Guide to a Successful Research Ethics Application

SCHN Research Ethics

May 2019
Important

BOTH Research Ethics AND Research Governance approvals are required BEFORE you can start your research.

For further information about obtaining Research Governance Authorisation, contact the Research Governance Office at the relevant sites (link to the SCHN Research Governance website).
BEFORE you start: determine the level of risk involved

Negligible risk

- foreseeable risk is no more than inconvenience (e.g. medical records reviews or short non-personal surveys).

Low risk

- foreseeable risk is one of discomfort (e.g. anxiety as result of a simple interview/survey or non-invasive medical assessments)

Greater than Low Risk

- Risk is more serious than discomfort
- The types of projects outlined in the National Statement, clause 5.1.6

Researchers are strongly encouraged to consult the Research Ethics Office in determining the level of risk involved in their research projects.
Submission Guidelines

• Once you know the level of risk, use the relevant submission guidelines on the SCHN Research Ethics website: https://www.schn.health.nsw.gov.au/research/ethics-governance/ethics

• The guidelines provide detailed instructions and guidance regarding the following:

  REGIS

  All applications to the SCHN HREC must be submitted via REGIS.

  The submission guidelines provide information on how to navigate REGIS, common system issues and how to overcome those issues

  Mandatory supporting documents

  The submission guidelines also provide details on what mandatory supporting documents must be attached to your application including submission checklist, protocol, information sheets and consent forms etc.
Submission Guidelines

• Please **READ** the submission guidelines carefully before preparing and submitting your application. Incomplete applications are not accepted.

• If your project involves biobanks, registries, opt out consent or a program of research, please contact the Research Ethics Office to book an appointment for further consultation and guidance.
Writing your research ethics application

The submission guidelines provide instructions regarding the administrative process for preparing and submitting research ethics applications.

The upcoming slides will provide guidance on how to write a successful research ethics application.
The National Statement on Ethical Conduct in Human Research

To approve a study, HRECs need to be satisfied that it meets requirements of the National Statement on Ethical Conduct in Human Research 2007 (updated 2018)

This is what reviewers will use to assess your application

If you read nothing else, read Chapter 3.1

Link to the National Statement
The National Statement: Chapter 3.1

• Practical criteria for the ethical acceptability of research projects.

• 7 elements of human research projects:
  
  **Element 1:** Research Scope, Aims, Themes, Questions and Methods
  
  **Element 2:** Recruitment
  
  **Element 3:** Consent
  
  **Element 4:** Collection, Use and Management of Data and Information
  
  **Element 5:** Communication of Research Findings or Results to Participants
  
  **Element 6:** Dissemination of Research Outputs and Outcomes
  
  **Element 7:** After the Project
What causes delay?

**Poor study design** – when the study is not appropriately designed to answer the research question, and the study procedures are not adequately developed to meet the ethical and regulatory requirements.

You must ensure that your study is well-designed AND feasible!

Use the SPIRIT template for protocols

*NOTE: not all sections apply to all projects*
What causes delay?

Lack of sufficient information and details in the application – HREC members are not mind-readers!

They need all the required information and details about your research project so that they can make an informed assessment.

Note: In addition to scientific review applications are read by lay people – educated but not expert
What causes delay?

Lack of consistency and accuracy within study documentation

Proof-read all your documents to ensure consistency, accuracy and no typographical and grammatical errors.

Poorly prepared applications take a very long time to achieve approval!
More tools to help you?

Utilise the current resources & templates available on the Research Ethics website

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**Ethics**
- Low | Negligible Risk
- Greater than Low Risk
- Amendments and study reports
- Authorised prescribers
- Resources | Templates

### Resources | Templates

- The National Statement on Ethical Conduct in Human Research 2007 (updated in 2018)
- Consent & Recruitment
- Waiver of Consent
- Opt-Out Consent
- Invoicing Authorisation Form
- Forms, Templates & Resources Specific to Greater than Low Risk Applications

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This webpage is continuously updated with new resources and templates!
Talk to us if you need more help or if you’re unsure

Research Ethics Contact Details
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