

Ethical Review In NSW Health

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Presentation Overview

- Update on the NSW system
 - 2009 evaluation
 - How NSW Health is responding
- Collaboration across Eastern states - Summary

The NSW System

- Single ethical review introduced July 2007
- Key features
 - Each research project reviewed once only
 - Lead HRECs accredited to conduct a single review on behalf of all public health organisations and NSW Health
 - Co-ordinating Investigator chooses lead HREC
 - Each site undertakes a site-specific assessment (governance)
 - A research project may commence with HREC and SSA approval

The NSW System

- 23 HRECS serve the public health system
 - 13 lead HRECs
 - 3 specialist HRECs: Justice; AHMRC; state owned data collections
- Public Health Organisations
 - HREC Executive Officers (n=20)
 - Administrative support
 - Research Governance Officers (n=19)
 - Directors of Research or equivalent position in Area Health Services

The NSW System

- The system is supported by:
 - Policy directives and guidelines
 - On-line forms and AU RED
 - Learning and development program: NEAF, AU RED, Orientation, Forums
 - Preferred legal advisor
 - Clinical trial agreements
 - Enquiry line (n=1,020 in 2008/09)

The NSW System

- Volume of applications:

<u>Applications</u>	<u>2007–08</u>	<u>2008 - 09</u>
Single centre	793	760
<u>Multi-centre</u>	<u>486</u>	<u>607</u>
<u>Total</u>	<u>1279</u>	<u>1367</u>

- Clinical trials:

- 23% of all applications
- 37% of all multicentre applications

Evaluation - Methods

- Evaluation conducted after first 18 months
- Methods
 - Quantitative data from AU-RED (e.g. numbers, timelines)
 - Stakeholder interviews (individual, group)
 - Administrators (HREC Chairs, EOs, RGOs)
 - Users (researchers, industry)
 - Call for written submissions (n>30)

Evaluation – Major Findings

- 763 multicentre research projects (July 07 – Dec 08)
- System ‘saved’ approx 2000 reviews
- Outcomes of lead HRECS appear to be accepted

Evaluation – Major Findings

- Ethics approval
 - 6/13 lead HRECS <60days
 - Timeliness improved each six months
- SSA authorisation
 - 4 RGO median <35days
 - Timeliness decreased each six months

Evaluation – Major Findings

- Multiple reviews replaced by multiple SSA
- SSAs have led to increased workload for PHOs, and researchers, particularly at lead sites
- Inadequate information/training: Researchers, RGOs
- Timeliness vs quality of review

Evaluation – Recommendations

- System improvements, in particular SSA, LNR
- IT system, data collection and reporting
- Ongoing training and development
- Process improvements – all stakeholders

Evaluation – Recommendations

- Process improvements – industry
 - Ensure information provided to researcher for NEAF/SSA complete/accurate
 - Timely submission SSA
 - Use standard clinical trial agreement and approved schedule 7s
 - Meet with CPI and PI early to clarify roles/responsibilities

Evaluation – NSW Response

- Actions to refine system and improve timelines:
 - Introduce more streamlined site authorisation processes ✓
 - Introduce expedited review for low and negligible risk research ✓
 - Develop KPIs for Chief Executives ✓
 - 30 days for LNR applications (Ethical approval and SSA)
 - 60 days for greater than LNR (Ethical approval and SSA)
 - Report on Performance measures

Evaluation – NSW Response

- Actions to improve information and support include:
 - Publish updated policies, guidelines and standard operating procedures ✓
 - Maintain RGO/EO forums ✓
 - Regular liaison: Medicines Australia ✓
 - Establish and/or participate in stakeholder forums
 - Improve communication with industry and researchers

Evaluation – NSW Response

- Actions in relation to education and learning include:
 - Continue current programs (eg researcher, RGO/EO training) ✓
 - Develop and promote learning and development calendar ✓
 - Conduct EO/RGO training needs assessment
- Actions to improve IT system, data collection and reporting:
 - Employ business analyst to improve AU RED and online forms ✓
 - Establish regular reporting to PHOs

Questions or comments?

For More Information

Research, Ethics and Public Health Training Branch
NSW Health
(02) 9391 9427

- <http://www.health.nsw.gov.au/ethics/research/governance.asp>

Evaluation Report and NSW Health Response at:

- <http://www.health.nsw.gov.au/ethics/research/resources.asp>

Eastern States - Summary

- Strong collegial relationships, on-going communication and system alignment
 - Bi-monthly teleconference, Invite to forums/education sessions
 - Share policies, guidance, eg SSA
 - Investigating mutual acceptance for clinical trials
- Standard research agreements, schedule 7 and 4
 - Clinical trial research agreement
 - Industry sponsored/CRO/CRG
 - Devices (clinical investigation research agreement)
 - Investigator-initiated trials

Eastern States - Summary

- AU-RED and On-Line Forms enhancement
 - On-line form 'refresh'
 - Enhancements to AU-RED to improve usability, reporting capability
 - Regular teleconference to local enquiries, AU-RED and NEAF helpline calls
- DLA Philips Fox – preferred legal advisor across states
- Ongoing advocacy re national single ethical review through NHMRC