Research Ethics and Governance
Emergency Medicine Foundation
6th February 2017

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Research Governance Officer
Redcliffe and Caboolture Hospitals and CISS
Aims of this session

- What is ethics?
- What is research governance?
- Funding and budgets
- What do you need to do next?

* Remember there is assistance available to you
Ethics & authorisation

- Ethics considers the ethical implications for the study
- Site-specific authorisation (‘governance’) considers the appropriateness of conducting the research project at the site:
  - The resource implications (financial, human, equipment, infrastructure)
  - The expertise & experience of the researchers
  - The legal requirements of the research project
  - The compliance of the research project with relevant laws, policies & codes of conduct
Core Ethics Documents

- Study protocol
- Relevant ethics forms
  - Low-negligible risk (LNR) or full application (NEAF)
- Relevant study documents
  - Data collection form
  - Questionnaire
  - Patient information sheet
  - Patient consent form
- Brief CV for investigators

https://www.ethicsform.org/au/SignIn.aspx
Operate within an ethical framework: know relevant principles

- **Respect**
  - Consent for obtaining & using information

- **Research merit & integrity**
  - Benefits justify the risks/resources

- **Justice**
  - Data collected in a fair manner that does not burden those involved

- **Beneficence**
  - Minimisation of risk of harm, inconvenience or discomfort

**Independent review**

National Statement on Ethical Conduct in Human Research (2007)

Australian Code for the Responsible Conduct of Research (2007)
Know how to navigate the ethics & authorisation process:

- Be informed on what approvals are required
- Seek advice early: e.g. QA waiver vs. low risk ethics application vs. full ethics application
- Put effort into the ethics & SSA applications – this avoids delays
- Have realistic timeframes
- Prepare study budget properly
- Speak to RGO early about any contractual or regulatory requirements
Site-specific authorisation

- **Site-specific assessment (SSA)**
  - An SSA contains what is happening at the site. Each site might be different.
  - 1 SSA per site is required
  - Study budget – what money is coming into the site?
  - CVs for all investigators
  - All documents approved by ethics
  - Public Health Act application
    - If consent is waived (the HREC will prompt this for you)
  - Research agreement – Legal component of SSA’s
    - For studies involving entities external to MNHHS
    - The RGO will organise this for you if you are the PI
  - Other regulatory documents - for clinical trials
Public Health Act (PHA)

- A PHA is required when you are seeking a waiver of consent.
- If it is impractical for you to gain consent from each participant in your study then you can apply for a PHA.
- Examples include: retrospective chart audits and accessing databases to obtain patient demographics
- Submit the PHA to PHA@health.qld.gov.au (note: you are not automatically permitted to access this data because you are a health practitioner).
Research funding

- In-kind contribution + real costs
  - You will need a study budget as part of obtaining site authorisation

- Funding sources:
  - Hospital (e.g. PPTF)
  - EMF
  - Research grants
  - External grants
Study Budget

- Sufficient funds (either from an external source or from approved internal funds) are required for a research study.

- Detail **all costs** to be incurred in the research. These costs may be real (covered by the funds) or “in-kind” (costs absorbed by the hospital).

- Even in-kind staff costs need to be quantified: provide an estimate of the number of work hours of staff directly involved (Principal Investigator, Co-Investigators, Study Co-ordinators) with the study & associated cost based on their hourly rate.

- “In-kind” support must be approved by the relevant Head of Department.

- If the study involves other departments or services (e.g. pharmacy, radiology), quotes should be provided.
# Cost centre creation form

1. To be completed by Principal Investigator:

<table>
<thead>
<tr>
<th>Site Location</th>
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<tbody>
<tr>
<td>Name of Principal Investigator</td>
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<tr>
<td>Study Name (short title)</td>
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<td>HREC Number</td>
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**Funding Organisation/Sponsor Details:**

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<thead>
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<th>Name of Sponsor/Contract of Collaborative Research Organisation</th>
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<tbody>
<tr>
<td>Contact Person</td>
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<tr>
<td>Address</td>
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<tr>
<td>Telephone</td>
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<td>Facsimile</td>
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<tr>
<td>Email Address</td>
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<td>Special Instructions</td>
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<tr>
<th>Signature of Principal Investigator</th>
<th>Date</th>
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2. To be completed by Research Governance Officer (RGO):

<table>
<thead>
<tr>
<th>Name of Research Cost Centre</th>
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<th>Name of RGO (or delegate)</th>
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<td>Signature of RGO (or delegate)</td>
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3. Finance Authorisation:

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<th>Name of Director of Finance (or delegate)</th>
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