Streamlining ethical review of multi-site clinical trials
Progress report 2011–2013
‘Great to have experienced people talking – helps and encourages…’
Streamlining ethical review of multi-site clinical trials
Progress report 2011–2013
The Victorian Government has played a key leadership role in streamlining ethical review of multi-site clinical trials in Victoria and across the eastern seaboard states. The initiative has been operational for three and a half years. A system of Interstate Mutual Acceptance of ethical review commenced in October 2011.

The Victorian program for streamlining ethical review aims to:

- provide faster, more efficient processes to conduct clinical trials at multiple sites;
- grow clinical trial activity in Victoria; and
- deliver new treatments to patients sooner and improve health outcomes and quality of life.

Formal evaluation demonstrated that in the first 18 months of operation the program saved over 500 ethics reviews – a significant advance in reducing the work of Human Research Ethics Committees (HRECs). A report on ‘Developing Best Practice in Human Research Ethics Review’ is intended to assist HRECs and find further efficiencies in the process.

The evaluation demonstrated that respondents had positive perceptions of the streamlining process and thought that it would assist clinical trials in the future. The seven recommendations of the evaluation report supported further investment to achieve the objectives of clinical trial growth and health outcomes.

Before the streamlining program was implemented, there was a lack of data on clinical trials. The introduction of a research ethics database has enabled reporting of clinical trial activity. Since July 2010, the number of clinical trials has doubled. This level of activity has continued throughout 2011–2013 despite global factors that have impacted on the clinical trial sector and pharmaceutical industries. The streamlining program appears to have had a significant effect on attracting clinical trials to Victoria.

The annual workshops held in May 2012 and 2013 were a resounding success with over 120 attendees in each year from the clinical trial sector and users of the streamlined system.

The theme of the 2012 workshop was ‘Advances in Clinical Trial Research’ and included presentations by:

- representatives from New South Wales, Queensland and Victoria informing on the Interstate Mutual Acceptance initiative;
- the Chair of the Pharmaceutical Industry Council Research and Development Taskforce on an overview of the Clinical Trial Action Group (CTAG) Report; and
- a representative from the medical devices industry.

The 2013 May Workshop focused on Clinical Trials – Process Improvements.

There were three presentations from stream-specific groups including Research Governance Officers, Sponsors/Contract Research Organisations and Clinical Trial Coordinators/Investigators followed by a panel discussion. Other expert speakers provided information on complementary medicines, medical devices and pharmaceutical industry issues.

Forums were held with expert speakers who presented on a range of topical issues that included:

- patient recruitment;
- consumer issues for participation in clinical trials;
- Interstate Mutual Acceptance of ethical review;
- progress on the implementation of the CTAG Report recommendations and an industry perspective;
- Clinical research registries;
- Research governance; and
- Updates from the Therapeutic Goods Administration (TGA) and National Health and Medical Research Council (NHMRC).
Victoria’s streamlining program is leading the way in providing metrics on clinical trial activity to government, participating hospitals, industry and other organisations involved with clinical trials, as well as centrally coordinating data collection and reporting for the Victorian system and Interstate Mutual Acceptance initiative.

The metrics on the following pages show the types of clinical trials conducted in Victorian hospitals. In 2011–2013 there were 340 new clinical trial protocols ethically reviewed for multiple sites, and 978 trials were conducted at hospitals. This represents consistent growth and a significant saving of ethics reviews conducted by HRECs. The benchmark for timeliness of ethics is 30 working days and from commencement of the program this has been met by HRECs in 71 per cent of approvals, which is a high level of achievement considering the complexity of clinical trials.

Most clinical trials are commercially sponsored (70 per cent) although investigator-initiated and collaborative groups contribute significantly to clinical trial research in Victoria. Cancer trials continue to be predominant with 34 per cent, followed by trials on hepatitis and neuroscience.

‘Very interesting and good to hear from people having long time experience in industry.’
Clinical trial approvals

Number of HREC applications and SSAs by month

The number of ethics applications increased over the years. The January decline is a reflection of only one ethics committee conducting limited reviews during that month.

NHMRC primary research discipline
1 July 2011–30 June 2013

Cancer clinical trials constitute about one third of all trials although a range of disease types are significantly represented in multi-site trials.

Distribution of trial phases 1 July 2011–30 June 2013

Phase three is the predominant activity with earlier phases accounting for twenty five percent of trials.

Research application type 1 July 2011–30 June 2013

Seventy percent of multi-site clinical trials are commercially sponsored. Trials funded through non-commercial processes constitute the residual thirty percent.
Manager's report

From 2011 to 2013 it has been a very productive time with further growth in clinical trial applications in Victoria. In addition, the Interstate Mutual Acceptance initiative that commenced in October 2011 now enables single ethics review across the eastern seaboard states. The smooth transition to linking up with other states was backed up with stakeholder consultation and training. The initiative is well supported by industry and other users of the streamlined system judging from the number of ethics applications submitted to certified ethics committees.

The information management system, the Australian Research Ethics Database (AU RED), has been modified to link ethics and site specific assessment (SSA) applications across Victoria, New South Wales and Queensland borders. Flow of information is necessary for administration of applications and timely completion of regulatory processes required for clinical trial commencement.

The office

COCTR has five members of staff within the Department of Health, they are from left to right:
Ms Abigail Cooper, Operations Officer
Mr Gavin Murnane, Senior Information Management Officer
Dr Suzanne Hasthorpe, Manager
Ms Voula Phelagti, Project Officer, Finance
Dr Campbell Simpson, Senior Coordination Officer
To support users of AU RED at Victorian hospitals the Coordinating Office produced a training manual that provides step-by-step instructions on how to process ethics and site specific applications before and after approval. High quality data within AU RED has allowed Victoria to lead the way in metric analysis on clinical trial activity and the Coordinating Office works with users to ensure sound reporting. Data management is a large part of the Coordinating Office’s operations and now this unique dataset can provide Victoria with actual data for the first time. Innovative use of this data provides a tool for the Coordinating Office to devise new approaches to improve efficiency and timeliness of the regulatory processes for clinical trials.

A considerable part of the Coordinating Office’s work has involved revising the Standard Operating Procedures (SOPs) for ‘Streamlining ethical review of clinical trials’ jointly with the subcommittee. There have been a number of changes that impact operations, such as the Victorian Managed Insurance Authority (VMIA) Clinical Trials – Insurance and Risk Management Guidelines and introduction of the Interstate Mutual Acceptance for single ethics review.

In preparation for the implementation of a national approach to single ethical review of multi-site clinical trials, participant information consent forms were reviewed and changes made to the forms developed by the National Health and Medical Research Council (NHMRC). In agreement with NHMRC and the eastern seaboard states these standard forms have been adopted.

Collaborative work between the Subcommittee of the Consultative Council and the Coordinating Office was undertaken to review all standard reporting and monitoring forms, checklists, ethics and governance contact details, legislative guidance, monitoring and reporting and an ethics submission cover letter. All documents have been integrated with the single ethical review and research governance framework.

Quarterly meetings were held between the Chair of the Consultative Council, the Chair of the Subcommittee, the Coordinating Office, and reviewing ethics committee research managers to discuss issues with the Interstate Mutual Acceptance initiative and other related matters. These meetings were also a forum for VMIA to gain expert advice on revision of the VMIA Clinical Trials – Insurance and Risk Management Guidelines.

The Coordinating Office has worked with the Consultative Council and assisted in development of the Consultative Council’s strategic plan, engaging a facilitator to help identify themes to advance clinical trials and the streamlining initiative in Victoria.

Communication with users of the streamlined system is a crucial part of the Coordinating Office’s work to support stakeholders using the streamlined system efficiently. The website is regularly updated with new information and improved tools for stakeholders, presentations given at forums and workshops, and publications relating to streamlining clinical trial research.

The Streamline E-bulletin communicates the latest news to the clinical trial sector about modifications and new directions. There are more than 1,000 subscribers in Victoria and interstate, including industry, hospital-based research ethics and governance, investigators and trial coordinators as well as others with allied interest.

On behalf of the Coordinating Office staff we look forward to supporting system users in the coming year and we extend our appreciation to those who have been supportive and given their time. It has been a pleasure to deliver operational services and collaborate with all who are involved in clinical trials.

Dr Suzanne Hasthorpe
Chair’s report

The council is now in its fourth year of operation. As part of its formal governance process the Minister for Health appointed new members. Ms Charlene MacLeod, Ms Kirsten Mander, Associate Professor James King, Ms Kerren Clark, Mr Bill Karanatsios, Professor John Seymour, Dr Leslie Cannold and Dr Roland Scollay.

The Council underwent a formal process to develop a strategic plan to support the initiative on streamlining ethical review of multi-site clinical trials. This created a vision for the council’s activity from 2012 to 2014. The strategic plan is aligned with the recommendation(s) of the Clinical Trials Action Group (CTAG) Report released on 3 March 2011.

The outcomes identified in the strategic plan were continued improvement in attracting clinical trials to Victoria and in the timeliness of the ethical and governance processes for multi-site clinical trials, as well as, extending this nationally.

The Council was aware of information that the value of the pharmaceutical industry support for clinical trials is around $1 billion per annum in Australia. This includes the value of new medications and devices undergoing trial, as well as employment of research staff and payments for diagnostic investigations.

This has provided a stimulus for the recognition of clinical trials and research, not only for related activity but of considerable economic value. Given that Victoria performs at a high level in clinical research activity, this boosts employment and reduces healthcare costs.

This has given impetus for, as part of the strategic plan, documentation of the numbers of multi-site clinical trials over time, increase in patient participation and improved trial quality. These activities are in line with the CTAG report.

The council is aware that by raising the profile of clinical trials in Victoria it not only raises the standard of cutting-edge healthcare but contributes significantly to the economic wellbeing of the state.

Professor Richard Fox AM
Consultative Council members

Professor Richard Fox (Chair) AM is employed part time as Director of Research at St Vincent’s Health (Melbourne). He has a strong background in clinical research, oncology, research administration and has been chair of a human research ethics committee at Melbourne Health. Professor Fox has been appointed Chair of the Consultative Council and brings a wealth of experience and expertise in clinical and scientific research, oncology and cancer leadership and initiatives in research and cancer as from his work in Victoria and internationally. He has published over 200 articles in internationally renowned books and journals and has presented in television series on cancer. He is a Member of the Order of Australia.

Ms Kerren Clark is Principal of Numbat Consulting and is a community member on the Medical Practitioners Board. She has a strong background in non Victorian Government community committees and community groups, holds a science degree, a Graduate Diploma in Health and Medical Law and a Diploma of Company Directorship. Ms Clark brings experience in ethics of human research including clinical trials, clinical medicine, knowledge of stakeholder issues, understanding of health service delivery and knowledge of Government to the Council.

Associate Professor Noel Cranswick is a full time Director of Clinical Pharmacology at the Royal Children’s Hospital and part time private paediatric consultant. He has considerable experience in the areas of clinical trial ethics, paediatrics and clinical pharmacology. Associate Professor Cranswick brings to the Council expertise in clinical trials methodology, scientific expertise and ethics in clinical trials.

Mr Bill Karanatsios is currently a consultant in Healthcare and Medical Research assisting clients in the establishment of Research Governance, Risk Management and Business Development. He has had significant experience in clinical trials management in relation to insurance and indemnity and has developed initiatives to underpin efficient clinical trials conduct for health care services in Victoria. Mr Karanatsios brings expertise in stakeholder management, risk management, knowledge of pharmaceutical industry clinical trials and has well developed networks in ethics and clinical trials. Mr Karanatsios has a degree with Honours in Medical Laboratory Science (Haematology) and Cytopathology.
Ms Kirsten Mander is currently a senior executive with Australian Unity. She has also been the Company Secretary and legal counsel for Sigma Pharmaceuticals Limited. She has a strong background in law, business management and government and regulatory affairs. Ms Mander brings expertise and experience in legal and governance compliance, risk management and ethics experience, having been Chair of the Law Institute of Victoria Ethics Committee.

Professor John Seymour is currently the Head of the Department of Haematology at the Peter MacCallum Cancer Centre. He has had substantial involvement in clinical trials with extensive experience in haematological malignancies and has published 14 book chapters and over 200 peer reviewed international journal articles. Associate Professor Seymour brings expertise in clinical services, clinical research and clinical information management.

Ms Charlene MacLeod is the Director of Strategy and Planning at Southern Health. She has worked in strategic planning in both private and public organisations and has a Bachelor of Arts, a Bachelor of Commerce (First Class Honours) and a Masters of Organisational Dynamics. She has expertise in health service management through working in the Department of Health, the Royal Children's Hospital and Southern Health. She also brings experience in health service planning, strategic planning, change management, performance management, stakeholder management and successful business case development to the Council.

Associate Professor James King graduated in medicine from the University of Melbourne in 1964. He pursued a career in obstetrics, maternal/fetal medicine and perinatal epidemiology, studying at the Universities of Dublin, British Columbia and Oxford. Recent positions included being Chair of the Victorian Consultative Council on Obstetric and Paediatric Mortality and Morbidity, Chair of the Royal Women's Hospital Research Committee, and advisor to the Royal Women's Hospital Human Research Advisory Committee. He holds an honorary fellowship at the University of Melbourne.
Consultative Council members

**Dr Leslie Cannold** has a Master in Medical Ethics, and a PhD in Education and is expert in medical ethics, research methods and the art of written expression. She has held public ethics positions at the University of Melbourne and now at Monash University's School of Public Health and Preventative Medicine. She has published in peer-reviewed journals, books and book chapters. In 2011 she was honoured as the Australian Humanist of the Year. She has served on the Monash Human Research Ethics Committee and is a member of the Victorian Department of Health’s Human Research Ethics committee, the Victorian Boards of National Physiotherapy and National Nurses and Midwifery.

**Dr Roland Scollay** is a board member of the Bio21 Cluster and the chairman of its scientific advisory council and is a consultant in biotechnology and research management. He has a long history as a practitioner and manager in basic and applied research, has been responsible for a number of clinical trials and has published more than 150 research papers. He has been a director, CEO or senior executive in a variety of biotechnology and big pharma companies in Australia and in the US and Europe. He brings to the council experience in a wide range of biomedical research in both academic and commercial contexts.
Reviewing HREC and Research Governance Standards Subcommittee

Subcommittee Chair’s report

The subcommittee has worked actively to provide advice on operating procedures and tools for users of the streamlined ethical review system. Regular meetings are held throughout the years to keep pace with new developments to facilitate single ethical review.

The commencement in 2011 of the Interstate Mutual Acceptance initiative required the drafting of a number of different documents to help with accurate information flow and standardisation of procedures and processes. One important issue was reducing duplication of reporting for reviewing HRECs to the Health Services Commissioner in Victoria and the New South Wales Privacy Commissioner. Meetings were held with the subcommittee, Coordinating Office and representatives from the Health Services Commissioner’s office in Victoria to draft a common reporting form for use by jurisdictions to report to these state commissioners where required.

Another issue was the ethical review and approval of the use of ionising radiation in research and managing the differences between jurisdictions in reviewing this research. This matter was addressed by the development of a simple form to be completed by investigators in states other than Victoria. This form ensures every reviewing HREC can comply with the requirements set out in the Australian Radiation Protection and Nuclear Safety Agency Code of practice for the exposure of humans to ionising radiation for research purposes, a code which applies Australia-wide.

The subcommittee initiated revision of the Standard Operating Procedures (SOPs) for Reviewing HREC Coordinators and Research Governance Officers. This addresses incremental changes that have occurred since commencement of streamlining ethical review of multi-site clinical trials. These changes included the Interstate Mutual Acceptance initiative, national certification of HRECs (by the NHMRC) and the introduction of revised VMIA Clinical Trials – Insurance and Risk Management Guidelines.

Review and revision of other core documents included a standard cover letter for ethics review and governance submissions, a revised ethics submission checklist and numerous reporting and monitoring forms. Considerable input was contributed to the development and refinement of a suite of national participant information and consent forms, drafted by NHMRC.

The subcommittee contributes a wealth of experience and expertise to the management and oversight of clinical research in Victoria and around Australia and provides expert advice on operational policies and guidance. This input is invaluable for helping to meet the issues and challenges that continue to arise with the further development of the single ethical review initiative and the associated research governance processes.

Members have given generously their time to assist in the development and implementation of processes designed to facilitate the conduct of clinical trials as efficiently and effectively as possible. This ultimately benefits Victorian patients and their healthcare.

Dr Angela Watt

Subcommittee members

Dr Angela Watt, Melbourne Health
Ms Anne Spence, Cabrini Health
Ms Malar Thiagarajan, Monash Health
Ms Bernice Davies, Barwon Health
Ms Kym Short, Lilly
Dr Suzanne Hasthorpe, Coordinating Office
Dr Campbell Simpson, Coordinating Office
Secretariat: Ms Abigail Cooper, Coordinating Office
The Consultative Council members are from left to right: Ms Kerren Clark, Ms Charlene MacLeod, Professor John Seymour, Professor Richard Fox, Ms Kirsten Mander, Associate Professor Noel Cranswick, Mr Bill Karanatsios and Associate Professor James King – Dr Leslie Cannold and Dr Roland Scollay are absent.

The Subcommittee has seven members, they are from left to right: Ms Anne Spence – Cabrini Health, Ms Bernice Davies – Barwon Health, Dr Campbell Simpson – COCTR, Dr Angela Watt – Melbourne Health, Dr Suzanne Hasthorpe – COCTR, Ms Malar Thiagarajan – Monash Health and Ms Kym Short (absent) – Lilly.
Interstate mutual acceptance

The Victorian and Queensland Departments of Health and the NSW Ministry of Health have signed a Memorandum of Understanding (MOU) to introduce mutual acceptance of ethical and scientific review in public hospitals regarding multicentre clinical trials being conducted in more than one of these states.

Mutual acceptance of ethics review for multi-centre clinical trials for Queensland and Victoria commenced from Monday 24 October 2011. Commencement of mutual acceptance for NSW was from 1 February 2012.

Ethics committees that review for other State publicly funded health services have been certified under the National Health and Medical Research Council scheme.

Certified Reviewing HRECs

**NSW Health**
- Cancer Institute NSW Clinical Research Ethics Committee (EC00414)
- Hunter New England HREC (EC00403)
- Nepean Blue Mountains Local Health District HREC (EC00151)
- Northern Sydney Local Health District HREC (EC00132)
- South Eastern Sydney Local Health District HREC (Northern Sector) (EC00134)
- St Vincent’s Hospital HREC (EC00140)
- Sydney Children’s Hospitals Network HREC (EC00130)
- Western Sydney Local Health District HREC (EC00152)
- Sydney Local Health District Ethics Review Committee (RPAH Zone) (EC00113)
- Sydney Local Health District HREC (CRGH) (EC00118)
- University of Wollongong and Illawarra Shoalhaven Local Health District Health and Medical HREC (EC00150)

**Queensland Health**
- Children’s Health Services HREC (EC00175)
- Darling Downs – West Moreton (Toowoomba & Darling Downs) Health Services District HREC (EC00182)
- Gold Coast Health Service District HREC (EC00160)
- The Prince Charles Hospital HREC (EC00168)
- Metro South Health Service District HREC (EC00167)
- Royal Brisbane & Women’s Hospital HREC (EC00172)

**Victorian Department of Health**
- Austin Health Human Research Ethics Committee (EC00204)
- Melbourne Health Human Research Ethics Committee (EC00243)
- Peter MacCallum Cancer Centre Ethics Committee (EC00235)
- The Royal Children’s Hospital Human Research Ethics Committee (EC00238)
- Monash Health Human Research Ethics Committee A (EC00382)
- Monash Health Human Research Ethics Committee B (EC00383)
- St Vincent’s Hospital (Melbourne) Human Research Ethics Committee D (EC00343)
Events and publications

Annual May workshop

Wednesday 1 May 2013, Melbourne

Clinical Trials – Process Improvements

Introduction
• Professor Richard Fox (Chair of CCCTR)

Research Governance
• Dianne Snowden, Peter MacCallum Cancer Centre
• Charrise Spence, Barwon Health
• Allan Bukuya, TrialDocs (formerly Quintiles)

Additional discussion panel members, Bernice Davies, Jason Russell, Karen Aitken, Donna Campbell.

Clinical Trials and Australia’s Position
• Paul Komesaroff (Monash University)
• Catherine Bourgeois (St. Jude Medical)
• Deborah Monk (Medicines Australia)

Wednesday 2 May 2012, Melbourne

Advances in Clinical Trials Research

Introduction
• Professor Richard Fox (Chair of the Consultative Council)

Interstate Mutual Acceptance
• Dr Suzanne Hasthorpe (Victorian Department of Health), Anne O’Neill (New South Wales Ministry of Health), Melissa Hagan (Queensland Health)

Clinical Trials
• David Lloyd (Southern Star Research, CTAG Report)
• Falko Thiele (Biotronik, Medical Devices)

Research Ethics and Governance Forums 2011–2013

The Research Ethics and Governance Forums provide information about clinical trials, aspects of research and the streamlined system. Representatives from all Victorian organisations conducting human research and others from the clinical trials sector attend.

• Friday 28th June 2013: National Ethics Update
  Speaker: Dr Gordon McGurk, NHMRC

• Friday 19th April 2013: Consumer Issues in Clinical Trials
  Speakers: Christine Veljanoski, Clinical Trials Connect and John Stubbs, canSpeak

• Friday 15th March 2013: TGA Update on Clinical Trials
  Speaker: Dr Tony Gill, TGA

• Friday 26th October 2012: Research Governance
  Speakers: Bernice Davies, Manager of Office for Research, Barwon Health and Deborah Dell, Administrative Officer & HREC Coordinator, Monash Health

• Friday 24th August 2012: Use of Clinical Research Registries to address improvements in healthcare
  Speakers: Dr Sue Evans, Centre of Research Excellence in patient Safety and Ms Angela Brennan, Centre of Cardiovascular Research and Education

• Friday 22nd June 2012: Clinical Trial Action Group – implementing
  Speakers: Margaret Corcoran, Dept. Industry, Innovation, Science, Research and Tertiary Education
  CRO industry review
  Speaker: Allan Bukuya, Quintiles
• Friday 27th April 2012:
  Consumer Issues for participation in clinical trials
  Speakers: Wallace Crellin, PMCC and Gabriel Silver, RMH

• Friday 9th March 2012:
  Clinical Trials – Mutual acceptance and other initiatives
  Speakers: Dr Suzanne Hasthorpe – COCTR, Melissa Hagan, Queensland Health and Dawn Arneman, NSW Ministry of Health

• Friday 28th October 2011:
  Consent to Medical Research – Some Controversies
  Speaker: Professor Paul Komesaroff, Faculty of Medicine Monash University

• Friday 26th August 2011:
  Clinical Trials – Site Selection, Start-Up and Patient Recruitment
  Speakers: Michele Sallabanger, Flinders Coordinating Centre and John Varigos, Mediclin

Conferences – Invited speaker

• Victorian medical device cluster and infrastructure, Panel member – Dr Suzanne Hasthorpe
  Victorian Government briefing for Medtech delegates, Melbourne, 15 May 2013

• Australian trials and multi site ethics review update – Dr Suzanne Hasthorpe
  Australasian Stroke Trials Workshop, 28 August 2012

• Interstate Mutual Acceptance Reporting Performance – Dr Suzanne Hasthorpe, Anne O’Neill and Melissa Hagan
  ARCS Scientific Congress 2012, Sydney, June 2012

• NHMRC Enabling Capabilities framework – Dr Suzanne Hasthorpe
  NHMRC, Canberra, 3 February 2012

• A case for a database – Dr Suzanne Hasthorpe
  Department of Innovation, Industry, Science and Research, Canberra, December 2011

• Capability – Cooperative approach to the clinical trial regulatory process – Dr Suzanne Hasthorpe

• Single Ethics Review of Clinical Trials – Past Performance and Future Developments – Dr Suzanne Hasthorpe
  Academic Clinical Stroke Trials Workshop, Adelaide, September 2011

• Research Ethics and Governance – Dr Suzanne Hasthorpe
  CRC Forum QLD Health and Medical Research Clinical Research Coordinators
  Brisbane, September 2011

• Single ethical review in Victoria – Dr Suzanne Hasthorpe
  ARCS Seminar, Melbourne, July 2011

Seminars – Invited

• Research Governance – Dr Suzanne Hasthorpe
  ARCS, Melbourne, 6 December 2012

• Streamlining ethics and mutual acceptance panel – Dr Suzanne Hasthorpe
  Victorian Association of Research Nurses, 7 September 2012

• Streamlining initiatives for clinical trials – Dr Suzanne Hasthorpe
  Victorian Coperative Oncology Group, 29 August 2012

• Streamlining clinical trials – Dr Suzanne Hasthorpe
  Nephrology Department, Royal Melbourne Hospital, 20 August 2012

• Standard schedule 7 and 4 for trial agreements – Dr Suzanne Hasthorpe
  Victorian Managed Insurance Authority, 15 August 2012

• Ethics and research governance – Dr Suzanne Hasthorpe
  Royal Children’s Hospital, Trial Coordinators Meeting, May 2012

• Streamlining ethical review initiative – Dr Suzanne Hasthorpe
  Northern Health, Grand Rounds, February 2012

• Online Form applications – Dr Suzanne Hasthorpe
  Peter MacCallum Cancer Centre, July 2011
Conferences attended

- BioMelbourne Network Briefing, Devices and diagnostics, 21 February 2013
- Clinical research and emerging e-health system in Australia DISERTE, Sydney, 22 October 2012
- CTAG Round Table Clinical Trials Portal Workshop, Sydney, May 2012
- MJA Clinical Trials Research Summit, Sydney, May 2012
- BioMelbourne Network Briefing – Can Australia afford to fund translational research, April 2012
- BioMelbourne Network Briefing, Clinically Competitive, March 2011

Publications

Houston Thomson, Developing Best Practice in Human Research Ethics Review Report, prepared by Professor Colin Thomson.

‘Lovely to get the perspective from consumer and clinical research coordinator.’
Appendix

Reviewing HRECs and participating organisations in Victoria

Reviewing Human Research Ethics Committees
Alfred Hospital
Austin Health
Melbourne Health
Peter MacCallum Cancer Centre
Monash Health (A and B)
St Vincent’s Hospital (Melbourne)
The Royal Children’s Hospital

Participating Organisations
Alfred Health
Austin Health
Melbourne Health
Peter MacCallum Cancer Centre
Monash Health
The Royal Children’s Hospital

Accepting Organisations
Acceptance of the review of an accredited HREC:
Cabrini Health
Breast Unit Mercy Private

St Vincent’s Hospital (Melbourne)
Ballarat Health Services
Barwon Health
Bendigo Health
Eastern Health
Goulburn Valley Health
Peninsula Health
The Royal Women’s Hospital
Western Health
Albury Wodonga Health
Northern Health
Latrobe Regional Hospital
Introduction

The streamlined system for ethical and scientific review of multi-site clinical trials in Victoria aims to:

• improve delivery of new treatments to patients earlier.
• provide faster, more efficient processes to conduct clinical trials.
• speed up product development for world markets.
• make the approval process more efficient.

Research governance is the framework by which institutions and investigators ensure accountability for research conducted according to ethical practices, scientific, regulatory and professional standards and the principles of good management.

Site-specific assessment (SSA) is an aspect of research governance. Public health organisations are required to undertake SSA for all multi-site clinical trials conducted at their institution. A separate SSA application is required for each site at which the research project is to be conducted.

The processes for ethics approval and SSA authorisation would be conducted in parallel. SSA authorisation cannot be completed until HREC approval has been received.

Ethical and scientific review Scope

The streamlined system for ethical and scientific review of multi-site research applies to research involving interventional clinical trials and placebo and device trials that we conduct by:

• commercial sponsors
• collaborative principal investigators
• investigational initiated groups.

The online forms website (www.ethicsform.org/au) is used to submit applications and allocate HREC applications.

The Coordinating Office hosts regular events which are open to representatives of all sectors of clinical trial research.

HREC applications

Approximately two weeks before an HREC applicant is ready to submit a new HREC application, the Coordinating Office will notify the applicant that the online forms website (www.ethicsform.org/au) must be used to submit the application. The Coordinating Office will also notify the institution as to which HREC will receive the application. The coordinating principal investigator (CPI) and the research project team must ensure that an HREC application is submitted.

Susan Murray, Chair

Cas and application is allocated to HREC

PI communicates with HREC at site

HREC conducts ethical and scientific review

PI submits SSA to institutional RGO

RGO conducts institutional ethical and scientific review

RGO notifies PI of outcome

The Coordinating Office is responsible for:

• coordinating multi-site trials
• providing a streamlined system for ethical and scientific review
• coordinating multi-site research applications
• providing project resources
• providing central ethical reviews
• ensuring high standards of safety
• providing support to sites to ensure timely ethical reviews
• providing support to develop the streamlining system
• providing support to the Coordinating Office on 9096 7394.

The Coordinating Office is available to answer any questions you may have about the streamlining system for ethical and scientific review of multi-site clinical trials in Victoria.
Mutual acceptance of ethical and scientific review for multi-centre clinical trials conducted in Public Health Organisations in NSW, Queensland and Victoria

April 2011

Which ethics application form should I complete?

Applications for site specific review must be submitted using the Online Forms website:

1. NSW SSA Form for research projects in NSW
2. QLD SSA Form for research projects in QLD
3. VIC SSA Form for research projects in VIC

Ethical and Scientific Review

Each principal for a multi-centre clinical trial conducted across the participating states will be ethically and scientifically reviewed once only by a Public Health Organization HREC that has been certified by the NHMRC in clinical trials. The exception is for those RUs who require ethics review.

Research Governance is the framework by which institutions, investigators and their managers share responsibility and accountability for Research conducted according to ethical principles, scientific, regulatory and professional standards and the principles of risk management.

Site Authorisation

Research governance is the framework by which ethics, institutions, investigators and their managers share responsibility and accountability for Research conducted according to ethical principles, scientific, regulatory and professional standards and the principles of risk management.

Site Authorisation is one aspect of research governance. Public Health Organisations will undertake this specific assessment. SSA forms must be submitted for each research project to be conducted at sites under the control of NSW, Queensland and Victorian Public Health Organizations.

Which SSA application form should I complete?

Applications for site specific review must be submitted using the Online Forms website:

1. NSW SSA Form for research projects in NSW
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Overview of processes for obtaining Human Research Ethics Committee (HREC) approval and site approval of multi-centre clinical trials conducted in Public Health Organizations in NSW, Queensland and Victoria

Figure 1: Overview of processes for obtaining Human Research Ethics Committee (HREC) approval and site approval of multi-centre clinical trials conducted in Public Health Organizations in NSW, Queensland and Victoria

Ethical & scientific review

HREC

Site Authorisation

Institutional head or delegate

Research Governance Officer

A facility, location or service where the research is being conducted.

Research that is conducted by an individual investigator or a Small Team of Investigators at one site.

Principal Investigator: The individual who takes specific responsibility for the oversight of an individual research project.

The individual who takes specific responsibility for the overall conduct, management, monitoring and reporting of a research project at one site.

The NSW, Queensland and Victorian Departments of Health have recently signed a Memorandum of Understanding to develop a national system of ethical and scientific review of multi-centre, clinical trials.

The aim is to reduce duplication of review requirements.

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Figure 1: Overview of processes for obtaining Human Research Ethics Committee (HREC) approval and site approval of multi-centre clinical trials conducted in Public Health Organizations in NSW, Queensland and Victoria

Ethical & scientific review

HREC

Site Authorisation

Institutional head or delegate

Research Governance Officer

A facility, location or service where the research is being conducted.

Research that is conducted by an individual investigator or a Small Team of Investigators at one site.

Principal Investigator: The individual who takes specific responsibility for the oversight of an individual research project.

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