

The Australian Health & Medical Research Ethics Roadshow

Ethics 101; what is ethics; a potted history; Human Research Ethics and Regulatory Requirements

Preparing Good Submissions: Part A
Working with the NEAF and other application requirements including research integrity and burden vs. benefit arguments

Day 1

Preparing Good Submissions: Part B
Use of data/privacy issues, Participant issues, populations, dual relationships, recruitment, incentives and coercion, diminished capacity
Process issues - investigator communications / talking to your HREC admin officers

Panel Q&A
Assessment review

Includes optional assessment for the Nationally Recognised HLTHIR506B: Implement and monitor compliance with legal and ethical requirements

Melbourne: 10-11 May 2010

Sydney: 12-13 May 2010

Adelaide: 9-10 August 2010

Brisbane: 14-15 September 2010

Preparing a good Patient information and Consent Form; plain language issues; procedures and risks section; additional/optional tissue sample collection/pharmacobiomarker-genetic analysis; financial disclosure and US legal requirements

Non-Clinical Trial Research Issues [Non-interventional clinical research and Basic Science/Laboratory/Human tissue research]

Day 2

Safety Reporting
The SAE labyrinth; Data Safety Monitoring Committees; other safety reports

Contracts, Indemnity & Insurance,
Legislative Issues (State and Commonwealth) including ICH GCP FOR CTN/CTX TRIALS
Panel Q&A

Content Development Panel & Speakers:
Dr Nik Zeps,
Prof. Colin Thomson,
Jeremy Kenner,
Dr Gary Allen, and
Melissa Hagan

CONTENT DEVELOPMENT PANEL & SPEAKERS

Jeremy Kenner

At Peter MacCallum Cancer Centre, Jeremy manages the ethical review and governance of research involving humans, advises management on clinical, research and administrative policy matters with ethical implications, and provides related training and educational programming. Jeremy has been involved in a variety of state and national initiatives regarding aspects of research ethics and governance and regularly participates as a speaker in educational events directed towards researchers, HREC members and health administrators.

A teacher and a lawyer by training, Jeremy has been involved in bioethics for nearly 20 years, including training clinical ethics committees and promoting advance care planning in the United States.

Dr Gary Allen

Gary has worked in the human research ethics area for more than 13 years, working with a number of research ethics committees in Australia, Canada, the United Kingdom and Vietnam. His doctoral thesis on the establishment of positive institutional research ethics arrangements was recognised with an Outstanding Doctoral Thesis Award from QUT. He has served on several occasions as a training facilitator for the NHMRC. Gary is a frequent presenter at conferences and workshops. In 2007 his work in contributing to the learning of research students in the human research ethics was recognised with a national teaching citation.

Dr Nikolajs (Nik) Zeps

Dr Zeps is involved in translational research in breast, gastrointestinal and gynaecological malignancies. He is chair of the National Research Advisory Group of Cancer Australia, the Research Group of the Clinical Oncological Society of Australia and the Biological sub-committee of the Australasian Gastro-intestinal trials Group. He is the Australian representative on the Consent and Data Access Advisory Committee of the International Cancer Genome Consortium. Dr Zeps works for St John of God Pathology and Radiation Oncology at Perth's Sir Charles Gairdner Hospital. He is an adjunct senior lecturer in the Schools of Surgery and Pathology and Laboratory Medicine at the University of Western Australia. He is a current member of AHEC.

Professor Colin Thomson

Colin is Professor of Law and Academic Leader for Health Law and Ethics in the Graduate School of Medicine at the University of Wollongong. He also works as a consultant. He has been a member, and chair, of several research ethics committees (1984–2004), and a member, and chair, of AHEC (1998-2002 & 2006-2009). He has designed and conducted a national training program for HREC members (NHMRC), undertaken a study of ethical review of multi-centre research and developed accreditation standards for lead HRECs (for NSW Health) and reviewed the Tasmania research ethics review system.

Colin was a member of the NHMRC working parties for the 1999 and 2007 versions of the National Statement and chaired the NHMRC National Ethics Application Form working party.

Melissa Hagan

Melissa has 16 years experience in Clinical Research and Training in the Pharmaceutical and Therapeutics industry in Australia. After majoring in Pharmacology (University of Queensland), she worked in Industry Sponsored Research at GSK and Quintiles. With an interest in professional development, she completed a Masters Degree in Education with a focus on curriculum development within Industry and managed the Association of Regulatory and Clinical Scientists (ARCS Australia). After returning to Queensland in 2005, she now delivers training for the Queensland Clinical Trials Network Inc. (A Not for Profit, Industry Association) and manages their Human Research Ethics Committee.

Cost: \$990 inc. GST

Dates & Venues: 10-11 May 2010: The Como, South Yarra, Melbourne
12-13 May 2010: The Stamford Grand, North Ryde, Sydney
9-10 August 2010: The Stamford Grand, Adelaide
14-15 September 2010: The Tattersall's Club, Brisbane

**Register
Now**

Contact

Queensland Clinical Trials Network Inc. (QCTN)

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The Australian Health & Medical Research Ethics Roadshow

Cost: \$990 inc. GST per attendee
\$880 inc. GST for QCTN Members

Melbourne:

Date: Monday 10 May - Tuesday 11 May 2010 - *registrations close 26 April 2010*
Venue: The Como, South Yarra, Melbourne, Victoria

Sydney:

Date: Wednesday 12 May - Thursday 13 May 2010 - *registrations close 28 April 2010*
Venue: The Stamford Grand, North Ryde, Sydney, New South Wales

Adelaide:

Date: Monday 9 August - Tuesday 10 August 2010 - *registrations close 28 July 2010*
Venue: The Stamford Grand, Adelaide, South Australia

Brisbane:

Date: Tuesday 14 September - Wednesday 15 September 2010 - *registrations close 30 August 2010*
Venue: The Tattersall's Club, Brisbane, Queensland

Time: 8.30am to 5.00pm daily

REGISTRATION ESSENTIAL - fax 07 3870 9101 or email marketing@qctn.com.au

Participant Name(s): <i>(inc. title if appropriate)</i>	<input type="text"/>	<input type="text"/>
Organisation:	<input type="text"/>	
Address:	<input type="text"/>	
Email:	<input type="text"/>	
Telephone:	<input type="text"/>	Mobile: <input type="text"/>
Venue:	<input type="checkbox"/> Melbourne <input type="checkbox"/> Sydney <input type="checkbox"/> Adelaide <input type="checkbox"/> Brisbane	
Payment method:	I/we enclose a cheque for \$ <input type="text"/> in favour of Queensland Clinical Trials Network Inc.	
OR Please debit \$ <input type="text"/> to:	<input type="checkbox"/> Mastercard <input type="checkbox"/> Visa Expiry: <input type="text"/>	
Cardholders name:	<input type="text"/>	
Card number:	<input type="text"/>	
Signed:	<input type="text"/>	

Queensland Clinical Trials Network Inc. (QCTN) ABN 40 200 718 279. This is a tax invoice for GST purposes when a payment is made. Please retain a copy for reimbursement purposes. No refunds, transfers or cancellations will be processed within two weeks of the event. Cancellations and transfers must be in writing and will incur a 10% administration fee. Substitutions are allowed at no cost.

Contact

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