

RESEARCH PROTOCOL TEMPLATE

Information for researchers

The primary role of the HREC is to protect the welfare and the rights of participants in research. It is a requirement that the HREC ensure that all research submitted to the Committee be considered both scientifically and ethical sound, and that all applications (including investigator-initiated applications) should have sufficient documentation to enable reviewers to make their assessment.

The Research Protocol

A research protocol outlines the plan for how a study is run.

The study plan is developed to answer research questions. It provides evidence for feasibility of a study, detailed objectives, design, methodology, statistical considerations and how the study will be conducted and evaluated. A well-written and complete protocol is essential for a high quality study, ensures clarity as to what has been ethically approved and will make publishing the results easier.

The research protocol need not be lengthy, but should include the following minimum information:

- Background information
- Aim(s) and hypothesis
- Study objective
- Study plan and procedures
- Statistical analysis

This process is not intended to increase the work of investigators. Although the ethics application form provides space for a description of a study, this may be insufficient to enable adequate scientific and ethical review. A research protocol will enable the HREC to have a better understanding of the research proposed and thus minimise questions that might arise and facilitate the review and approval process. Through the scientific and ethical review process the research protocol may need to be modified so that the final version clearly documents what has received ethical approval.

This is by no means a definitive layout for a protocol, but is intended to provide guidance of what is expected. Not all of the sections will be relevant to every study and will depend on the design and complexity of the study. Therefore you must adapt the template to customise it to your study.

Always number the pages of your protocol and indicate the version date in the header or footer.

1. PROJECT TITLE

Title of the study (including acronym and lay title)

2. INVESTIGATORS

Include the names of the principal and associate investigators, their respective roles and responsibilities and their association with ISLHD (i.e. employee, clinical academic, honorary associate, student).

Also indicate the ISLHD clinician(s) responsible for the supervision of the involvement of study participants whether patients or healthy volunteers.

3. RATIONALE / BACKGROUND

This should provide an introduction to the study, what is already known, what is missing, what the study is going to find out, how this is going to be achieved and what impact the study will have.

4. AIMS / OBJECTIVES / HYPOTHESES

Provide a clear and concise statement of primary and secondary objectives and a clearly defined hypothesis (where relevant).

5. PARTICIPATING SITES

List the sites and departments that will be involved

6. STUDY DESIGN

- *Describe the type of study, the source of participants, datasets or collections to be accessed.*
- *Describe the sample size, sample size calculation or justification of numbers, outcome measures used.*
- *Provide details of the linkage and analysis variables used and why they are required and what study comparisons are being made.*
- *Provide an analysis plan of how the aims will be met, the statistical methods to be used and who will be carrying out the analysis.*

Suggested sub-headings:

- *Type of study*
- *Data sources/Collection*
- *Population/Sample size*
- *Expected duration of study and start times*
- *Statistical analyses*

6. STUDY OUTLINE

Clearly outline what will be involved for participants in all aspects of the study. A flow-chart may be helpful in demonstrating this.

7. ETHICAL CONSIDERATIONS

- *Provide information on where, when, how participants will be recruited, what the inclusion /exclusion criteria are. Identify and justify any dual relationships, coercion or inducement.*

- *Describe how voluntary informed consent will be sought or if a waiver of consent is being sought. Identify and justify any waiver of consent.*
- *Describe how confidentiality, anonymity and the identity of participants will be maintained, who is undertaking the data linkage, whether identifying information will be provided to researchers and a rationale for this.*
- *What security steps are in place for the transfer of data, where and how the data will be stored.*
- *Identify and justify any non-negligible risk or burden.*

Suggested sub-headings:

- Recruitment and selection of participants
- Informed consent
- Enrolment procedure
- Confidentiality and Privacy
- Safety
- Data storage and Record retention

8 . REFERENCES

9. APPENDICES

- All protocol-specific appendices
- Patient Information and consent forms
- Questionnaires
- Data collection sheets
- Case Report Forms
- Advertisements