Queensland Health Single Ethical Review Process and Central Coordinating Service

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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
QH Single Ethical Review consultation

2008: QH SERP Project Officer appointed

2010: QH Central Coordination Service (CCS) Project Officer appointed

- 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
QH Single Ethical Review Process

Introduced for all multi-centre studies

• 8 NHMRC certified lead QH HREC
  – 6 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
Process for studies submitted for review in Qld

- For multi-centre studies a CPI must be nominated – may be outside Qld but must be Australian based

- Online NEAF or QH LNR research form must be used

- All signatures must have been obtained & application ready to submit

- For NEAFs: supporting documents must be uploaded onto online forms site
Submission of applications

• Multi-centre studies submitted through QH Central Coordinating Service: 1300 753 227

• Single centre studies can be submitted directly to HREC

• Mandatory documents
  – Cover letter
    • Brief overview of study
    • Applicable sites identified
    • For industry sponsored studies – details for invoicing
  – Protocol
  – CV for CPI & PIs if not submitted within 2 years previously
QH 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
Which studies are submitted to CCS?

• All multi-centre studies, even if only 1 QH site

• Single site studies if there is a possibility of expanding to multi-centre
  – Prepares for HoMER & MOU
  – Single site studies expanded to multi-centre
  – Multi-centre studies with only 1 QH site expanded to QH multi-centre
  – Ensures correct documentation is submitted

• If in doubt, contact CCS 1300 753 227
How to track HREC applications

### Pegasus - TIMI S4

**Form Type:** NEAF  
**HREC Reference:** None  
**Form Section:** N/A  
**Signatures:** This form is attached with electronic signatures, any changes to the form will invalidate the signatures.

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<th>Submission Code</th>
<th>HREC name</th>
<th>Action</th>
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SSA process

• Once HREC approval is granted SSA Form can be submitted to the RGO

• Each site must have a site contact person

• Local PIs should commence discussions with data custodians & supporting departments as early as possible and prior to HREC submission
SSA process

• SSA Tab is in the NEAF Actions Tabs

• CPI creates a separate SSA for each site and transfers the SSA to local PI
SSA process

• When SSA has been transferred recipient can then make changes, send for signing authorisation and create a submission code.

• Local PI completes SSA Form according to local requirements e.g. specific recruitment details

• Researchers are responsible for obtaining relevant signatures not the RGO

• Local PI generates SSA submission code
SSA process

• Local PI submits SSA and all supporting documentation to RGO

• Await District CEO or delegate authorisation

• Local PI notifies CPI when study approved

• CPI notifies approving HREC
Ensuring a smooth RG process

• Know what needs to be completed on the SSA Form
  – ? Public Health Act application
  – ? Authorisation from CaSS
  – ? Queensland Civil and Administrative Tribunal (QCAT) application (one to be submitted by CPI)

• Engaging all stakeholders early e.g departments, finance, RGO

• Use of standard CTRA & approved Schedule 7 clauses

• Use of QH standard schedule of fees
QH Central Coordinating Service Review
Review of studies submitted to QH HREC 1 July – 31 Dec 2010

616 applications ethically reviewed by QH HRECs

196 multi-centre studies (32%)

50 multi-centre clinical trials (8%)
Central Coordinating Service – July 2010 – Nov 2010

73 studies booked through CCS
  – 192 potential reviews saved

Cost saving for HREC Administrators & HREC Chairs: $92,160.00

Cost saving for researchers: $109,248
Studies submitted to QH HREC
July 2010 – Dec 2010

No of studies reviewed and decision time

- No of studies
- Average days for HREC review
- Av days for RGO review
- Total review time
- Average time 53 days / 45 days for HREC certified in clinical trials

HREC & RGO

Office of Health and Medical Research
Contact REGU

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Visit the REGU site:

Central Coordinating Service information: