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 (2023)](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) 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** |
|  |  |  |

#

# **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**

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

Your focused research question(s) may need to be further refined as 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(s).

**Outcomes and significance**

The primary outcome should be the most important and clinically relevant outcome (e.g. clinical, psychological, economic, or other) of the study. This is the measure used to answer your study aim. However, it is also the outcome used to calculate study sample size and power and test the primary research hypothesis. Generally, no more than 1-2 primary outcome measures are pre-specified.

Secondary outcome(s) are measures of additional or less important research interest. They may include additional clinical, psychological, economic, or safety outcomes (e.g. treatment related side effects/adverse events). However, as these endpoints are not used to calculate study power and sample size it is often not possible to draw robust conclusions from the results.

For qualitative research, you should describe the form that you expect your findings to take (presentation of themes, critical episode presentation, life history) and the way in which you will present these (report, papers for publication, conference presentation, feedback to participants etc.).

# **3.0 Study Design and Methods**

State the design of the research (e.g. randomised controlled study, cross-sectional survey, prospective or retrospective cohort/case-control, observational, focus groups/interviews, action research).

Whatever the study design, you need to ensure that you provide the reader with a clear statement and description of your proposed design. You should also explain why the particular study design has been chosen in preference to other possible designs (i.e. justification for choice of study design).

**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 how retrospective data (e.g., medical records, registries, databases) will be accessed.

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 (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. Dot points are often best to represent this.

**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 culturally and linguistically diverse (CALD) participants and to seek the services of translators. If this is not within the scope of the project, provide justification for why CALD participants are excluded.

**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.

*Note*: if applying for a waiver of consent, please refer to section 2.3.10 of the National Statement (2023) and address each criteria. Please also use the Waiver of Consent Checklist and Waiver of Consent Application available on the RDU website and submit these with the application.

# **4.0 Study setting and location**

The location of where the study will be conducted (e.g., Baxter 7, University Hospital Geelong). You need to mention whether the study is going to be a single-centre study or a multi-centre study (i.e. conducted in more than one location).

Include all organisations involved in the study (e.g. where the participants will be recruited, where any datasets are being received from, where the data will be stored, who is initiating the research etc.).

# **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.
* Tools that will be used to collect the data (e.g., REDCap, Qualtrics).

# **5.0 Data Management**

Provide details on:

* Where records will be kept and how long will they be stored.
* 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. References to the literature are required to justify the chosen qualitative methodology and analysis framework.

# **7.0 Ethical considerations**

Refer to Chapter 2.1 of the [National Statement (2023)](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) when writing this section. Identify the likely risks as a result of the research and provide an overview of how these risks will be managed (e.g., distress during an interview, having to disclose sensitive or personal information, the potential for coercion during the recruiting and consent process). Management techniques may include a distress protocol, referring participants to support services, and secure storage of data.

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

Describe plans for:

* How the 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

# **9.0 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.