are also critiques of child co-research. These come under the ethical concern about the need for children to be protected and not exploited.

Little attention is paid to ethical difficulties faced by child co-researchers in the existing literature and there is nothing that guides Human Research Ethics Committees (HRECs) by identifying questions HRECs should be asking when faced with projects involving child co-researchers. This presentation addresses this gap. Data from interviews conducted with researchers who use co-research methodology is used, and the significance of what researchers using this methodology say about it and how this can help inform the ethics review of child co-research is discussed. This session concludes with important questions for Human Research Ethics Committees to ask when they review projects using child co-research and questions for reflexive researchers to ask themselves when they use child co-research methodology.

Dr Merle Spriggs
Research Fellow, Children's
Bioethics Centre
The Royal Children's Hospital

**Honorary Research Fellow,
Murdoch Childrens Research
Institute**

**Melbourne School of Population and
Global Health,
The University of Melbourne**



Merle has a PhD in Bioethics and expertise in the area of informed consent, patient autonomy and the ethics of research practice. Her publications are predominantly in this area and she has developed substantial educational

resources about consent for Human Research Ethics Committees (HRECs) and researchers who conduct research involving children. She has presented her research at national and international conferences and has delivered training and professional development for Australian Human Research Ethics Committees primarily on research with children.

Other research includes ethical issues and responsibilities in paediatric biobanking and

e-health ethics, specifically the ethics of internet-based research and the ethical issues of electronic health records. She has developed educational content for an ethics engagement study for a large-scale longitudinal birth cohort to find out what potential participants (parents) think and want when they are well informed. Her current projects include

- Ethical considerations of using research participants as co-researchers;
- Involving children in social research: balancing the risks and benefits; and
- Telling the truth to seriously ill children.

Merle has over 20-years of experience on hospital and university Human Research Ethics Committees. She has been an expert witness for two US law firms in a series of cases involving child research. She is a member of the Royal Children's Hospital Clinical Ethics Committee and Clinical Ethics Response Group.

3PM - 3.45PM

IDENTIFYING VULNERABILITY

This workshop has examined the idea of vulnerability and its occurrence in several categories of research participants. By providing a hypothetical case study for discussion, this final session recognises that researchers and human research ethics reviewers need to be alert to recognise contextual, ethically relevant characteristics of vulnerability affecting potential participants, even those who would not commonly be regarded as vulnerable.

“These ethical guidelines are not simply a set of rules. Their application should not be mechanical. It always requires, from each individual, deliberation on the values and principles, exercise of judgement, and an appreciation of context.”

National Statement on Ethical Conduct in Human Research, NHMRC, ARC, UA, 2007 (updated 2015) p.11.

Professor Colin Thomson

Academic Leader for Health Law and Ethics, Graduate School of Medicine and Health, University of Wollongong



Colin Thomson BA, LLB, LLM (Hons) has a fractional appointment as Professor of Law at the University of Wollongong where he is the Academic Leader for Health Law and Ethics in the Graduate School of Medicine and Health. He was Chair of the

Australian Health Ethics Committee of the National Health and Medical Research Council (NHMRC) from 2006 - 2009 and a member of that committee from 1998 - 2002.

Between 2002 - 2006, he was the Consultant on Health Ethics for the NHMRC. During this period, Colin provided consulting services to the NHMRC, the NSW Health Department and the NSW Department of Community Services (DoCS).

In 1983, he introduced the second Australian university course on law and medicine, at the Australian National University, and has since

taught health law and ethics to graduate students at the University of Wollongong and conducted numerous on-site teaching sessions in health law and ethics for health professionals in ACT and NSW hospitals. He has been a member of human research ethics committees since 1984, both in universities and the public health sector and currently chairs two committees.

He has published and spoken widely, nationally and internationally, on issues in health law and ethics. He has been Executive Officer and Chair of the Board of the Australian and New Zealand Institute of Health, Law and Ethics and Vice-President of the Australasian Bioethics Association - now combined as the Australasian Association of Bioethics and Health Law and is Secretary for the Journal of Bioethical Inquiry Pty Ltd.

The Healthy Regions Study

Have the changes in regional health care delivery provided better outcomes for patients, better workplace satisfaction for staff and better conditions for contracted providers?

A State Health Department initiated significant organisational and funding changes in the delivery of health care to regional areas in the State. These areas are extensive, with some mid-sized towns, but because of their geographical spread, the demanding terrain and climate, depend on smaller centres of co-ordinated health care and on outsourcing some service delivery to contracted providers. The populations of several of the larger geographical regions include higher proportions of Aboriginal and Torres Strait islander peoples than urban regions.

The changes have been effective in rationalising some care provision and reducing some overlap and duplication, with resulting savings in State revenue.

There is now a need to find out if these changes have improved:

- The experience and health outcomes for patients and their families;
- The workload and job satisfaction of State Health department employees; and
- The conditions and satisfaction of contracted providers of some health services.

The State Health Department wants to conduct a research project to answer these questions.

The Department has approached you for advice on ethical aspects of the design and conduct of the project, particularly to address the following questions:

- What is the data that you will need?
- What are the methods you will use to collect those data?
- What and who are the sources of those data?
- Where those sources are people,
 - What data would you seek from them?
 - How you would identify and recruit them?
 - How would their consent be sought and established?
 - Should any of the categories of people be considered vulnerable and, if so, what are the sources of that vulnerability and the measures to reduce or eliminate it?

The Department has also asked you to consider the ethical implications for the project and the processes you recommend of either:

- A. Engaging an external research team to conduct the project, or
- B. Engaging a senior staff member in the largest health care centre in each region to conduct the project.

Funding has not been determined but will be assessed on receipt of a proposal.

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