

Facilitating ethics review in large multi-discipline hospitals

Rowan Frew
Ethics Manager
Research & Ethics Unit
Alfred Hospital
Bayside Health

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Facilitating Ethics Review

- Current situation in Australia
- Bayside Health
- HREC
- Ethics Office
- Possibilities

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Current situation

- National Statement on Ethical Conduct in Human Research
- Institutions
 - Eliminate unnecessary duplication of review
 - Own processes for ethical review, or use those of another institution
 - Single review of multicentre research
 - Delegated review
 - Cross approval
 - Low risk review

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Current situation cont.

- Common application form
- Electronic submission & review
- Low risk/delegated review
- Single review of multicentre research
- Common database

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BUT, is it enough?

- Load on HRECs
 - Commercial pressures (volume and speed)
 - Legislation/increased accountability (privacy, consent)
 - Single site research
 - Early phase trials
 - Complex specialised researcher-initiated studies
 - New procedures
- Researcher issues
 - Sponsors
 - Hospital resources
 - Communication with HREC/secretariat

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Bayside Health

- One of twelve Public Health Services in Victoria
- Located in Prahran, Melbourne (inner southeast)
- The Alfred Hospital, Caulfield General Medical Centre and Sandringham & District Memorial Hospital.
- Research from major trauma to aged-care
- Partnerships with Monash and LaTrobe Universities and other universities in Victoria and nationally
- Research links with the Baker IDI Heart & Research Institute, the Burnet Institute and Monash University

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Alfred Hospital HREC

In 2007

- >400 applications
- Drug/interventional studies – 156
- Health & social sciences – 135
 - Including expedited & cross-approval
- Low risk – 135

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Alfred Hospital HREC structure



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HREC review process

- Emailed submission
- Screening
- Applications to HREC on CD
- First round review
 - Research Review Committee (drugs & interventions)
 - Health & social sciences
 - Two primary reviewers for each project
- Main meeting
 - Interviews
 - General business
 - Split committees
 - Drugs & interventions (D&I)
 - Secondary reviewers
 - Health & social sciences (H&SS)
- Approvals

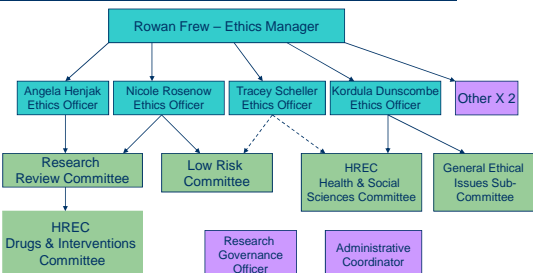
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HREC review process cont.

- Low risk review process
 - Form & checklist
 - Sub-committee
 - HREC members
 - Ethics Officer
 - Two weekly meetings
- Discarded tissue

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Ethics Office structure



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Ethics Office cont.

- Rowan Frew
- Ethics Manager
 - Management
 - Problem solving
 - Complaints
 - Serious adverse events
 - Ideas
 - RRC, HREC, GEI
- Qualifications & experience
 - BSc, Grad Dip Computing, MBioeth
 - 14 years at Bayside Health
 - Lay member

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Ethics Office cont.

- Kordula Dunscombe
- Ethics Officer
 - Health & Social Science Projects
 - General Ethical Issues Sub-committee
- Qualifications & experience
 - BA (Hons), Grad Dip Children's Literature, MSocial Health (Health Ethics) (In progress)
 - Lay member
 - Ethics Committee Secretary & Clinic Administration Coordinator (previously)

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Ethics Office cont.

- Angela Henjak
- Ethics Officer
 - Commercially sponsored drugs & interventions applications
 - Indemnity, insurance, contracts
- Qualifications & experience
 - BSc (Hons), PhD (Immunology)
 - Researcher

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Ethics Office cont.

- Nicole Rosenow
- Ethics Officer
 - Researcher-initiated drugs & interventions applications
 - Phase I trials
 - Low risk applications
- Qualifications & experience
 - BPhysio, MPH (in progress)

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Ethics Office cont.

- Tracey Scheller
- Ethics Officer
 - Health & Social Science Projects
 - Low risk
- Qualifications & experience
 - BSc, Grad Cert Applied Stats
 - Research, recruitment

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Ethics Office cont.

- Anna Parker
- Research Governance Officer
- Qualifications & experience
 - MBioeth (in progress)
- Eve Kovesdy
- Research Coordinator
- Qualifications & experience
 - MApplied Science

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Facilitating ethics review

- New applications
 - Advising researchers
 - Screening applications
 - Reviewing applications
 - Input at meetings
 - Resolution of conflicting opinions
 - Reviewing final responses and approval

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Facilitating ethics review cont.

- Post-approval
 - Advising researchers
 - Processing amendments
 - Resolution of conflicting opinions
- Serious adverse events
- Monitoring (progress reports)

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Possibilities

- Institutional requirements
 - Accreditation of secretariats
 - Adequate qualifications/training/experience
- HREC – Secretariat
 - Supplement existing HRECs – separate category?
 - Perform reviews
 - Approvals
 - Amendments

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