Memorandum of Understanding with Queensland Health, New South Wales Health and Department of Health Victoria
Presentation

Aim of the MOU

Background

Conditions of the MOU

Key elements
  • Legislative requirements – National & State
  • Reporting requirement
  • Certified HREC
  • Revisit of the SERP
Aim of the MOU

The MOU seeks to:

- Implement a system of mutual acceptance of ethical review across the three jurisdictions
- Reduce the number of reviews of multi-centre clinical trials research across the three states
- Reduce research start up times and costs
- Improve the environment so patients and clinicians have access to early Phase treatments
- Increase Australia’s global competitiveness in attracting clinical trials
- Inform the national Harmonisation of Multi-centre Ethical Review system
- Demonstrate strong jurisdictional leadership in this area.
Background to MOU

• New South Wales Health (NSW) implemented a single ethical review process in 2007
• Victorian Department of Health implemented a single ethical review process, incorporating a Central Allocation Service, in November 2009.
• Queensland Health (QH) implemented a single ethical review process on 1 July 2010, incorporating a Central Coordinating Service, using NHMRC HoMER certified QH HRECs.
• In April 2010 NSW Health and Victoria Health approached QH regarding establishing a single ethical review process for multi-centre clinical trials in NSW, Victoria and Queensland.
• Approximately 76% of all multi-centre clinical trial activity in Australia is conducted in Queensland Health, NSW Department of Health and Victorian Department of Health.
Conditions under the MOU

Adoption of a common Information Technology (IT) platform (AU RED) to allow electronic submission of research projects and support ethical review and research governance systems, including adopting common enhancements of the platform.

Development of similar approaches to research governance through the use of the Site Specific Assessment Form and District authorisation.

Development and adoption of standard clinical trial agreements negotiated with Medicines Australia, the peak industry body.

Development of clinical trial agreement standard Schedule 7 clauses for industry sponsored studies.
Legislative requirements and Guidelines - National

Gene Technology Act 2000
Gene Technology Regulations 2001
Office of the Gene Technology Regulator (OGTR) Guidelines
Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code on Exposure of Humans to Ionizing Radiation for Research 2005
Prohibition of Human Cloning for Reproduction Act 2002
Research Involving Human Embryos Regulations 2003
Clinical Trial Notification Clinical and Trial Exemption (CTX) Scheme (CTN & CTX) Scheme of the Therapeutic Goods Administration
Legislative requirements & Guidelines - State

- Coroners Act 2003
- Queensland Health Integrated Risk Management Policy 2008
- QH Research Management Policy and Implementation Standards
- Guardianship and Administration Act 2000
- Public Health Act 2005
- Financial Accountability Act 2009
- QH Intellectual Property Policy
Reporting requirement

Qld Standard monitoring & reporting templates on REGU site:
QH HRECs Certified for clinical trials

Metro South Health Service District
Clinical trials Phase I, II, III & IV

Prince Charles Hospital, Metro North Health Service District
Clinical trials Phase I, II, III & IV

Royal Brisbane & Women’s Hospital Health Service District
Clinical trials Phase I, II, III & IV

Children’s Health Services District, Royal Children’s Hospital, Brisbane
Paediatric clinical trials of drugs and devices Phase II, III & IV

Toowoomba & Darling Downs Health Services District
Clinical trials Phase III & IV  Clinical trials devices

Gold Coast Health Service
Clinical trials Phase I, II & III & devices

HREC accessed through the Central Coordinating Service
Process for studies submitted for review in Qld under MOU

- On REGU website:
- Table of legislative requirements
- HREC closing dates
- Checklist for mandatory documents to be submitted e.g. protocol, cover letter etc
- No. of copies required QH HREC approval letter will list all applicable sites
- CPI guidance document
- Research Governance review and authorisation as per State requirements
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Queensland Health Fee Schedule

and

Standard Clinical Trial Agreements
Queensland Health Fee Schedule

- This schedule is intended for use by Industry Partners and Researchers in the development and negotiation of study budgets for all commercially sponsored clinical trials research to be conducted within Queensland Health Institutions.

Queensland Health Fee Schedule

Section 1 of the schedule provides information relating to fees and charges for services provided for research projects undertaken within Queensland Health. It also provides guidance on application processes, contract requirements, correct nomenclature and preferred forms. Information in this section applies to all sites within Queensland Health.
Queensland Health Fee Schedule

Section 2 provides information on individual Health Service Districts, Human Research Ethics Committees, Research Governance Offices and other research related contacts within major hospitals.
Standard Clinical Trial Agreements

- CTRA
- CRO
- Collaborative
- Device
- Phase 4/Observational (soon to be released)
- Investigator Initiated (soon to be released)
Standard Clinical Trial Agreements

- Encourage use of Standard Agreement
- Alternative Schedule 7 clauses need legal review and approved
Coordinating Principal Investigator Guidance for Multi Centre Research

- Commercially Sponsored

- Investigator initiated