Queensland Government

Research Ethics and Governance Emergency Medicine Foundation 6th February 2017

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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 and funding

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

https://www.ethicsform.org/au/SignIn.aspx

- 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

TIP

Operate within an ethical framework: know relevant principles

National Statement on Ethical Conduct in Human Research (2007)

Australian Code for the Responsible Conduct of Research (2007)

- **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**

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

Australia Online Forms for Research

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:

Site Location	
Name of Principal Investigator	
Study Name (short title)	
HREC Number	

Funding Organisation/Sponsor Details:

Name of Sponsor/Contract of Collaborative Research Organisation	
Contact Person	
Address	
Telephone	
Facsimile	
Email Address	
Special Instructions	

Signature of Principal Investigator		**Date**	

2. To be completed by Research Governance Officer (RGO):

Name of Research Cost Centre	

Name of RGO (or delegate)			
Signature of RGO (or delegate)		Date	

3. Finance Authorisation:

Name of Director of Finance (or delegate)			
Signature of Director of Finance (or delegate)		Date	