**Research Protocol Template**

|  |  |
| --- | --- |
| **Protocol template**  | This template has been developed by the Research Team for South West Healthcare Projects. It is based on the project description template provided in the Human Research Ethics Application (HREA) on Ethical Review Manager (ERM). <https://au.forms.ethicalreviewmanager.com/Personalisation/DisplayPage/9#ProjectDescription> |
| **What is a protocol?**  | The protocol is a document that provides the scientific and academic background and context of a research project. It should have sufficient detail to enable understanding of:* 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.
 |
| **Why do you need a protocol?** | Inclusion of a protocol is a mandatorycomponent of any research application. It facilitates the review, conduct, monitoring, reporting and interpretation of any research. |
| **How to use this template?** | * the section headings in this template represent a generic structure for presentation of information about a research project that meets the needs of ethics review;
* not all headings or sub-headings in this template are relevant for each research project;
* delete any sections that are not relevant to your study;
* researchers may choose to submit an existing document that has already been developed instead of developing a new document;
* if researchers choose to submit an existing document instead of using the templates provided, the submitted document must be clearly indexed to ensure areas corresponding to the template can be easily located;
* Language that is understandable to non-technical reviewers should be used, including a list of abbreviations (as required); and
* submissions of clinical trial/ interventions must use alternative protocol templates, such as the VCCC[Investigator Initiated Clinical trials](https://www.viccompcancerctr.org/what-we-do/clinical-trials-expansion/investigator-initiated-trials/resources/).
 |
| **Protocol Amendments**  | The protocol may need to be updated due to queries raised by the Human Research Ethics Committee (HREC), or changes required during the life of the project. A transparent audit trail with dates of important changes in project design and conduct is an essential part of the scientific record. Any protocol amendments need to be reviewed and approved by the reviewing HREC prior to implementation. This is supported by maintaining up to date information in the document footer (version number and protocol date). |

*We strongly recommend that you engage with the Research Office at* *swhresearch@swh.net.au* *in the early stages of protocol and research project development. Support available through the Research Office can be accessed to help ensure your protocol meets scientific standards and review requirements.*

*You are reminded that a research protocol is a standalone document and depending on the nature of your study or project, you will be required to create other documents e.g. participant information & consent form, withdrawal of consent form, advertisement flyer, advertising materials etc. The ethics forms – Low and Negligible Risk (LNR VIC) or Human Research Ethics Application (HREA) must be completed on Ethical Review Manager (ERM) in addition to the protocol. The aim of these forms on ERM is to ensure that every project meets all ethical requirements as per the* [*National Statement on Ethical Conduct of Human Research*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)*, whereas the aim of protocol is to provide the scientific and academic context of a research project. The information provided in both documents needs to be consistent.*

1. **Project Title:** [Insert full study title]
2. **Protocol Number (if applicable):** [Insert protocol number]

1. **Protocol Version No. & Date:** [Insert version no. & date dd/mm/yyyy here and in footer]

**Document history:**

[Record protocol changes, with the most recent version at the top of the table. The amended protocol must also “Track Changes” to display the amendments.]

|  |  |
| --- | --- |
| **Version Number and Date** | **Summary of Changes** |
| *2.0 dated dd/mm/yyyy**(Amended protocol)* | *Include simple reason for why the change was made, for example “updated post HREC review"* |
| *1.0 dated dd/mm/yyyy* | *Original protocol*  |

1. **Author /s:** [List Author/s]
2. **Sponsor/s:** [(List Sponsor/s]

[An individual, company, institution, or organisation that takes responsibility for the initiation, management, and/or financing of research. For the studies conducted by SWH staff, your line manager should be consulted to ensure the project aligns with the department’s priorities and the organisation’s strategic plan, and that there are sufficient resources within the department to conduct the study. In the absence of any commercial or collaborative group sponsor, SWH is automatically the study sponsor and has the responsibility for the conduct of the study.]

1. **Project Team Roles and Responsibilities:**

[Include names, affiliations, and role in project including participation start date.]

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Position**  | **Department** | **Role in research project** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **Resources**
	1. **Resources necessary for the conduct of project**

[Staff, equipment, time, and any other resource.]

* 1. **Funding/support (sought or secured)**

[This section should describe how the study will be financed; you are not required to provide any specific dollar amounts.]

1. **Introduction/ Background Information**
	1. **Lay Summary**

[Information provided in this section must be in language that can be understood by an interested person without a scientific or clinical background. Do not use abbreviations, scientific jargon, or citations. This summary should provide the reviewers with an overview of the research aims, participants, methods and expected outcomes. Please keep the total characters below 1250.]

* 1. **Background Information**

[What research has been undertaken in this subject area before? The information should convince the reader of why the study needs to be done. *Hint: Conduct a comprehensive* [*literature review*](https://www.monash.edu/rlo/graduate-research-writing/write-the-thesis/introduction-literature-reviews) ]

* 1. **Rationale/Justification**

[What are the limitations of these previous studies? What is the gap in current knowledge/understanding that this project aims to fill?]

* 1. **Expected Outcomes**

[How will the research fill any gaps, contribute to the field of research, or contribute to existing or improved practice?

* What are your anticipated results?

Some questions to consider include:

* What are the primary and secondary outcomes?
* What are the potential benefits of answering the research question and conducting the project?
* What are the implications of the potential results?
* How might the results of this study inform future practice, policy, or research?]
1. **Study Objective and Hypothesis (if applicable)**

[List specific research aims and/or any scientific hypothesis to be answered.]

1. **Study Design and Methods**
	1. **Research Project Setting**

[Is it a stand-alone project?

Are there any other partner organisations involved?

Or is it a student project being conducted in collaboration with another organisation to fulfill the requirements for any university degree/dissertation?

Outline in detail including who is responsible for the project.]

* 1. **Methodological approach**

[Provide rationale for choices of method/s (tied to project aims/objectives)]

* 1. **Participants**

[Who will be asked to participate? Where will this be carried out and by whom? Include inclusion and exclusion criteria. You are advised to read [Guidelines Under Section 95 of the Privacy Act 1988](https://www.nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988) if in case consent is not being sought from the participant.]

* 1. **Participant recruitment strategies and timeframes**

[Describe how the sample size was determined? *Hint: based on a power calculation (if applicable), or a convenience sample of all people attending a clinic or program*.]

* 1. **Approach to provision of information to participants and/or obtaining informed consent.**

[Please include details of the team member responsible for this. Describe here and attach the Participant Information and Consent Form.]

* 1. **Please provide more information on methods of obtaining consent if this will be sought differently for different participant groups and outline any arrangements to confirm or renegotiate that consent.**

[Please include details of the team member responsible for this.]

1. **Study Procedures**
	1. **How will the study be carried out?**
	2. **What will the participants have to do during the study, when and how often?**

 **Please describe it in detail.**

[How is it different from standard care or process?]

* 1. **What will the investigator(s) do and when?**
1. **Data Collection/Gathering**
	1. **What data will be collected and how?**

[From medical records, questionnaires/ surveys, images, audio recordings?]

* 1. **Impact of and response to participant withdrawal**

[Participants are entitled to withdraw from the research at any stage. Describe the procedures to be followed when a participant is withdrawn from the study, and whether it will be possible to withdraw data once identifiers have been removed. Include what impact this will have on the statistical significance of the sample size for the study.]

1. **Data Management**

[How will you store, provide access to, disclose, use/re-use, transfer, destroy or archive the information that you collect/gather? Include a data management plan in accordance with [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) 3.1.44 and 3.1.55. Note: SWH requires data to be stored for minimum of 7 years post study completion.]

1. **Data Analysis**

[How will you measure, manipulate and/or analyse the information that you collect/gather?]

1. **Data Linkage**

[What [linkages](https://www.aihw.gov.au/our-services/data-linkage) are planned or anticipated (if any)?]

1. **Results, Outcomes and Future Plans**

[Plans for dissemination of results of research to participants, include an ethically defensible plan in accordance with [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) 3.1.64 or 3.2.15 or 3.3.36-3.3.61, as appropriate.

Include:

* Plans for dissemination and publication of project outcomes to participating health service;
* Project closure processes;
* Plans for sharing and/or future use of data and/or follow-up research; and
* Anticipated secondary use of data.]
1. **Appendix**

[List and attach all additional relevant documents e.g. any questionnaire, advertisements, standard tests or procedures, participant information sheet and consent form.]

 **List of Attachments included:**

|  |  |
| --- | --- |
| **Document Name and Date** | **Version Number** |
|  |  |
|  |  |
|  |  |

1. **References**

[List any literature or web references cited in protocol here.]