

# Ethics and Governance | a beginner's guide

## 1 Ethics and governance

Research applications have two parts:

1. **Ethics** ensures the research is well-designed and considered, with methodology that can meet the research aims and objectives, respect for all participants and that the benefits of the research outweigh any risks to participants.
2. **Governance** is concerned quality, safety, privacy, risk management, financial management and ethical acceptability of research at SALHN.

You only need governance if your research project involves SALHN staff, patients or facilities.

The SALHN Office for Research encourage the Site Specific Assessment (SSA) or the Low and Negligible Risk application form be submitted with the ethics application

## 3. Errr...what is the National Statement?

The National Statement is the foundation document for all research in Australia.

To approve a study, HRECs need to be satisfied that it meets the requirements of The National Statement on Ethical Conduct in Human Research.

**Section 3** has guidance, key questions and information that will help with your study design.

**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

**Element 6:** Dissemination of Research Outputs and Outcomes.

**Element 7:** After the project

The Office for Research has National Statement Training Guide on our [Training resources webpage](#). Go check it out!

## 6. Contact details for SALHN Office for Research

If you need assistance, please contact us.

We can arrange a meeting or discuss your project over the phone.

We are here to help you.

T: 8204 6453

E: Health: SALHNOfficeforresearch@sa.gov.au

## 2. Application type...

Before you start writing your ethics application, you need to know what level of risk your research is.....

Reviewed via the Expedited Review Panel

- Negligible risk - the foreseeable risk is no more than inconvenience e.g. brief non personal survey or audit
- Low risk - the only foreseeable risk is one of discomfort e.g. non-invasive assessments, interviews that do not discuss sensitive issues

Reviewed at Full Committee

- Greater than low risk - the foreseeable risk is more than inconvenience or discomfort or includes a vulnerable population.

The National Statement section 2 provides guidance on risk. Section 4 provides guidance on ethical considerations specific to participants

## 4. What causes application delays?

**Incomplete applications:** documents missing and sections not filled out in forms and templates

**Poor quality**

- The study design must answer the research question
- The study procedures must meet the National Statement and regulatory requirements
- Not enough information – the HREC need to know exactly what you are doing and how, so they can make an informed decision about your application. Ask yourself: *Could my Mum read my application and understand what I am planning to do?*
- Grammar and spelling mistakes throughout the documents, making it difficult to read
- The governance application is not signed by the relevant data custodian or heads of departments.

## 5. Resources

- Good Clinical Practice Certificate (GCP)
- Research Ethics and Governance Essential Guides
- National Statement training guide
- NHRMC Clinical Trials Toolkit
- Global Health Training Centre
- [Office for Research website](#)
- Research GEMS – information and user guides
- [Research Governance at SALHN](#)