Ethical Review
In NSW Health

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Presentation overview

- The NSW system
- The 2009 evaluation and recommendations
- What’s new in NSW
- Ongoing actions in NSW
- Cross-state collaboration
- Focus for 2011
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

- 22 HRECS serve the public health system
  - 13 lead HRECs
  - 9 HoMER-certified committees
  - 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 Local Health Networks/Clusters
The NSW system

- The system is supported by:
  - Policy directives and guidelines
  - On-line forms and AU RED
  - Learning and development program
  - Preferred legal advisor
  - Clinical trial agreements
  - Enquiry line (~1000 per year)
The NSW system

• **Volume of applications:**

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<tbody>
<tr>
<td>Single centre</td>
<td>793</td>
<td>760</td>
<td>795</td>
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<tr>
<td>Multicentre</td>
<td>486</td>
<td>607</td>
<td>521</td>
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<td><strong>Total</strong></td>
<td><strong>1279</strong></td>
<td><strong>1376</strong></td>
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• **Clinical trials:**
  - ~25% of all applications
  - ~35% of all multicentre applications
Evaluation – overview

- Evaluation conducted after first 18 months
- Data, interview and submissions
- 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
What’s new in NSW

- Expedited review for low and negligible risk research

- More streamlined site authorisation
  - SSA (standard and LNR)
  - Access request

- Performance measures for LHNs
  - 30 days for LNR applications (Ethical approval and SSA)
  - 60 days for greater than LNR (Ethical approval and SSA)
  - Average HREC approval time
  - Average SSA approval time
What’s new in NSW

- Guideline: research governance framework

- Policy: insurance and indemnity for clinical trials
  - FAQ
  - Training for RGOs

- Changes due to national health reform
  - Organisational changes
  - HREC names
Ongoing actions in NSW

- Communication, training and support
  - Maintain RGO/EO forums
  - Annual chairs meeting
  - Researcher training (ARCS)
  - HREC new member training
  - Regular liaison: Medicines Australia
  - Ad-hoc presentations
  - Enquiries: phone and email
Ongoing actions in NSW

- Project to improve IT system, data collection and reporting
  - Employ business analyst to improve AU RED and online forms ✓
  - User group ✓
  - Defects/incident investigation
  - Change management and release process
Cross-state collaboration

- Strong collegial relationships, on-going communication and system alignment
  - Bi-monthly teleconference, Invite to forums/education sessions
  - Share policies, guidance, eg SSA
  - MOU for mutual acceptance (clinical trials)

- Standard research agreements, schedule 7 and 4
  - Clinical trial research agreement (sponsored, CRO/CRG)
  - Devices (clinical investigation research agreement)
  - Investigator-initiated trials
Cross-state collaboration

- 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 through HoMER
Focus for 2011

- Continue to support implementation of LNR process
- Evaluation framework
- Public reporting against performance measures
- Guidance for researchers
- Learning and development needs assessment
- Progress mutual acceptance and HoMER
Questions or comments?
For more information

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