**Research Protocol Template (Low Risk Research Project and Clinical Audits)**

A well written and complete protocol is essential for a high quality research project. A study protocol generally follows a conventional layout. There are several templates already available although most are developed for commercially-sponsored randomised controlled studies. This research protocol template aims to offer Northern Health surgical medical, nursing, midwifery and allied health researchers a more generic guide suitable for a broader range of scientific research enquiries.

The preparation of a protocol is an important first step in the research process for the following reasons:

1. It states the research question you aim to answer;
2. It encourages adequate consideration and planning of project detail *before* you begin;
3. It allows co-investigators or peers a living and dynamic document for contribution and early review prior to its completion;
4. It acts as a record and reminder for you and your supervisor (co-investigator or co-worker) of the initial project aims and stated procedures. This record also enables you to monitor the progress of your project; and
5. It provides the basis for funding or human research ethics applications.

When drafting your protocol:

* Discuss project design and scope with supervisors/peers.
* Discuss appropriate statistical analysis methods with a statistician.
* Delete sections that are not applicable.
* Add version number and document date in the footer.

**STUDY TITLE**

**STUDY INVESTIGATOR(S)**

## Principal Investigator

|  |  |
| --- | --- |
| Title and Name |  |
| Appointment/s |  |
| Department / Affiliation with Northern Health |  |
| Qualifications |  |
| Phone |  | Fax: |
| Mobile/ Pager |  | Email: |
| Is this person the contact person for the project? |  Yes / No (please circle / highlight) |

**Associate Investigator**

|  |  |
| --- | --- |
| Title and Name |  |
| Appointment/s |  |
| Department / Affiliation with Northern Health |  |
| Qualifications |  |
| Phone |  | Fax: |
| Mobile/ Pager |  | Email: |
| Is this person the contact person for the project? |  Yes / No (please circle / highlight) |

*Note: Copy and paste the above table if there are more investigators on this study.*

1. **INTRODUCTION**

The introduction is a very brief overview of study.

1. **BACKGROUND**
2. **AIM(S) AND OBJECTIVES OF STUDY**

Your aim(s) should arise from your literature review and state what the study hopes to accomplish.

1. **RESEARCH PLAN/METHODOLOGY**

**4.1 Participants**

Selection criteria (Source of patients/data, identification, inclusion and exclusion criteria, start and end dates of entry)

Participant/data (de-)identification procedures

Suggested wording: Identifiable patient data will be replaced with a code/unique number. The master list of names and matching codes will be stored electronically and password protected by the PI / or kept in locked facilities of the Northern Health (in the Department of ………).

**4.2 Measures**

Describe primary and secondary endpoints (if applicable). Identify all data that will be collected for use in evaluating project outcomes.

**4.3 Procedures**

Consent process(es) (if applicable)

Include a detailed description of proposed recruitment method, including how approach will be made and by who. Include all documents to be used in the recruitment process as separate documents e.g. letters, brochures, PICFs

Privacy issues (if applicable)

Consider issues such as collecting data from another centre, data being analysed by an external statistician or involve an external researcher.

Details of data collection, processing and analysis

Record keeping procedures, including storage of data access and destruction

Please state: what data is being stored e.g. consent forms, demographic data; where it is being stored; how it is secured e.g. password protected; who is responsible for security; how long is the information being kept; who is responsible for destruction of the information.

Examples of wording:

• The patient data will be kept strictly confidential according to the National Statement on Ethical Conduct in Human Research 2007 and the Australian Code for Responsible Conduct of Research 2007.

• Patient research data will be accessed only by the named investigators.

• Electronic records of research data will be retained on password protected computer(s) in databases requiring password access. This data will be stored separately from the master list of patient names.

• Any hard copies of data will be kept in locked facilities of the Northern Health (in the Department of ………).

• Any laptop computer will be password-protected and electronic records stored on it will be coded and in databases requiring password access. Only study investigators will have access to the data.

• Patient data will be only be transferred and analysed in a coded form

• Individual patients will not be identifiable from the presented or published material.

1. **STATISTICAL CONSIDERATIONS**

(Include detailed description of statistical analyses to be used)

1. **ETHICAL CONSIDERATIONS**

 The study will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research (2007 and updates).

Proposed publication or presentation of results

1. **REFERENCES**
2. **APPENDICES**

Include a list of appendices. Provide the appendices as separate documents and any documents to be provided to participants should be presented in the form that they will be provided to the participant.