RGO and HREC Administrator’s Meeting
17 May 2012

Melissa Hagan
Manager, Research Ethics and Governance Unit
Office of Health and Medical Research
Agenda

Agenda Item 1
• Welcome
• Apologies
• Acceptance of previous minutes
Feedback from decisions at November 2011
  – Redcliffe closure and commercial research at Non-Q Health sites
Update on MOU NSW, QLD and Victoria
Start with some QLD data (SERP started on 1 July 2010)
QH Single Ethical Review Process

741 Multicentre HREC Reviews

<table>
<thead>
<tr>
<th>Year</th>
<th>Multicentre Reviews</th>
<th>Average Review Time (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>418</td>
<td>34</td>
</tr>
<tr>
<td>2012</td>
<td>323</td>
<td>25</td>
</tr>
</tbody>
</table>
Distribution Fin 2010-2011 Multicentre Research Reviews by QLD HRECs
Why HREC Chosen

- 57% Already submitted single-multi
- 6% Convenience
- 9% Data linkage
- 2% Linked to another study submitted
- 2% Local HREC
- 1% No reason listed
- 2% Previous exp with HREC
- 6% Timing on next HREC meeting
MOU with NSW, Victoria & Queensland, Identified issues and solutions

QH Six 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
Reporting for Multi-site Clinical Trials - Interstate Mutual Acceptance

Number of HREC reviews saved

- 186
- 68
- 254

- No. SSAs
- No. HREC Apps.
- No. HREC Apps. Saved
Who is using the MOU?

![Pie chart showing the distribution of major sponsor types.]

- **Commercially Sponsored**: 100
- **Collaborative Group**: 13
- **Investigator Initiated Group**: 4
- **Not Stated**: 13
- **Total**: 100%
Access to Unapproved Goods

CTN vs CTX

- CTN: 52
- CTX: 0
- Neither: 16
25% (17/68) Approved

HREC Approval Times

Days Taken (Calendar Days)

Benchmark (Calendar Days)
SSA Turn Around Time
Observational research and evaluation of a trial, developing a registry and other post-marketing surveillance activities

- Have amended the MOU to add this to the definition of a trial
- Clinical Trial= Interventional research involving a drug/device trial, radiation therapy, surgery, treatment or diagnostic procedure and studies associated with ongoing activities relating to trials that have been conducted. This may include observational research and evaluation of a trial, developing a registry and other post-marketing surveillance activities
- In practice already
- Exploration of possibility of extending even further
“Private Sites”

• Differing approaches to them as participating sites
• Issues surrounding agreements and monitoring
The sky hasn’t fallen in!
Advanced Reporting

Agenda Item 2
Demonstration

http://qld.bay3.infonetica.net
Standardising Processes

Agenda Item 3. 1

What documents does each DCEO want to have supplied with the SSA form to enable sign off? This is a carry on from the last meeting. CRC’s have requested a table of documents to be submitted to the HREC and RGO not finalised.
Standardising Processes

Agenda Item 3. 2
Requirements for Data Custodian sign off, sign the SSA or email. Any way is OK as long as intent.
**Standardising Processes**

**Agenda Item 3.3**

Single site studies being submitted to HRECs without consultation with the HREC administrator, when the submitting site is not local to the HREC. Right of refusal? Certification implications?
Standardising Processes

Agenda Item 3.4 Multi-Centre Topics

3.4.1 Discussion: How to add a Victorian site (and Victorian module) to an MCR study already approved with no other Victorian sites already included. Vic module has to be provided with a full NEAF and go to a full committee and attract another full fee.
Standardising Processes

Agenda Item 3. 4 Multi-Centre Topics

3.4.2 Discussion: Victorian Module: Should it be proactively reviewed even if there are no participating Victorian sites in the original application?
Standardising Processes

Agenda Item 3. 4 Multi-Centre Topics

3.4.3 What is the definition of site you’d it would be easy!!!!!

3.4.4 Listing sites on approval letters

3.4.5 Should the CPI CRC role send ALL docs to the CRA for distribution to Accepting Sites (Commercially sponsored studies only)? What is the impact on remuneration?
Standardising Processes

Agenda Item 3. 4 Multi- Centre Topics

3.4.6 Process for reviewing multi centre low risk applications – which form do you use, what review process is followed?

3.4.7 Reviewing applications where your institution is not represented
Standardising Processes

Agenda Item 3. 4 Multi-Centre Topics
3.4.8 and 3.11 Guidance for RGOs for dealing with SAEs from their site

SAEs How do you handle SAEs that come in to your institution as an RGO that have not been reviewed by your HREC.

Page 13 and page 14 Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research
Safety reports that are distributed ‘upward’ are, in the main, related to adverse events occurring at a research site. Reports of various types related to events occurring outside of any one research site are distributed ‘downward’.

* Individual reports (e.g. SUSARs) should only be forwarded with a recommended action
**Progress Reports**

- PI
  - Institution
  - CPI
  - HREC

**Annual Reports**

- Part A – Institution
  - PI
  - Institution

- Part B – HREC
  - PI
  - CPI
  - HREC

**Final Reports**

- PI
  - CPI
  - HREC
  - Institution

*
Standardising Processes

Agenda Item 3. 4 Multi-Centre Topics

3.4.9 New process for CCS bookings including single site to multisite issues.
Standardising Processes

Agenda Item 3. 5

3.5 How to correctly log a study as “closed” at the site, and how to log it as “closed and archived” and what to write in the “notes” section ... (archiving location) consistency across states?
Standardising Processes

Agenda Item 3.6 New CASS Procedure

• Dissolution of the CaSS Research Committee

• On 7 March 2012 the CaSS Research Committee and the requirement to obtain CaSS Administrative Approval was formally abolished. However, the requirement to seek approval to access CaSS resources for the purposes of research still remains.

• Read more from the Clinical and Statewide Services eBulletin.

• New Process for Accessing tissue Samples held by CaSS

• Researchers requiring access to tissue or other pathology samples held by CaSS are now required to make application directly to the relevant Pathology Queensland Laboratory Director.
Standardising Processes

**Agenda Item 3. 7**  An IEC or HREC? Does your HREC name have the word “Institutional” in it? Ensure that documentation matches official name.

**Dissolution of the CaSS Research Committee**

**Agenda Item 3. 8**  RGO Authorisation Letters 
Who signs, when do you issue one when governance amendments arrive? Email, hard copy ??

**Agenda Item 3. 10**
RGO Authorisation of Protocol and other Amendments: Clerking and Charging

**Agenda Item 3. 18**
Governance only amendment what to charge and how to ”authorise”. (CEO or RGO).
Standardising Processes

**Agenda Item 3.9 Waiver of requirement for SSA**. What circumstances should you do this?

**SECTION 6: SITE-SPECIFIC ASSESSMENT OF LOW RISK RESEARCH**

**General Policy:**

6.1 A low risk reviewing body that reviews research involving only low or negligible risk, has the authority to waive, in consultation with the RGO, the need for an SSA Form on the basis of a review. Local administrative requirements will be implemented.

6.2 If a SSA is required, the site principal investigator must complete a separate SSA for each site and submit the completed SSA Form(s) and all other relevant documentation to the RGO as per usual.
Standardising Processes

Agenda Item 3. 12
What do RGOs do with the email from CCS (is it required)?

Agenda Item 3. 13
Review of AURED letters, district input
Standardising Processes

**Agenda Item 3. 14**
Naming Convention for contracts when Local Health and Hospital Boards commence

**Agenda Item 3. 15**
Latest travel policy NONE
Standardising Processes

**Agenda Item 3. 16**

Don’t underestimate the “lightness” of a registry study. Recent Issues how can make it smoother?

**Agenda Item 3. 17**

Changes to guidance documents and SOPs
Standardising Processes

**Agenda Item 3. 19**
Low and Minimal Impact Statewide review so far...

**Agenda Item 3. 20** Form of indemnity HREC only when it should be submitted? Last lot of minutes says HREC only if you are not participating but now sands are shifting... HREC only
Standardising Processes

Agenda Item 3. 21
List of All Hospital and Districts

Agenda Item 3. 22 New Standard Contracts, proposed release
Standardising Processes

Agenda Item 3. 23

The Victorian CPI checklist, have you received any feedback from researchers regarding this

See the checklist
Questions
REGU

Office of Health and Medical Research,
Centre for Healthcare Improvement,
Queensland Health
ohmr@health.qld.gov.au
Phone +61 7 3434 0134
Fax +61 7 3405 6131
PO Box 48, Brisbane Qld 4001