

Protocol for

Research at

Bendigo Health

Please erase the above title, and write your project title on this title page; choose a font size that allows for the title to fit.



This guide has been developed collaboratively by the Research and Innovation Department and the Research Governance Office in consultation with members of the Human Research Ethics Committee (HREC) to support Bendigo Health staff in planning their research study and submitting their application to the HREC.

If you need assistance to complete the protocol please contact:

Research and Innovation on 5454 6397 or email randd@bendigohealth.org.au or

Research Governance Office on 5454 6412 or email researchoffice@bendigohealth.org.au.

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Glossary of Abbreviations and Acronyms

|  |  |
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| CPI/PI/AI | Coordinating Principal Investigator/Principal Investigator/Associate Investigator |
| DSMC | Data Safety Monitoring Committee |
| HREA | Human Research Ethics Application |
| HREC | Human Research Ethics Committee |
| LNR VIC | Low/Negligible Risk Form for Victoria |

[Please delete the Template Glossary and its heading above, and provide your own abbreviations and glossary under Section 1.1]

Instructions for Completing this Template [please delete when done]

The purpose of a Project Description or Protocol is to provide the scientific and academic background and context of a research project. Providing this is a *mandatory component* of a submission using the Human Research Ethics Application (HREA) and is *encouraged* for any Low/Negligible Risk (LNR) VIC applications submitted to Bendigo Health. Information from the protocol can be directly transferred (copied and pasted) across to the HREA/LNR VIC form on ERM, as relevant to any particular section.

This protocol template is a guide only. As research is a very broad area the template can be adapted to suit your particular research project. You can therefore modify the document so that it is relevant to your project or submit an existing document if the content addresses the requirements. Submission of clinical trials proposals may use alternate protocol templates, such as the [SPIRIT statement](http://www.spirit-statement.org/).

**Requirement:** The document Table of Contents (ToC) will be required to be updated after the document is completed. To update the Table of Contents page numbers, select Ctrl+A to select the whole document, and then use F9 on the keyboard to update the page numbers in the ToC. Alternatively, right click on the mouse when the ToC is highlighted and select “Update Field” followed by “Update entire table”.

**IMPORTANT:**

* Text should be at least font size 12 in an easily readable font style.
* If any of the headings suggested in this template are not applicable, please delete with tracked changes and a comment N/A, and replace with a more appropriate heading. Save the document with tracked changes.
* If more space for graphics etc. is required, attach any supporting pages as appendices clearly named to correspond with the question answered.
* Please **delete the Instructions section**, including the above table of Abbreviations and Acronyms and instructions given under each section heading as you go, and **start with section 1. Research Description.**

1. Research Description

* 1. Abbreviations, Definitions and Acronyms

List any abbreviations definitions or acronyms specific to the research.

Click here to enter text.

* 1. Full Research Title

Ensure the title reflects what you are planning to do, and matches the one on title Page.

Click here to enter text.

* 1. Short Research Title

Acronyms are acceptable if explained in the Full Research Title.

Click here to enter text.

* 1. Investigators

Names, affiliations, position and responsibilities on this project, including contact details of investigators and other key project team members, including the management committee/steering group/DSMC as applicable. [Delete/add rows as needed.]

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* 1. Resources

List the resources necessary for the project to be conducted and the funding/support being sought or secured. Consider any capital (equipment etc.), personnel and operating (travel, accommodation, disposables etc.) requirements.

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| ***Resources*** | ***Required*** | ***Secured*** |
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* 1. Summary

Include the following:

* A brief literature review (around 500 words). A longer review can be attached as an appendix
* Rationale/Justification (i.e., how the research will fill any gaps identified in your literature review, contribute to the field of research or contribute to existing or improved practice)
* Research aims, and, if applicable, research hypothesis or question (i.e., a short statement, question or hypothesis that identifies the key objectives you hope to achieve)
* Research objectives (the statements that help focus your research by describing what the research is to accomplish in order to reach the aims of the project). Good research objectives are specific, measurable, achievable and goal/aim-relevant; often you can also make them time-framed and in that way trackable in terms of outcomes of the project.
* Project management-type objectives are optional. They describe the components or steps in the research project management, that will enable you to realise your project and meet your research aims or answer your research question in a timely manner.
* Expected outputs (arising from your research, e.g., reports, recommendations or scientific publications.) Sometimes, an ‘output’ is only fully completed when a report is accepted or ‘recommendations’ are approved by a senior authority.
* Expected outcomes (the benefits of your research to participants, patients, staff, health care/service delivery and/or the wider (scientific) community in the future?)

[Please delete the instructions once you have completed this section.]

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1. Project Design
	1. Research Project Setting (physical sites, online forums and alternatives)

List the site/s where you are planning to conduct your research.

Click here to enter text.

* 1. Method

Describe your research method and the rationale for choosing this method/s. Tie this to the project aims and objectives.

Click here to enter text.

* 1. Participants

Include information about participants such as:

* Description of the population from which the participants will be drawn
* Inclusion and exclusion criteria
* Sample size and justification for this size, e.g., based on statistical power estimation, data availability, prior research, time or other constraints.

Click here to enter text.

* 1. Participant Recruitment

Describe participant recruitment strategies and timeframes. Address any relevant sampling or randomization strategies, accounting for potential bias, confounding factors, and missing information.

Click here to enter text.

* 1. Participant Consent

Describe approach/es to provision of information to participants and/or consent.

* If necessary, describe the type of consent provided to different participant groups; when and where, and any arrangements required to confirm that consent.
* If necessary, provide details of who will be confirming or re-negotiating consent with participants and explain the process/es that will be undertaken.
* Indicate arrangements for withdrawal of consent.

If you are applying to waive the requirement for consent, provide a detailed justification informed by the Subsection 2.3.10 in the National Statement ([National Statement on Ethical Conduct in Human Research, NHMRC, 2007; Updated 2018](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__235)).

Click here to enter text.

* 1. Research Activities

Describe what you are going to do and what will be required of participants (including, e.g., patients and staff plus the research team on site); Project duration; Participant follow-up.

Click here to enter text.

1. Risk and Benefit
	1. Risk

Identify any potential harm, discomfort or inconvenience associated with participation. Include some idea of likelihood of occurrence, severity and any processes in place to minimise risk.

Click here to enter text.

* 1. Benefit

Identify potential benefits to participants and the wider community. There may be no direct benefit to participants other than satisfaction in contributing to research that may benefit the community as a whole in the future (including themselves).

Click here to enter text.

1. Project Data
	1. Data Collection/Gathering

What information is going to be collected/gathered. When and how will it be collected? Make sure this aligns with BH policy on Privacy and Confidentiality (available via Prompt on Intranet), and with the National Statement ([National Statement on Ethical Conduct in Human Research (NHMRC, 2007; Updated 2018](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)).

Click here to enter text.

* 1. Data for participants who withdraw consent

Describe the impact of and response to participant withdrawal. Will data already collected prior to withdrawal be retained or not?

Click here to enter text.

* 1. Data Management

How will you store, provide access to, disclose, use/re-use, transfer, destroy or archive the information that you collect/gather in order to meet data security, privacy, anonymity and confidentiality requirements? Specify data identifiability in your study and explain/justify the approach taken (Please refer to the National Statement on Ethical Conduct in Human Research (NHMRC, 2007; Updated 2018, p.23 and 35-36/[online section 3.1.44](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018%22%20%5Cl%20%22toc__155%3A~%3Atext%3Dlinkage%2520is%2520completed.-%2CData%2520management%2C-3.1.44%2520When%2520multiple)).

Click here to enter text.

* 1. Data Analysis

Describe how collected data will be measured, manipulated and/or analysed. Relate these methods of analysis clearly to achieving the aims/objectives. If not explained in detail in section 2.4 “Participant Recruitment”, address any matching and sampling strategies, accounting for potential bias, confounding factors, missing information and statistical power calculation.

Click here to enter text.

* 1. Data Linkage

What linkages are planned or anticipated? ([Please refer to the National Statement on Ethical Conduct in Human Research (NHMRC, 2007; Updated 2018, sections 3.1.43 and 3.3](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__155:~:text=Print%2520this%2520page-,Table%2520of%2520contents,-Preamble)).

Click here to enter text.

1. Outcomes of the Research Project
	1. Expected outcomes of your project

Describe what outcomes you expect from your research project and how these are linked to your aims and objectives. Consider the possible benefits of your research to participants, patients, staff, health care/service delivery and/or the wider (scientific) community in the immediate and long-term perspective.

Outcome measures may include the quality and cost targets healthcare organizations are trying to improve or, e.g., reduction in readmission and mortality rate, improvement in patient experience or quality of life. The World Health Organization defines an outcome measure as a “change in the health of an individual, group of people, or population that is attributable to an intervention or series of interventions.”

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1. Clinical Trials and Investigational Drugs or Devices [Delete this section (section 6), if your project is not this type of a trial]

For research involving an investigational drug or device as part of a clinical trial, explain what is/are the drug(s) and/or device(s)?

* 1. Approved name

Click here to enter text.

* 1. Trade name (if any)

Click here to enter text.

* 1. Manufacturer

Click here to enter text.

* 1. Supplier of drug/device (e.g. manufacturer/pharmacy)

Click here to enter text.

* 1. Approved therapeutic indication, dosage/duration in Australia

Click here to enter text.

* 1. Believed mode of action

Click here to enter text.

* 1. Dosage regimen

Click here to enter text.

* 1. Mode of excretion

Click here to enter text.

* 1. Known adverse events

Click here to enter text.

* 1. Known contra-indications or warnings

Click here to enter text.

* 1. Dispensing arrangements

If arrangements have been made for the Bendigo Health Pharmacy Department to receive or dispense the drugs involved in this project, explain how the drugs will be received and dispensed for the purposes of the research project.

Click here to enter text.

1. Results, Outputs and Future Plans
	1. Plans for return of results of research to participants

Describe the intended plans for disseminating the findings to participants. Describe how these plans will contribute to knowledge or practice or serve the public and provide the participants with a timely and appropriate summary of the outcomes. (Please refer to the National Statement on Ethical Conduct in Human Research (NHMRC, 2007; Updated 2018, [Element 6: Dissemination of project outputs and outcomes](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__155:~:text=Element%25206%253A%2520Dissemination%2520of%2520project%2520outputs%2520and%2520outcomes)).

Click here to enter text.

* 1. Plans for dissemination and publication of project outcomes

Declare the intended plans for disseminating the findings to a wider audience and the HREC.

Click here to enter text.

* 1. Other potential uses of the data at the end of the project

Describe in full any other potential uses of the collected data.

Click here to enter text.

* 1. Project closure processes

Describe how you will close the project, including the storage and subsequent destruction of data.

Click here to enter text.

* 1. Plans for sharing and/or future use of data and/or follow-up research

Describe in full any plans for sharing data, any possible future use of data and/or follow up data, including any secondary use of data.

Click here to enter text.

1. Research Timelines

Specify time frames for completing key components (milestones) of the research project. Adding a flowchart (such as a Gantt Chart) is useful. Include the anticipated start date and end date.

Click here to enter text.

1. References

Add your literature references.

Click here to enter text.

1. Appendix

List and attach all associated study documents, including any supporting pages for questions above.

Click here to enter text.