A research protocol is a complete written description of, and scientific rationale for, a research activity. In keeping with best practice, all research activity undertaken at Barwon Health should be documented in an up-to date study protocol. All Barwon Health projects must have a Barwon Health affiliated Principal Investigator (PI). The PI is responsible and accountable for designing, conducting, and monitoring the research protocol.

All research activities conducted at Barwon Health that involve human participants, their tissue or data, require ethics oversight.

The full protocol and associated documents must be submitted to the Research Development Unit (RDU) for ratification or approval by Barwon Health’s Human Research Ethics Committee (HREC).

The protocol should provide sufficient detail to enable:

Understanding of the background, rationale, objectives, study population, interventions, methods, statistical analyses;

Ethical considerations, dissemination plans, and administration of the project;

Replication of key aspects of project methods and conduct; and

Appraisal of the project’s scientific and ethical rigor from ethics approval to dissemination of results.

Protocol amendments should be reported to the RDU by submitting an HREC amendment form as they occur. Information on the application process, amendments and reports can be found on the [RDU website](https://www.barwonhealth.org.au/research/for-researchers/rdu).

# PROTOCOL

|  |
| --- |
| [Insert study Title] |
| Barwon Health Reference [00/00]Version [0]Date: [DD/MM/YYYY] |
|  |
|

|  |  |
| --- | --- |
| Principal Investigator\* | [Investigator name] |
| Associate Investigator | [Investigator name] |
| Associate Investigator | [Investigator name] |

**\*must be Barwon Health affiliated unless an HDR project** |
| **CONFIDENTIAL**This document is confidential and the property of <<Insert Name of Institution>>. No part of it may be transmitted, reproduced, published, or used without prior written authorization from the institution.**STATEMENT OF COMPLIANCE**This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007, Updated 2018) and the ICH Guidelines for Good Clinical Practice (ICH-GCP) |

SUMMARY

|  |  |
| --- | --- |
| **Principal Investigator** |  |
| **Funding** |  |
| **Sponsor** ***institution with overall responsibility*** |  |
| **Study site(s)** |  |
| **Study summary**  | Provide details covering the aims, objectives, outcomes, study design, sample size, intervention & duration. |
| **PROTOCOL AMENDMENTS** |
| **Protocol version number** | **Protocol date** | **Summary of amendment** |
|  |  |  |

# **1.0 Introduction and Background Information**

This section should explain the research question being addressed and should convince the reader of the need for the research. The following points may be used as a guide:

* Provide a short but comprehensive literature search (including references).
* Indicate how the research question has emerged and fits logically with the evidence detailed above.
* Explain how your study will contribute to existing research and how it will fill any gaps in the field.
* Discuss the importance of the topic to justify the research (e.g., public health, clinical importance, community, incidence, prevalence, mortality and morbidity)

# **2.0 Study Objectives**

**Aim/s, hypothesis and /or research question**

State the hypothesis to be tested if your study is a hypothesis testing method. If it is not hypothesis testing state the key research aim/s or question/s to be addressed.

**Study aims/objectives**

List the broad study aims.

Your focused research question needs to be further refined into one or more study objectives. The study objective(s) should be single and quantifiable statement(s) that will allow you to answer your research question. Provide a list of objectives (i.e. statements that indicate how the aims will be addressed and how the research question will be answered).

**Outcomes and significance**

This section provides the justification for the study in terms of the anticipated results. Some questions to consider include:

* Provide a short but comprehensive literature search (including references).
* Indicate how the research question has emerged and fits logically with the evidence detailed above.
* Explain how your study will contribute to existing research and how it will fill any gaps in the field.
* Discuss the importance of the topic to justify the research (e.g., public health, clinical importance, community, incidence, prevalence, mortality and morbidity)

# **3.0 Study Design and Methods**

Provide an overview of the study design and summarise how and where the study will be conducted. Provide a rationale for the choices of method/s. Provide an indication of timeframe and workflow.

**Recruitment procedure**

Describe the group of people who will be invited to take part in the research. Explain how potential participants will be identified and recruited (e.g., clinics, referring doctors, advertisements etc.) and retrospective data (e.g., medical records, registries, databases).

Include information on exactly who will recruit participants or collect data (e.g. PI, Research Nurse, External university student).

Describe how controls will be identified and recruited if relevant (e.g., advertisements, letters from GPs, family members) and describe how they will be matched if the study is a matched control study. Provide a description and justification of the sampling population.

**Inclusion criteria**

Clearly describe the criteria or characteristics that are required to include a person in the study. The criteria may be based on factors such as age, gender, type and stage of disease, previous treatment history etc.

**Exclusion criteria**

Provide details of characteristics or criteria that would make a potential participant ineligible to participate and justify why they have been excluded.

* Note: In most cases inability to read/speak/ understand English is not a valid exclusion criteria. Researchers are strongly encouraged to include language other than English (LOTE) participants and to seek the services of translators.

**Consent**

Describe the method of obtaining consent e.g., individual consent, waiver of consent, no consent required). Detail the approach to provision of information to participants and/or consent (as required in addition to that outlined in the HREA). Provide details of the degree of participant commitment, project duration and any requirements for participant follow-up.

# **4.0 Data Collection**

Provide information on:

* Type of data you going to collect/gather (as required in addition to that outlined in the HREA).
* Data collection/gathering techniques to be used.
* Impact of and response to participant withdrawal.

# **5.0 Data Management**

Provide details on:

* Where records will be kept and how long will they be stored for.
* The personnel who will have access to the data and how that access will be granted (password, key, code etc.).
* Disclosure of information.
* The use/re-use and transfer of data (if applicable).

Note: All records for non-drug trials should be kept for a minimum of 7 years post study closure, if your study contains a Clinical Trial Notification (CTN) drug/device, then records must be kept for a minimum of 15 years.

# **6.0 Data Analysis**

**Analysis of quantitative data**

Describe the statistical methods that will be undertaken for this study. It is recommended this section is written in collaboration with a statistician. Statistical analyses should directly relate to the aims/hypotheses outlined above. Include details about:

* Power calculations.
* The estimated sample size and justify how this will ensure that your study numbers will reach statistical significance.
* The statistical analyses that will be employed for each analysis undertaken.
* Outcome measures.

**Analysis of qualitative data**

Describe how qualitative data (interviews, focus groups, free text surveys, audio recordings, photographs etc.) will be analysed. Include justification of and theoretical framework and provide details of proposed use of any software to be used for analyses. The theoretical/philosophical framework should be with the method section and the data analysis should be consistent with the method

# **7.0 Results, Outcomes and Future Plans**

Describe plans for:

* Results of the research will be shared with participants
* Plans for dissemination of results (e.g. publishing, conference presentations, websites, newsletters etc.).
* Other potential uses for the data at the end of the project.
* Project closure processes
* Plans for sharing and/or future use of data and/or follow-up research

# **8.0 Budget and Funding**

Provide information on budget, financing, indemnity and insurance if not addressed in a separate document.

**References**

Researchers must include up-to-date references to evidence the study background and rationale for their study.