Protocol for Research at Bendigo Health

This guide has been developed collaboratively by the Research and Innovation department and the Research Governance Office to support Bendigo Health staff in planning their research study and submitting their application to the Human Research Ethics Committee.
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

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

Instructions for Completing this Template

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. There is no need to duplicate information in the HREA/LNR VIC or vice versa.

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.

Requirement: The document Table of Content will be required to be updated after the document is completed. To update the Table of Content page numbers select "Ctrl+A to select the whole document, and then the user hits F9 to update the page numbers in the ToC".

IMPORTANT:

- Text should be at least font size 12 in an easily readable font style
- If the heading is not applicable, please write N/A
- If more space is required, attach any supporting pages as appendices clearly named to correspond with the question answered

1. Research Description

1.1 Abbreviations, Definitions and Acronyms

List any abbreviations definitions or acronyms specific to the research.

Click here to enter text.

1.2 List your Full Research Title

Ensure the title reflects what you are planning to do.

Click here to enter text.

1.3 Short Research Title

Acronyms are acceptable if explained in your Full Research Title.

Click here to enter text.

1.4 Investigators

List the names, affiliations, positions and responsibilities and contact details of investigators and other key project team members, including your management committee/steering group/ DSMC if applicable.

Name	*Affiliations*	*Position (CPI/PI/AI)*	*Research Responsibilities*	*Email*	*Phone (landline and mobile)*
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1.5 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.

Resources	*Required*	*Secured*
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1.6 Summary

Include the following:

- Your literature review – this can be attached as an appendix
- Rationale/Justification (i.e. how the research will fill any gaps, contribute to the field of research or contribute to existing or improved practice)
- Research questions/aims/objectives/hypothesis
- Expected outcomes.

Click here to enter text.

2. Project Design

2.1 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.

2.2 Method

Describe your research method and the rationale for choosing this method/s. Tie this to the project aims and objectives. (The aim/s is your research question/s, the objectives are the *measurable* steps needed to be taken to achieve the aim/s).

Click here to enter text.

2.3 Participants

Include information about participants such as:

- Description and number
- Inclusion and exclusion criteria
- Sample size and statistical or power issues.

Click here to enter text.

2.4 Participant Recruitment

Describe participant recruitment strategies and timeframes (as required in addition to that outlined in the HREA/LNR).

Click here to enter text.

2.5 Participant Consent

Describe approach/es to provision of information to participants and/or consent (as required in addition to that outlined in the HREA/LNR).

- If necessary, the type of consent provided to different participant groups, when and where, and any arrangements to confirm that consent.
- If necessary, details of who will be confirming or re-negotiating consent with participants and the process/es that will be undertaken.

Click here to enter text.

2.6 Research Activities

Describe what you are going to do - Participant commitment; Project duration; Participant follow-up.

Click here to enter text.

3. Project Data

3.1 Data Collection/Gathering

What information are you going to collect/gather? (as required in addition to that outlined in the HREA/LNR).

Click here to enter text.

3.2 Data collection/gathering techniques

How will you collect/gather the information? Describe the impact of and response to participant withdrawal.

Click here to enter text.

3.3 Data Management

How will you store, provide access to, disclose, use/re-use, transfer, destroy or archive the information that you collect/gather? (as required in addition to that outlined in the HREA/LNR).

Click here to enter text.

3.4 Data Analysis

How will you measure, manipulate and/or analyse the information that you collect/gather? (Matching and sampling strategies; Accounting for potential bias, confounding factors and missing information; Statistical power calculation).

Click here to enter text.

3.5 Data Linkage

What linkages are planned or anticipated?

Click here to enter text.

4. Outcome Measures

Definition: 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." Outcome measures (mortality, readmission, patient experience, etc.) are the quality and cost targets healthcare organizations are trying to improve.

4.1 Describe the expected outcome measures in your project that can inform your objectives.

Click here to enter text.

5. Clinical Trials and Investigational Drugs or Devices

For Research Involving an Investigational Drug or Device as part of a clinical trial, what is/are the drug(s) and/or device(s)?

5.1 Approved name

Click here to enter text.

5.2 Trade name (if any)

Click here to enter text.

5.3 Manufacturer

Click here to enter text.

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

Click here to enter text.

5.5 Approved therapeutic indication, dosage/duration in Australia

Click here to enter text.

5.6 Believed mode of action

Click here to enter text.

5.7 Dosage regimen

Click here to enter text.

5.8 Mode of excretion

Click here to enter text.

5.9 Known adverse events

Click here to enter text.

5.10 Known contra-indications or warnings

Click here to enter text.

5.11 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.

6. Results, Outcomes and Future Plans

6.1 Plans for return of results of research to participants

Declare the intended plans for disseminating the findings to participants.

Click here to enter text.

6.2 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.

6.3 Other potential uses of the data at the end of the project

Describe in full any potential uses of the collected data.

Click here to enter text.

6.4 Project closure processes

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

Click here to enter text.

6.5 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.

7. Research Timelines

Adding a flowchart (such as a Gantt Chart) is useful. Include the start date and end date.

Click here to enter text.

8. References

Add your literature references.

Click here to enter text.

9. Appendix

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

Click here to enter text.