Single Ethical Review of Multi-centre Research Studies

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Background

• Previous system of ‘mutual acceptance’ by HRECs ad hoc and not uniform – no direction for researchers

• Follows decisions by NSW & Victoria

• Aligns with HoMER initiative

• Delay in implementation of national system
QH Single Ethical Review Process (SERP)

- Ongoing communication with QH Network Groups
  - HREC Chairs
  - HREC Administrators
  - Research Governance Officers
  - Clinical Research Coordinators
  - Central Coordinating Service Advisory Group

- QH Director General directive to commence SERP 1 July 2010
QH Single Ethical Review Process (SERP) – certified HRECs

• Jan 2010 NHMRC requested institutions to nominate their HREC processes for national certification
• 39 institutions nominated for certification
  • 8 QH institutions
  • Submit nomination form
  • NHMRC desk top audit
  • Onsite visit by NHMRC certification committee
  • Feedback report

• From 1 July, if study reviewed by a certified HREC then will not require ethical ‘re-review’
Processing of multi-centre studies – Low and Negligible Risk Research Forms

• No change in forms to be used – LNR Research Form on REGU website & SSA

• All studies must have a LNR Research Form & SSA submitted

• All studies must include a protocol – the LNR Research Form is not the protocol

• Online LNR Research Form late 2010

• To be decided at HREC Chairs meeting 18 June the process of review
Processing of multi-centre studies - Forms

• No change in forms to be used – online NEAF & SSA

• All studies must have a NEAF and SSA submitted

• All studies must include a protocol – the NEAF is not the protocol
Processing of multi-centre studies - Research Team

- All multi-centred studies must nominate a Coordinating Principal Investigator (CPI) – Australian based

- All sites must have a site contact person
Converting a NHMRC NEAF to an online NEAF

- Save the NHMRC to your computer as an .xml file
- Do not open the .xml file
- Upload to your online form
Process of creating an application

- Creation of online forms unchanged:
  - Create NEAF on [https://ethicsform.org/au/SignIn.aspx](https://ethicsform.org/au/SignIn.aspx)
  - Upload all supporting documents through the ‘Documents’ Tab
Transferring the application

- Allows creator of NEAF to transfer NEAF to another Online Forms user
- Version control – can only be transferred to one person at a time
- Must be transferred back to creator of NEAF to create submission code
Process of obtaining signatures

- NEAF can now be signed electronically by Coordinating Principal Investigator, Principal Investigators, Associate Investigators, Heads of Department, Heads of Supporting Departments and Authority for Data Provision
Process of obtaining signatures

- Ability to send a message to signatory
Submission

• From 1 July allocation for HREC review for all multi-centre studies will be through the Central Coordinating Service located at REGU

• Submissions must be by the CPI or delegate e.g. study coordinator

• A separate SSA application must be made to each site.
In summary - Submission process

• CPI (or delegate)
  • Creates online NEAF and generates submission code
  • Contacts CCS for allocation to a certified HREC
  • Submits all hard copy documentation as per normal procedure to reviewing HREC
  • Once HREC approval is granted obtain other authorisations
Other authorisations

- Public Health Act 2005 – DG approval

- Information or resources of Clinical and Statewide Services (CaSS)

- Adults with impaired capacity to consent - Queensland Civil and Administrative Tribunal approval
SSA Process

• Local PIs should commence discussions with data custodians & supporting departments as early as possible and prior to HREC submission
• SSA Tab is in the NEAF Actions Tabs
• CPI creates a separate SSA for each site and transfers SSA to local PI
Transferring the SSA

- Allows creator of SSA to transfer SSA to another Online Forms user
- When SSA has been transferred recipient can then make changes, send for signing authorisation and create submission code.

![Screenshot of form transfer interface]
SSA Process

• 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
Where to find out more

Office of Health and Medical Research Webpage

Researcher User Guide

NEAF Online Form User Manual

Contact us
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