CALHN Research Services

Low/Negligible Risk Protocol Guideline

Overview

The Study Protocol must contain sufficient detail for both ethical and governance review.

Ethical review is conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2007) (incorporating all updates), available here. Researchers are encouraged to read the National Statement carefully before preparing their Research Protocol.

Governance review assesses a range of areas including availability of local resources, financial arrangements, insurance arrangements, and the training and expertise of investigators at the proposed research sites. For multi-site studies, the protocol must make clear any differences in the project at each site (e.g. investigators, recruitment processes or study procedures).

This document provides a guide only. It is not intended to be used as a template. Low/negligible risk health and medical research is a very broad area. Researchers may need to delete some sections and add others so their protocol suits their particular research project.

The Study Protocol must be submitted in MS-Word or a searchable pdf format (not scanned).

PLEASE NOTE: All documents submitted for review must contain the document label, version number, date, page number, and total number of pages in the footer.

Document Formatting:

Logos:	The institution/organisation that will own the study results
Font:	Arial (default)
Size:	10pt
Alignment	Left align the text
Desirable footer format:	<Document type>, Version XX, Dated XX XXX XXXX Page X of X

1. Project Title

2. Sponsor Name

The sponsor is the institution responsible for the ownership of the protocol/results.

3. Investigator details

Include the following for each investigator:

Name:

Employment and qualifications:

Employing Institution: *(If investigators have multiple affiliations, list the affiliation/capacity the investigator will be using for the duration of this project. **One** affiliation must be nominated*)

Contact details *(Institutional email address)*:

Role and duties in the study:

***Please note:** The research project must have one designated Principal Investigator responsible for the overall project coordination.*

In cases where the research project involves multiple sites, clearly state the Principal Investigators for each site and the Co-ordinating principal Investigator.

4. Introduction

Provide a brief overview of the study.

5. Background

Provide a brief description of the background of the study including its theoretical basis, any relevant previous studies and any relevant contextual information (e.g. if it is part of a larger project).

Include appropriate references relating to the literature.

6. Purpose

The purpose of the study should be clearly connected to the background information and gaps in the current research literature.

a) Aims
b) Objectives
c) Hypotheses

7. Study Design

This section needs to provide information about exactly what the study will entail at each site.

Anticipated start and finish dates:

Anticipated data collection period:

Study site(s):

Participants

Describe the population that participants will be recruited from and include a target sample size.

Inclusion criteria

- Describe the characteristics that clearly describe the study population that are required for a participant to be included in the study.

Exclusion criteria

- Describe the characteristics/basis on which prospective participants will be excluded from the study, and the rationale for the exclusion.
- Criteria may include factors that interfere with participants' ability to give informed consent.

Recruitment

- Explain the pre-screening processes that will be used to identify eligible participants.
- How participants will be approached/recruited to participate (for example face to face, via a letter), and by who.
- Who will make the first approach?
- Explain how informed consent will be sought.
- Which investigator(s) will be responsible for obtaining consent?
- How long will potential participants be given to consider participation?
- How many participants will be recruited?
- What is the period expected to recruit the required number of participants?

Informed consent

Provide information about how informed consent will be sought.

If informed consent of participants will not be sought and the researchers who will access data and/or conduct study procedures are not in the direct care of each participant, provide justification with reference to the provisions in Chapter 2.3.10, a) through i), of the NHMRC National Statement. Please use the CALHN Waiver of Consent Template - Appendix 1: Waiver of Consent Information and Template.

Methodology

Comprehensively describe what study procedures will occur at **each site**.

Include exactly what will happen to any participants once they enrol in the study and what is expected from them.

If a questionnaire compiled from existing sources will be used, include a reference to those sources.

If **existing data** will be used:

- Identify the source.
- Specify what data will be extracted (whole record, specific elements or information).
- Which investigators/research personnel will be responsible for extracting the data?

Access to existing data table*:

Name/Description of data	*e.g. RAH Electronic Medical Records*
Data Custodian	*Which institution? e.g. CALHN*
Database Name	*e.g. Sunrise*
Agency Type State	*(State / Commonwealth / Private Sector)*
Data Collection Format	*Identifiable (identifiable / re- identifiable / non-identifiable)*

**Mandatory if accessing existing data. A table must be included for each database that will be used.*

Data collection

- What data will be collected?
- Describe how the data will be collected (e.g. patient survey, focus group etc.).
- Specify what format the data will be collected in (written notes, audiotape, questionnaire responses etc.).
- Specify what data will be extracted (whole record, specific elements or information).
- Who will be responsible for data collection?

If existing tissue/samples will be used

- Identify the source and custodian (which laboratory/tissue bank etc.).
- Who will access the samples?

If samples will be collected as part of the study:

- Who will collect samples?
- How will samples be collected?
- Is consent being sought for the samples?
- Outline which samples are standard of care and which samples are being collected for research purposes

Analysis

Clearly detail the statistical analysis methods that will be used to meet the study aims and/or test the study hypotheses.

8. Confidentiality, data storage and security

Data storage during the study

- How will data be de-identified and who will be responsible for this?
- Outline how data re-identification will occur (e.g. enrolment log)
- Outline which investigator(s) will have access to de-identified data and/or identifiable data.
- Where will data be stored and how will it be secured?
- Who will have access to the data?
- **Please note:** REDCap is mandatory for data management purposes for all CALHN studies. For further information: The Standard Operating Procedure – “P0032: Source

Documents, Case Report Forms, Data Management and Archiving" is available to CALHN staff via eCentral.

Data storage post project completion

- What format will data be stored in?
- Where will data be stored?
- Who will have access to the data and for what purpose?
- What strategies will be put in place to ensure data security?
- How long will data be stored, who will be responsible for its disposal, how will disposal occur?

***Please note**: Data must be stored at the institution that owns the study results. If data is identifiable, it must be stored at CALHN unless consented.*

Electronic data should be stored on a 'shared departmental drive with password protection' and hard copy data should be stored in locked filing cabinets (or similar) only accessible to the study team.

Sample storage

- If any samples will be collected from participants, where will they be stored during and after the project?
- Will samples be identifiable, de-identified, re-identifiable?
- Which institution owns the samples?
- Which Institution will be responsible for analysing samples?
- How long will samples be stored, who will be responsible for its disposal, how will disposal occur?

9. Publication

- Outline the authorship and publication policy.
- What is the plan for reporting, publishing or otherwise disseminating the outputs/outcomes of the research?
- Will participants in the research be informed of the study findings?

10. Ethical Considerations

Benefits

- Benefits of the study - identify and explain the expected outcomes and potential benefits of the study. Consider:
    - Participants
    - Researchers
    - The local community.

Risks

- Risks - identify and explain any potential risks of the study. Consider:
    - Participants
    - Researchers
    - The local community.

- Explain the level and likelihood of risks during and after participation. Include any risks that may result from the dissemination of study findings.
- Risk mitigation - explain any strategies that will be put in place to manage the listed risks.
- Responsibility for liability of injury (where applicable) - include information about any relevant compensation schemes.

Conflicts of interest

Describe any possible conflicts of interest of the researcher(s). Consider:

- Dependent or unequal relationship issues between investigators and participants
- Whether investigators have any affiliation or involvement in any organisation or entity with direct or indirect interest in the subject matter of this research.

Other

Any other ethical issues

11. Consumer and Community Engagement

Investigators are encouraged to consult with Consumer and Community groups with the design of their research. Please outline any consultation that has occurred.

12. Protocol Deviations

Protocol deviations occur when an investigator conducts a procedure or task that is not detailed in the study protocol and/or the Participant Information and Consent Form. It may comprise participant contact, laboratory work or management of data/documentation. Protocol deviations will be reported to the reviewing ethics committee as soon as practicable following the investigators becoming aware of the deviation.

13. Serious Breaches

A serious breach is a breach of Good Clinical Practice or deviation from the protocol that is likely to affect to a significant degree the safety or rights of a trial participant, or the reliability and robustness of the data generated in the clinical trial. The principal investigator will use continuous vigilance to identify and report any suspected breaches to the institution responsible for the study (the ‘sponsor’) within 72 hours of becoming aware of the event and report any serious breaches confirmed by the sponsor as occurring at the site to their institution (research governance office) within 72 hours of being notified of the serious breach.

14. Safety Considerations

Provide information about how the safety of research participants and researchers will be ensured. Outline any safety monitoring and reporting responsibilities.

15. References

16. Attachments

All Patient Information Sheets/Consent Forms, copies of all questionnaires, recruitment flyers or information brochures and any other documents relevant to the study must be submitted via email as separate attachments to the application.

Appendices

Appendix 1: Waiver of Consent Information and Template

Using the below proforma, address each point of the NHMRC National Statement on Ethical Conduct in Human Research 2007, updated 2018, 2.3.10.

Please justify the Waiver of Consent request in the study protocol by listing the points 'a-i' with responses provided below each point of the Waiver. The CALHN HREC will not accept references to sections of the Protocol as a response.

Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that the project meets all requirements of Chapter 2.3.10 of the NHMRC National Statement on Ethical Conduct in Human Research (2007) (incorporating all changes) as set out below.

Include an introduction sentence to the waiver, stating what type of waiver is being requested (for example Pre-screening for eligibility or retrospective medical records looking at years from XXXX to XXXX) and who will be accessing the medical records?

Template

Pre-screening: A waiver of consent for pre-screening is sought for this project. In order to identify suitable participants for this research project, <investigator> will be required to access <specify what is being accessed>, prior to obtaining consent from the patient.

Access to records: A waiver of consent for retrospective access to medical records is sought for this project. <investigator> will be required to access <specify what database(s) is being accessed>.

a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants
Response:

b) the benefits from the research justify any risks of harm associated with not seeking consent
Response:

c) it is impracticable to obtain consent.
Response:

d) there is no known or likely reason for thinking that participants would not have consented if they had been asked
Response:

e) there is sufficient protection of their privacy
Response:

f) there is an adequate plan to protect the confidentiality of data
Response:

g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
Response:

h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
Response:

i) the waiver is not prohibited by State, federal, or international law.
Response:

Essential Tips

For part C, address:

- Why is it impractical to gain consent?
- Time period (MM/YYYY to MM/YYYY)
- How many records will be accessed? (*estimate is suitable)*
- Are there limitations to resources?
- Mortality rate of participants *(estimate is suitable)*
- Lost to follow up - inability to contact participants due to access to contact details or due to likelihood of contact details having changed due to time or due to characteristics of participant groups *(estimate is suitable)*

For part F, please include the following information:

- What format will data be stored in?
- Where is data being stored?
- Who will have access to identifiable data?
- Will data be re-identifiable?
- Which investigator is responsible for de-identifying data?
- Will the research team using REDCap?

Please note: Where possible, informed consent should be sought from individuals to participate in research or to access their data for research purposes.

For more information

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