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 (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). 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**

2. **Investigator details**

   Include the following for each investigator:

   - Name:
   - Position:
   - Qualifications:
   - Employing Institution:
   - Email address:
   - Role in the study:

3. **Introduction**

   Provide a brief overview of the study. Include the anticipated duration of the study (months/years).

4. **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.

5. **Purpose**

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

   - **Aims**
   - **Objectives**
   - **Hypotheses**

6. **Study design**

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

   - **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

   - **Informed consent**

     Provide information about how informed consent will be sought.

     If informed consent of participants will not be sought and you 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.
c. Methodology

Comprehensively describe what study procedures will occur at each site.

Include exactly what will happen to any participants once they enroll in the study. If a questionnaire compiled from existing sources will be used, include a reference to those sources.

i. If existing data will be used
   - Identify the source.
   - Specify what data will be extracted (whole record, specific elements or information).
   - Who will be responsible for extracting the data?

ii. 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).

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

iv. If samples will be collected as part of the study:
   - Who will collect samples?
   - How will samples be collected?

d. Analysis

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

7. Confidentiality, data storage and security

a. Data storage during the study
   i. How will data be de-identified and who will be responsible for this?
   ii. What format will data be stored in?
   iii. Where will data be stored and how will it be secured?
   iv. Who will have access to the data and for what purpose?

b. Data storage post project completion
   i. What format will data be stored in?
   v. Where will data be stored and how will it be secured?
   ii. Who will have access to the data and for what purpose?
   iii. How long will data be stored, who will be responsible for its disposal, how will disposal occur?

c. Specimen storage
   i. How will specimens be de-identified and who will be responsible for this?
   ii. Where will they be stored during and after the project?
   iv. How long will the specimens be stored for, who will be responsible for its disposal, how will disposal occur?

8. Publication

How will the results of the study be disseminated?

9. Ethical considerations
a. Benefits of the study - identify and explain the expected outcomes and potential benefits of the study. Consider:
   i. Participants
   ii. Researchers
   iii. The local community.

b. Risks - identify and explain any potential risks of the study. Consider:
   i. Participants
   ii. Researchers
   iii. 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:
   i. Dependent or unequal relationship issues between investigators and participants
   ii. 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.

10. Attachments

All Participant 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.