Streamlining clinical trial research
Annual Progress Report
2013–2014
‘…views from all invested parties provided thought provoking ideas’
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This work is available at: www.health.vic.gov.au/clinicaltrials/publications.htm
Achievements and highlights

In 2013–2014 further progress in streamlining clinical trial research was made with the establishment of single ethical review of multi-site clinical trials under National Mutual Acceptance (NMA) on 1 November 2013. This NMA applies to public health services in four states: New South Wales, Queensland, South Australia and Victoria. Other jurisdictions will join when their local arrangements are in place. A forerunner to NMA was interstate mutual acceptance that operated for two years between the eastern seaboard states. From the operation of these interstate mutual acceptance initiatives there were 520 human research ethics committee applications (HREC applications) and 1,683 site specific assessments (SSAs) for multi-site clinical trials between participating states. The trial phase activity showed almost 50 per cent were phase III clinical trials followed by phase II (22 per cent). The initiative was well supported by commercial sponsors, investigator initiated and collaborative groups.

The introduction of the streamlining ethical review has enabled recording of clinical trial activity for multi-centre clinical trials. The level of activity in Victoria has increased throughout 2013–2014 despite factors that have impacted on the location of clinical trials to other global destinations. The streamlining program has continued to attract more clinical trials to Victoria in this very competitive environment. In 2013–2014, there were 180 new clinical trial ethics reviews.

Throughout the year, forums were held with expert speakers who presented on a range of topics including:

- an update on the Australian Research Ethics Database and e-submission of applications
- regulations for complementary medicines from the Therapeutic Goods Administration (TGA).

The 2014 annual May Workshop was sought-after, with 200 registrants from interstate and Victoria filling the venue. The theme was ‘Quality in clinical trials’ with a focus on recruitment of clinical trial participants. This session was a collaborative effort and included presentations by experienced trial coordinators, industry sponsors and contract research organisations. The cooperative project initiative at the 2013 workshop resulted in the release of the *Research governance and site specific assessment – process and practice* booklet, which has been well received by the clinical trial sector. The location of clinical trials and global considerations session gave an overview of current and future challenges from the commercial industry perspective.

The May Workshop also included an impromptu audience survey of positive and negative aspects of conducting trials in Australia. Quality was a big positive in relation to good data, healthcare, safety, highly trained professionals, frontier technologies, CTN scheme and sound governance practices. Other aspects included seasonal diseases (flu) and time zone advantage. On the other hand, significant challenges still exist, including recruitment of participants due to population size, the competitive landscape, timeliness for trials, regulatory approvals and cost efficiency.

The metrics on the following pages show the types of clinical trials conducted in Victorian hospitals in 2013–2014. Overall, there were 180 new clinical trial protocols ethically reviewed for multiple sites. The program met the 30-day benchmark for timeliness of approvals in 67 per cent of trials approved, which is lower than the previous period (73 per cent).

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 38 per cent, followed by cardiovascular trials and neuroscience. Phase III trials are the predominant activity but there has been a significant rise in early phase trials from 22 per cent to 37 per cent of all clinical trials.
‘...great ideas and reinforcement we are working appropriately, exposes issues facing all arms involved in research area to improve understanding of each other’s perspectives.’
Clinical trial approvals

Number of multi-site clinical trial ethics applications and site-specific assessments (SSAs) notified for 2013-2014

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

Primary clinical disease type

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

Clinical trial phases

Phase III is the predominant activity with earlier phases accounting for 37 per cent of trials.

Sponsorship of clinical trial application

Seventy per cent of multi-site clinical trials are commercially sponsored. Trials funded through non-commercial processes constitute the residual 30 per cent.
Manager’s report

The 2013–2014 year has been very productive, with further growth in clinical trial applications in Victoria. In addition, the transition from Interstate Mutual Acceptance to National Mutual Acceptance (NMA) now enables ethics applications to be reviewed across the four participating states. The initiative has been well supported by industry and other users of the streamlined system, judging from the number of ethics applications submitted to certified ethics committees participating in NMA.


The Australian Research Ethics Database (AU RED) information management system underpins communications for NMA and links applications for ethics and site-specific assessment across Victoria, New South Wales, Queensland and South Australia. Flow of information occurs for administration and timely completion of regulatory processes. All the Victorian streamlining documents have been integrated with NMA single ethical review, including research governance, and the framework is applicable to Victorian and NMA multi-site reviews and site-specific assessment.

Data management is a considerable part of the Coordinating Office’s operations and can now provide clinical trial information derived from AU RED, which was previously not available. This includes information on NMA progress as a cooperative effort between participating states. There are more than 100 ethics applications registered under NMA, indicating positive support from the clinical trial sector.

To reduce time in the research governance/site-specific assessment process, the four states participating in NMA have worked cooperatively to review clinical trial research agreement variations contained in schedules 7 or 4.

The Southern Eastern Border States (SEBS) panel meets monthly and works through a standardised review process; in some cases a separate requirement for legal review also occurs. This results in a listing of agreed schedules for sponsors of clinical trials that is made available to research governance officers at health services to enable faster processing.

A year-long project that began in 2013 was realised at the 2014 May workshop with the release of the Research governance and site specific assessment – process and practice booklet. This was a cooperative effort involving trial coordinators/investigators, research governance officers and sponsors/contract research organisations providing their expertise and experience. The publication has received excellent reviews from those working in the clinical trials sector and is the first comprehensive guidance document on this relatively new regulatory process to assist the sector and inform those moving into clinical trial research.

Quarterly meetings with reviewing ethics committee research managers were hosted by the Coordinating Office, to discuss clinical trial operational issues for the NMA initiative and related matters. These meetings were also an opportunity for the Victorian Managed Insurance Authority to provide expert advice to research office managers and the department.

The Coordinating Office has worked with the Consultative Council and assisted with a forum hosted by the Consultative Council on 3 December 2013. The forum engaged key stakeholders to identify themes to advance clinical trials in Victoria.

Communication with users of the streamlined system is a crucial part of the Coordinating Office’s work to support stakeholders. The website is regularly updated with new information and improved tools for stakeholders, forums presentations, workshops and publications relating to streamlining clinical trial research.
The *Streamline E-bulletin* provides the clinical trial sector with news about updates and new directions. There are more than 1,000 subscribers in Victoria and interstate, including industry, hospital-based research ethics and governance officers, investigators, trial coordinators and others with related interests.

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 cooperated with the Coordinating Office and given their time. It has been a pleasure to deliver operational services and collaborate with all who are involved in clinical trial research.

**Coordinating Office for Clinical Trial Research**

**The office**

COCTR has four members of staff within the Department of Health;

Dr Suzanne Hasthorpe, Manager

Mr Gavin Murnane, Senior Information Management Officer

Ms Abigail Cooper, Operations Officer

Ms Voula Phelagti, Project Officer, Finance
Chair’s report

Throughout 2013–2014, Victoria continued to participate in mutual acceptance and this is now well established in Queensland, New South Wales and Victoria, with South Australia recently joining National Mutual Acceptance (NMA) in November 2013. This created NMA for scientific and ethical review of multi-centre clinical trials conducted in the public hospital sector.

In 2013–2014, some 180 new clinical trial protocols were ethically reviewed for multiple sites. The program met the 30-day benchmark for timeliness of approvals in 67 per cent of clinical trials that were approved. About 40 per cent of approved clinical trials were Phase III and 27 per cent were Phase II. Overall, 70 per cent of trials were commercially sponsored. This is a good indicator of the interest of the international pharmaceutical industry in Australia as a location for clinical trials.

Interestingly, some 38 per cent of trials were for cancer and related neoplasms. This reflects the incredible range of new drugs under development for cancer treatments, some of which include small molecule tyrosine kinase inhibitors and monoclonal antibodies.

The Victorian Coordinating Office based in the Department of Health, hosted several forum presentations with attendance by hospital governance personnel, industry representatives, trial coordinators and researchers, throughout the year.

To further improve the Victorian (and Australian) role in industry sponsored trials, the Consultative Council invited attendees to a forum on 3 December 2013. Speakers included Professor Stephen Smith, Dean of Medicine, University of Melbourne; Dr C Maccarrone, Associate Director, Clinical Research, GlaxoSmithKline; Professor Stephen Holdsworth, Director of Research Strategy, Monash Partners’, Monash University; and Dr Angela Watt, Director Research Governance and Ethics from Melbourne Health.

The main points discussed included the function of academic health science centres, which in the UK established single research governance offices that serve several hospitals within a centre. This accords with the McKeon Report on the ‘Strategic Review of Health and Medical Research’ 2013, which suggested eight to ten national ethics committees in Australia. It was recommended that a simple move in Victoria would be to encourage a single research governance office associated with each of the academic health science centres in Victoria. There was considerable interest in this potential development.

Another major issue is that the new national standards for health service accreditation created by the Australian Commission on Safety and Quality in Health Care no longer include clinical research. Given the value of clinical research in Australia and Victoria in terms of cutting edge medical care and the economy, it was considered that the Consultative Council should pursue this matter. Victoria’s representative on the National Safety and Quality Health Service board has raised this issue.

Taking on board these issues would certainly lead to improvement in the efficiency of research ethics approval in the government’s processes for clinical trials in Australia. It would also increase clinical trial activity within hospitals, making Australia a more attractive site for the international pharmaceutical industry.

Professor Richard Fox AM
Chair, Consultative Council for Clinical Trial Research
Council member profiles

Professor Richard Fox (Chair) AM 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.

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.
Council member profiles

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/foetal 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.

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.
Roland Scollay PhD 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.

The Sub-Committee has six members.
Dr Angela Watt, Melbourne Health, Chair
Ms Anne Spence, Cabrini Health
Ms Bernice Davies, Barwon Health
Ms Malar Thiagarajan, Southern Health
Ms Kym Short, Lilly
Dr Suzanne Hasthorpe, Coordinating Office
Secretariat: Ms Abigail Cooper
The Victorian, Queensland and South Australian Departments of Health and the New South Wales Ministry of Health have signed a Memorandum of Understanding (MOU) for mutual acceptance of ethical and scientific review in public hospitals regarding multi-centre, clinical trials being conducted in more than one of these states.

Mutual acceptance of ethics review for multi-centre clinical trials for New South Wales, Queensland, South Australia and Victoria commenced on 1 November 2013. Commencement of mutual acceptance for other states and territories will occur as they have local arrangements in place.

Ethics committees that review for other state publicly funded health services have been certified under the National Health and Medical Research Council (NHMRC) 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 (EC00134)
South Western Sydney Local Health District HREC (EC00136)
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 & Daring 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**
Alfred Health Human Research Ethics Committee (EC00315)
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)
Southern Health Human Research Ethics Committee A (EC00382)
Southern Health Human Research Ethics Committee B (EC00383)
St Vincent’s Hospital (Melbourne) Human Research Ethics Committee D (EC00343)

**South Australia Health**
Human Research Ethics Committee (TQEH/LMH/MH) (EC00190)
Royal Adelaide Hospital Human Research Ethics Committee (EC003192)
SA Health Human Research Ethics Committee (EC00304)
South Adelaide Clinical Human Research Ethics Committee (EC00188)
Women’s and Children’s Health Network Human Research Ethics Committee (EC00197)
Events

Annual May workshop
Wednesday 7 May 2014, Melbourne
Quality in Clinical Trials

Introduction
- Professor Richard Fox AM (Chair of the Consultative Council for Clinical Trial Research)

Bernie Hobbs, MC

Session 1
Recruitment of clinical trial participants
Overview
- Lucas Litewka, St Vincent’s Health (Melbourne)

Sponsors and Contract Research Organisations
- Denise Ridgway, PPD
- Carlo Maccarrone, GlaxoSmithKline
- Elizabeth Wilson, Quintiles

Clinical Trial Coordinators
- Charisse Spence, Barwon Health
- Madeleine Chow, Eastern Health

Speaker panel session – question and answer
Research governance – process and practice
Representatives of ‘Research governance – process and practice’ groups with ‘top tips’
Release of the booklet

Session 2
Location for trials – global considerations
- Carlo Maccarrone, GlaxoSmithKline
- Sharon Charles, Mesoblast

Research ethics and governance forums 2013–2014

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 30 August 2013
  Electronic Submission of Ethics Applications
  HREC Members Portal
  Speaker: Ms Ainsley Martlew, Infonetica Ltd

- Friday 28 March 2014
  Regulations for Complementary Medicines
  Speaker: Dr Trisha Garrett, Therapeutic Goods Administration

Seminar
Data management and data integrity
Speakers: Peter Williams, Department of Health, Vaughn Moore, Department of Health
14 February 2014

Conferences – invited
Initiatives for clinical trial research – Dr Suzanne Hasthorpe
Victorian Association of Research Nurses, Melbourne
13 September 2013

Research Governance and Site Specific Assessment – Process and Practice – Dr Suzanne Hasthorpe,
Charisse Spence, Bernice Davies and Alex Dimitroff
ARCS, Sydney
4 June 2014
Conferences attended

BioMelbourne Network Briefing, How to achieve timely and successful patient recruitment for clinical trials  
16 July 2013

BioMelbourne Network Briefing, Creating a new language to support open innovation  
19 August 2013

National Health and Medical Research Council, National Forum – Clinical Trial Research Governance, Melbourne  
5 September 2013

Department of Health, Health Privacy Forum: Protection of Patient Data  
5 December 2013

Australian Clinical Trials Alliance, National Summit of Clinical Trials Networks, Melbourne  
28 March 2014

Jurisdictional AU RED Group, Annual Meeting, Adelaide  
4 April 2014

‘...a very valuable experience as it has provided greater depth to my existing knowledge. The diversity in the attending audience was wonderful and it was very reassuring to discover the common issues that exist in clinical research.’
Appendix

Reviewing HRECs and participating organisations in Victoria

Reviewing human research ethics committees
Alfred Hospital
Austin Health
Melbourne Health
Peter McCallum Cancer Centre
Southern Health (A and B)
St Vincent’s Hospital Melbourne
The Royal Children’s Hospital

Participating organisations
Albury Wodonga Health
Alfred Health
Austin Health
Ballarat Health Services
Barwon Health
Bendigo Health
Eastern Health
Latrobe Regional Hospital
Melbourne Health
Northern Health
Peninsula Health
Peter McCallum Cancer Centre
South West Healthcare
Southern Health
St Vincent’s Hospital Melbourne
The Royal Children’s Hospital
The Royal Women’s Hospital
Western Health

Accepting organisations
Acceptance of the review of an accredited HREC:
Breast Unit Mercy Private
Cabrini Health
The Coordinating Office for Human Research Ethics (CCHRE) is a part of the Public Health Organisations (PHOs) in Victoria. The Coordinating Office provides general information about all facets of clinical trials and research. The Coordinating Office also provides support to users to ensure timely ethical review and provides information about the latest updates on clinical trials conducted in Victoria.

### Site Specific Assessment

**Research Governance**

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

**Site Specific Assessment (SSA)**

 SSA is one aspect of research governance. Public Health Organisations are required to undertake SSA for all multi-site clinical trials conducted at an institution in compliance with the Standard Operating Procedures. SSA must be completed for all research projects to be conducted at any site in Victoria.

### Ethical and Scientific Review

**Scope**

The central system for ethical and scientific review of multi-site research applies to research involving interventional clinical trials and includes drug and device trials that are conducted by:

- Commercial sponsors
- Collaborative groups/Consortiums
- Investigator initiated groups

The scope includes research involving radiation therapy, surgery, and medical imaging. At this stage, it excludes research such as supportive care and palliative care. The central system applies to institutional clinical trials involving children commenced in March 2011.

### Events and Publications

#### Events

**Annual Mail Workshop**

A separate SSA application is required for each site at which the research project is to be conducted. You can commence the process for ethics approval and SSA authorisation cannot be completed until HREC approval has been received.

**National Ethics Application Form (NEAF)**

Applications and participating site principal Investigators are required to register for an account on the Online Forms website (www.health.vic.gov.au/cchre). The Online Forms website must be used to complete the NEAF. Supporting documents must be uploaded to the NEAF. SSA applications may have a “Hepatitis C” generated on online forms. Additional supporting documents can also be uploaded at a later date, as required.

### Victoria’s Regulatory Environment

In Victoria, there is a requirement to comply with legislation relating to human research involving information from health professionals and the use of human tissue and consent under Victorian law. The Victorian Human Research Ethics Review Panel is responsible for ensuring that ethical and scientific practices are maintained in all aspects of clinical research conducted in Victoria.
Definitions

Certified person Research Ethics Committee (RREC) An RREC which has been assessed and certified by a NHMRC certification committee to conduct the scientific and ethical review of multi-centre clinical trials.

Clinical Trial
terstrial research involving a drug/medication, surgery, therapy, treatment or diagnostic procedures.

Consulting Principal Investigator (CPI) The individual who bears overall responsibility for the research project and approves the project for scientific and ethical review. The CPI is responsible for ensuring competency with the RREC and any on the outcomes from this to the Principal Investigators.

Multi-centre research
that is conducted in more than one state or territory and in public health systems and under the authority of more than one RREC.

Principal investigator (PI) The individual who bears responsibility for the trial’s conduct, management, monitoring and reviewing of the research completed at one site and is responsible for the project to the public health organisation.

Public Health Organisation
State or territory health department services.

Research Governance Officer (RGO) The individual appointed within a Public Health Organisation who is responsible for the management of applications for site authorisation and oversight of approved research projects.

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

Site Specific Assessment (SSA) A system whereby to ensure the suitability of a multi-centre research study in a particular site. The Site Specific Assessment will be undertaken in accordance with the relevant state/territory Site Specific Assessment forms developed by each jurisdiction.

Overview

Scientific & ethical review

1. A separate SSA application must be made for each site
2. Applications for scientific and ethical review must be prepared using the National Ethics Application Form (NEAF) available on the website www.health.wa.gov.au/researchdevelopment/humanresearch
3. Applications for site specific assessment must be submitted using the SSA form for the state or territory in which the site is located.

Site Authorisation

1. If approved, the project may commence at site
2. If not approved, project may not commence

Making an Application

Application Form

Applicants for scientific and ethical review must be prepared completing the National Ethics Application Form (NEAF) on the National Ethics Application Form (NEAF) website www.ethics.anu.edu.au/human-research-ethics-committee. For clinical trials that will be undertaken in VIC, a Victorian Specific Module (VSM) must be completed (available at www.health.vic.gov.au/clinicaltrials). For clinical trials that will be undertaken in WA, a Western Specific Module (WSM) must be completed (available at www.health.wa.gov.au/researchdevelopment/home/hrform.cfm). For clinical trials that will be undertaken in ACT, a separate SSA application must be made for each site, and the application must be completed (available at www.health.wa.gov.au/clinicaltrials/hrform.cfm). For clinical trials that will be undertaken in NSW, a Separate Site Authority Form must be completed (available at www.health.nsw.gov.au/clinicaltrials/hrform.cfm). For clinical trials that will be undertaken in NT, an NT Specific Module (NSM) must be completed (available at www.health.nt.gov.au/clinicaleducation/clinicaltrials/hrform.cfm). For clinical trials that will be undertaken in SA, a South Australian Specific Module (SASM) must be completed (available at www.health.sa.gov.au/hrresearch/ethics/hrform.cfm). For clinical trials that will be undertaken in TAS, an specific Module (TASM) must be completed (available at www.health.tas.gov.au/hrresearch/ethics/hrform.cfm). For clinical trials that will be undertaken in QLD, a Queensland Specific Module (QSM) must be completed (available at www.health.qld.gov.au/hrresearch/ethics/hrform.cfm).

Research Governance – Site Authorisation

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 is one aspect of research governance. Public Health Organisations will undertake site specific assessments to ensure that the research project is conducted in accordance with the current local jurisdictional arrangements. Contact the relevant jurisdiction for further details.

Further Information

For jurisdictional detail, refer to the facsimile.

For details on the advice Application requires in each state or territory visit the relevant Health Department website.

National Mutual Acceptance

of scientific and ethical review

for multi-centre clinical trials

conducted in public health organisations

For further information: Review Project

New South Wales Queensland South Australia Victoria

November 2013