

Queensland Health Single Ethical Review Process & Schedule of Fees for Industry Sponsored Studies

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Queensland

- Qld population 4 500 000
- 126 Queensland Health (QH) hospitals
- 52 private hospitals
- 16 QH Health Service Districts
- 13 QH HREC
- 18 QH RGO

Queensland Health ethical review background

- Prior 1 July 2010 - for multi-centre studies being conducted at >1 QH District
 - Historically no standard mutual acceptance of ethical review between QH HRECs
 - No standard mutual recognition of other jurisdictional HREC approval
 - Submitted to each HREC individually
 - Numerous differing feedback
 - Numerous changes requested

Consequences

- Duplication of effort
- Poor use of resources
- Delays in start up times for studies
- Some studies completed before HREC & RG processes completed
- Delay in access to treatments otherwise unavailable outside context of clinical trial

Single Ethical Review background

- 2006 AHMAC agree to implement a national single ethics review system for all multicentre research studies
- 2008 QH SERP Project Officer appointed
- 2010 QH Central Coordination Service (CCS) Project Officer appointed
- Extensive consultation with stakeholder groups
 - HREC Chairs
 - HREC administrators
 - RGO
 - Clinical study coordinators
- CCS advisory group
 - HREC Chair (x4)
 - Researchers (x1)
 - Clinical trial coordinator (x2)
- QH HREC & RG SOPs revised to include SERP
- Sign off by DG to commence 1 July 2010

Single Ethical Review Process

- Introduced 1 July 2010 for all multi-centre studies
- 7 NHMRC certified lead QH HREC
 - 5 in clinical trials
- Studies allocated to reviewing HREC through Central Coordinating Service
- Multi-centre studies ethically reviewed once only for all QH sites
- After HREC approval is granted Site Specific Assessment (SSA) Form is submitted to the local Research Governance Officer (RGO)
- District CEO sign off to commence research

Central Coordinating Service

- All multi-centre studies submitted through QH Central Coordinating Service
- Short series questions will guide which HREC will review the study
 - Electronic database
 - Answers to questions generate a decision tree within the database
 - Suitable HRECs
 - Closing dates for HREC submissions
- 1st 3 months 40 multi-centre studies (12 clinical trials) submitted through CCS with 108 HREC reviews saved
- Database record for reporting

To come

- CPI 'how to' manual
- Evaluation of timeframes for ethical & RG review & approval
- Satisfaction survey of first 3 months of CCS
 - HREC administrators
 - HREC Chairs
 - Researchers
- Local Hospital Networks – how will this impact on SERP?

**Queensland Health standard
schedule of fees for industry
sponsored research**

Background

- 2008: ARCS conference – industry noted no standard of fees
- 2009: CRC 2 day forum – no consistency of fees
- 2009 Qld Govt *Financial and Performance Management Standard* (FPMS) QH required to establish systems for management of resources
- QH did not have in place publicly accessible information about the cost of goods and services for research
- No consistency in fees charged across QH sites
 - Resulting in duplication of effort by those negotiating budgets
 - Different budgets for the same research project
 - Fees charged may not cover the complexity of work

Standard schedule of fees for industry sponsored research

- Standard schedule of fees for industry sponsored research
 - Personnel costs
 - Pharmacy
 - Pathology
 - Radiology
 - Nuclear medicine
 - Other trial related costs

Development of fee schedule

- Consultation with QH:
 - QH departments
 - Clinical study coordinators
 - RGO
 - Finance Department
 - GST team
 - Clinical & Statewide Services

Example of development of fee schedule

- Personnel costs
 - CRC network group - time & motion studies
- Pharmacy
 - Society of Hospital Pharmacists (SHPA) 2005 & Pharmacy NSW Schedule of fees
- Nuclear Medicine
 - MBS + % (cover administration costs)
- Radiology
 - MBS + % (cover administration costs)

Results

- Decreased time spent obtaining information for the creation of “essential documents”
- Transparency of fees will allow sponsors immediate access to information that would otherwise take days or weeks to access, thus decreasing study start times.
- Improved budgeting process for commercially sponsored clinical trials.
- Reduced budget variations for single and multi-centre clinical trials.
- Greater transparency and consistency in budget development.
- Greater clarity for clinical trials Sponsors.
- Provides sponsors greater certainty in budgeting processes in Queensland Health.

Contact details

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Visit the REGU site:

www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Standard schedule of fees for industry sponsored research:

http://www.health.qld.gov.au/ohmr/documents/regu/resrch_fees_v1.pdf

Central Coordinating Service information:

http://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp