Low/Negligible Risk Research Study Protocol Guidelines

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), 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 (eg. start/finish dates, 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 format. Each page must contain the document label (Research Protocol, Participant Information Sheet/Consent Form, recruitment flyer, etc), version number, date, page number, and total number of pages in the footer.

1. Title

a. Short title

2. Investigator details

Include qualification and contact details for all Investigators at each site.

Explain the role in the study that each Investigator will perform at each site. Clearly state whether Investigators will work on or off the relevant CALHN site(s).

3. Introduction

Provide a brief overview of the study.

4. Anticipated start and finish dates

Report the anticipated study commencement and finish dates for each site.

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 (eg. if it is part of a larger project).

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**.

a. Participants

Describe the population(s) that the sample(s) will be drawn from.

Report the target sample size for each population group.

i. Inclusion criteria

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

ii. 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.

iii. Recruitment

Explain:

- The processes that will be used to identify participants for participation.
- How participants will be approached/recruited to participate (for example face to face, via a letter).
- How many prospective participants will need to be approached to get obtain the target sample size?

iv. Monetary reimbursement

Where there will be financial or other reimbursement of participants for any costs they incur, or for their time, provide details of the amount and source of reimbursement.

b. Informed consent

Provide information about how informed consent will be sought.

Identify any issues that may interfere with the participants' ability to give informed consent (language, literacy, age, mental capacity), and state what will be done to address this.

If informed consent of participants will not be sought, provide justification with reference to the provisions in Chapter 2.3 of the NHMRC National Statement.

c. 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.

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

i. Existing data

If existing data will be used (eg. medical records):

- Identify the source.
- Specify what data will be extracted (whole record, specific elements or information).
- Who will be responsible for extracting the data?
    - Is access to this data part of the researcher's standard care/employment?

ii. Data collection

What data will be collected? Consider:

- intervention data
- outcome data
- demographic data
- safety/adverse event data.

Describe how the data will be collected (eg patient survey, focus group etc).

Specify what format the data will be collected in (written notes, audiotape, questionnaire responses etc).

Will a databank be established?

Will participant consent be sought?

iii. Existing tissue/samples

If existing tissue/samples will be used in the study:

- Identify the source and custodian (which laboratory/tissue bank etc).
- Specify what data will be extracted (whole record, specific elements or information).
- Who will access the samples?

- Is access to these samples part of the researcher's standard employment?

iv. Tissue/sample collection

If samples will be collected as part of the study:

- Who will collect samples?
- How will samples be collected?
  - Will this collection be outside of the researcher's standard care/employment?
- Will a tissue bank be established?
- Will participant consent be sought?

v. For **all** data and tissue/samples

What is the identifiability category? (See National Statement Ch. 3.2, 3.4)

- **Individually identifiable** – the identity of a specific individual can be reasonably ascertained (eg from name, image, date of birth or address).
- **Re-identifiable** –identifiers have been removed and replaced by a code, but individuals can be re-identified by using the code or linking data sets.
- **Non-identifiable**- data/samples have never been labelled with individual identifiers **or** where identifiers have been permanently removed, and by means of which no specific individual can be identified.
  - Includes data/samples that can be linked with other data so it can be known that they are about the same individual, but the individual's identity remains unknown.

Who will be responsible for any data/sample de-identification (researchers, staff, another institution)?

d. Analysis

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

Where a hypothesis is being tested, the sample size should be based on an appropriate power calculation. Provide details.

8. Confidentiality, data storage and security

a. Data storage during the study

- Where will data be stored during the project?
- Who will have access during the project?

b. 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?

c. 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, reidentifiable?

9. Publication

How will the results of the study be disseminated?

10. Ethical considerations

a. Benefits of the study

Identify and explain the expected outcomes and potential benefits of the study. Consider:

- Participants
- Researchers
- The local community.

b. 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.

c. Risk mitigation

Explain any strategies that will be put in place to manage the listed risks.

d. Responsibility for liability of injury (where applicable)

Include information about any relevant compensation schemes.

e. 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 access to personal or other sensitive information required for the study beyond their role as investigators (eg. as a condition of employment)
- Whether investigators have any affiliation or involvement in any organisation or entity with direct or indirect interest in the subject matter of this research.

f. Any other ethical issues.

11. 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 as attachments to the application.