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 Barwon Health surgical, medical, nursing, midwifery and allied health researchers a more generic guide suitable for quality assurance and evaluation activities.

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.

|  |
| --- |
| **[Insert study Title]** |
| **Barwon Health Reference [00/00]**  **Date: [DD/MM/YYYY]** |

**STUDY INVESTIGATOR(S)**

## Principal Investigator

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Title and Name** | |  | | | |
| **Appointment/s** | |  | | | |
| **Department / Affiliation with Barwon Health** | |  | | | |
| **Qualifications** | |  | | | |
| **Phone** |  | | **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 Barwon Health** | |  | | | | |
| **Qualifications** | |  | | | | |
| **Phone** |  | | **Email:** | |  |
| **Is this person the contact person for the project?** | | | | Yes / No (please circle / highlight) | | |
| **Is this person a student investigator?** | | | | Yes / No (please circle / highlight) | | |
| If this person is a student, provide details of study and if access to BH premises and/or data are within their scope. Note that student investigators cannot be Principal Investigators. | | | | | | |

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

1. **INTRODUCTION**

The introduction is a brief overview of study. Include references to the literature that supports the need to undertake this QA project. You should also address the following questions:

* What activity has been undertaken in this subject area before?
* What are the limitations of this previous activity?

Why is this project important and what will it add to the literature or how will it improve patient care?

1. **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**

State the design of the research (e.g. retrospective cohort/case-control, survey, case study).

* 1. **Procedures**

This section should answer the following questions:

* How will the specific project be carried out?
* If there are participants, what will they have to do during the study, when and how often?
* What will the project lead do, where and when?
  1. **Measures**

Describe primary and secondary endpoints or outcome measures that will be used.

* 1. **Participants**

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

Provide details on participant/data (de-)identification procedures.

Provide details on the participant consent process and 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. If you are consenting participants, consider whether this remains a QA or minimal risk project, or if an application to HREC is required. Use the ethical risk checklist on the RDU website to check.

Provide information on potential privacy issues such as collecting data from another centre, data being analysed by an external statistician or involve an external researcher.

*Note: QA and minimal risk projects cannot apply for a waiver of consent. As per Section 2.3 of the National Statement (2023), applications for a waiver of consent must be reviewed by an HREC. Please use the Waiver of Consent Checklist on the RDU website to assess if you require a waiver.*

1. **DATA COLLECTION**

Provide details of what data will be collected, how it is being collected and who will be collecting it.

1. **DATA MANAGEMENT**

Provide details of where data is being stored; how it is secured (e.g. password protected); who is responsible for security; how long is the information being kept; and who is responsible for destruction of the information.

Examples of wording in this section may include:

• The patient data will be kept strictly confidential according to the National Statement on Ethical Conduct in Human Research 2023 and the Australian Code for Responsible Conduct of Research 2023.

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

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

• Only study investigators will have access to the data.

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

1. **DATA ANALYSIS**

Include detailed description of statistical analyses to be used.

1. **ETHICAL CONSIDERATIONS**

You should describe the major ethical considerations as a result of carrying out this QA or minimal risk activity.

If the activity involves more than assessing or comparing current, existing practices it may be categorised as research and, if so, would require ethics review and approval. Sere the RDU website for further information regarding risk classification.

Other ethical considerations include:

* Does the proposed activity pose any risk, burden or inconvenience for patients beyond that experienced or imposed as part of their routine clinical care?
* Does the proposed activity pose any risk to maintaining patient confidentiality and privacy?

Is the proposed activity to be conducted by a person who does not normally have access to the patient records for clinical care or a directly related secondary purpose?

1. **DISSEMINATION OF RESULTS**

Describe how you are intending to inform others of the results e.g. publishing, conference presentations.

1. **REFERENCES**

Note any literature or web references that may have been cited.