Navigating Research Ethics Approvals across Local Health Districts

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Objectives

- Overview of the Single Ethical Review Model in NSW Public Health System
  - Ethical Review
  - Site Authorisation
- Overview of the key features of the National Statement
  - Ethical principles/values
- Recommendations
  - General
  - Specific to participants

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NSW Single Ethical Review (SER) System: at a glance

- Commenced 1 July 2007 for multi-centre research
- Ethical Review and Research governance *split*
- Lead HRECs are accredited (clinical, general)
- Co-ordinating investigator chooses which lead HREC to submit to
- Each site accepts the ethical review of lead HREC without requiring further scientific/ethical review
- Each site undertakes a site-specific assessment (governance)
- A research project may commence with HREC and site-specific assessment approval

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NSW SER System: Specialist HRECs

- NSW Population & Health Services REC
  - Access to State-wide data collections owned or managed by NSW Ministry of Health
  - Involves data linkage via Centre for Health Record Linkage (CHeReL)

- NSW Justice Health HREC
  - Research involving persons in custody and/or staff of Justice Health

- Aboriginal Health and Medical Research Council Ethics Committee (AH&MRC)
  - Research that may affect the health and wellbeing of Aboriginal people and communities

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NSW SER System:
Types of Ethical Review

- Applications for Full HREC Review
  - Research that involves more than low risk to participants.

- Applications for Expedited HREC Review
  - Research that involves no more than low risk or negligible risk to participants

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NSW SER System:
Key Documents – Ethics Review

- NEAF
  - Completed once by Co-ordinating investigator
  - Submitted to lead HREC

- LNR Form
  - Completed once by Co-ordinating investigator
  - Submitted to lead HREC

- Forms completed via on-line forms website – www.ethicsforms.org/au

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NSW SER System: Site Authorisation

- Ethics focus – is on the participants

- Governance focus – is on
  - The actions of researchers;
  - Interests of institutions (including accountability);
  - Setting standards for research (quality + regulatory)
  - Framework and systems over ad hoc policy making
  - Defines the roles and responsibilities of all parties involved in research

- Site Specific Assessment or Access Request Review

- RGO recommendation to the Chief Executive or delegate

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NSW SER System:
Key Documents – Site Authorisation

- SITE SPECIFIC ASSESSMENT FORM (SSA)
  - Completed by Principal Investigator at each site
  - Submitted to RGO

- ACCESS REQUEST REVIEW (ARR)
  - Completed by Principal Investigator at each site
  - Submitted to RGO

- Forms completed via on-line forms website – www.ethicsforms.org/au

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National Statement (Governing Principles)

- Four values shape the relationships between researchers and participants
  - Research merit and integrity
  - Justice
  - Beneficence
  - Respect
- Applies to all human research
- Used to organise substantive content of NS
- Principles and guidelines expressed in these values

Well-being of participants is paramount

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Recommendations
General

- Read the National Statement and the ethical principles
- Familiarise yourself with sections on ethical considerations specific to participants
- View ethics as an integral part of research design and practice
- Liaise with experienced colleagues
- Contact EO/RGO prior to submission
- Ensure consistency of documentation
- Participants not *subjects*
- Research proposal - details of data analysis

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Recommendations
Specific to participants

- As a group, here are some of the types of issues you need to consider:
  - Population sample
    - Transient population (long term follow-up for longitudinal studies)
    - Good contact details and permission
  - Recruitment – identification, screening/selecting, initial contact and consenting
    - Dependent relationships almost always – hands off approach to recruitment to avoid perception of coercion
    - High prevalence of mental health disorders; susceptibility to discomfort /distress – contingency plans

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Recommendations
Specific to participants

- Informed Consent - limited cognitive capacity

  Inform HREC about determining capacity to consent

  - how is the decision made
  - what criteria
  - who will make the decision
  - review of ongoing consent

  You may need to seek consent from person's guardian or person or organisation authorised by law

- Minimise risk to Privacy
  - use of pseudonyms
  - removal of links between names and data
  - no identifying information to be published

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Recommendations - Essential Elements of Informed Consent

- Research Description
- Risks
- Benefits
- Privacy / Confidentiality
  - Illegal activities (study not specifically intended to discover such activity)
- Voluntary Participation, withdrawal
  - Consent – this study, future contact/studies
- Contacts, complaints clause

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Recommendations
Site Authorisation

- Start with the overall structure of the study
- What departments at the site will be affected by the research?
- Liaise with RGO prior to submission
- Researchers – make it easy for RGOs
    - Draw out the quality, safety, risk management, financial management aspects of your research
- Do submit your SSA/ARR in parallel with submission to Ethics
- Don’t get bogged down in the process

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Useful websites

- National Statement - http://www.nhmrc.gov.au/publications/synopses/e72syn.htm
- Australian Code for the responsible conduct of research http://www.nhmrc.gov.au/publications/synopses/_files/r39.pdf
- NSW Ministry of Health - Ethics: http://www.health.nsw.gov.au/ethics/Pages/default.aspx
- Contact the HREC coordinator where the application will be submitted: http://www0.health.nsw.gov.au/ethics/research/contactshrec.asp
- Contact the Research Governance Officer to whom the SSA Form will be submitted: http://www0.health.nsw.gov.au/ethics/research/contactrgo.asp
- Online Forms https://ethicsform.org/Au/SignIn.aspx
- Technical support : Tel: +61 2 9037 8404
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