# Research Protocol Template

Overview

A protocol is the primary document for the conduct of any audit or study. The protocol should describe in detail the study goals and how the study will be performed.

This template contains key section headings found in many research protocols, and questions or tips to consider when writing that section. Some sections will not be relevant for your proposed study, and so these may be modified or omitted.

If a study already has a protocol (e.g. a collaborative study*)* then that should be used. There is no need to write another protocol for every country or site. However, you may need to consider a country-specific appendix and other study documents will usually need to be modified for New Zealand.

The final page of this template contains a list of resources you may find useful as you develop your study protocol.

## Study title

**Be consistent** – use the same title across study documents (including regulatory applications).

Clearly and concisely describe your study.

Consider the PICO model- **p**opulation, **i**ntervention, **c**omparator/control, and **o**utcomes[[1]](#footnote-1)[[2]](#footnote-2)

## Lay/Short title

Should be easily understood by non-experts.

Sometimes requested by the Ethics Committee, or clinical study registries or on funding applications.

## Investigators

**Principal Investigator:** Title Name, Position, Department, Institution

 Email:

 Phone:

**Co-investigators:** Title Name, Position, Department, Institution

 Email:

Title Name, Position, Department, Institution

 Email:

 Title Name, Position, Department, Institution

 Email:

*Ensure you have appropriate experience and inter-disciplinary collaborators for the research question.*

**Protocol Version Number and date:**

Almost all research protocols will need to be revised at some point. This may be due to recommendations of peer reviewers, the ethics committee or your co-investigators before the study commences, or necessary amendments later. Including a version number and date on your research protocol and other study documents will help you and regulators (if applicable) keep track of changes.

**Funding:** (if applicable)

**Sponsor:** (if applicable) The Sponsor is the individual, company, institution or organisation that is responsible for initiating, managing and/or financing a study.

**Ethics Committee Reference:** (won’t usually be available for the first version)

## Table of Contents

## List of Abbreviations

### Introduction/Synopsis

Very brief overview of the study (~250 words).

Aim to introduce the main purpose, how the study will be conducted and its expected benefits.

Usually written last.

### Background

Clearly and logically set out the problem or knowledge gap the study will attempt to address.

Critically review and present the relevant literature.

Be concise - limit yourself to 20-25 key references rather than presenting a comprehensive literature review.

*Why does this study need to be done? What do we already know? Why is this topic important (public health/clinical impact, impact on individuals or community, incidence, prevalence, mortality and morbidity, equity)?*

*What is your approach to addressing the research question? How does your study fit into existing research and what are the expected benefits?*

For further support, resources and databases. Contact your librarian.

Health NZ | Te Whatu Ora Southern Library

* + - <https://southerndhb.ovidds.com>
		- email: library@southerdhb.govt.nz
		- Their services include literature search for staff.

University of Otago library

* + - <http://www.otago.ac.nz/library>

### Aim(s) / Objective (s)

The study objective(s) should be single and quantifiable statement(s) that will allow you to answer your research question.

### Study Design or Methodology

#### Study Overview

State the study type (e.g. randomised controlled study, cross- sectional survey, prospective or retrospective cohort/case-control).

Describe and justify choice of study design.

#### Study Setting / Location

Where will the study occur? Is it a single-centre or multi-centre study?

#### Study Population

Define the population that participants will be drawn from.

Describe how participants will be selected.

Can results from your study population be generalised to the total population of interest?

Any special considerations for recruitment? (e.g. achieving equal explanatory power for Māori).

##### Eligibility Criteria

Carefully define which individuals may and may not participate in the study to enable your research question to be answered and ensure participant safety.

May include characteristics such as age, gender, ethnicity, type or stage of disease, previous treatment history, co-morbid medical conditions, medications, location, employment, ability to consent (including language barriers if no interpreter available), willingness to comply with study/treatment restrictions or requirements, address, treatment dates.

Best presented as list.

Be clear if all criteria must be met or if some are either/or.

Usually split into:

##### **Inclusion Criteria**

##### **Exclusion Criteria**

#### Identification of and Recruitment of Participants

How will potential participants be identified (e.g. pre-screening of medical records, use of mailing lists, advertising)

Who will identify potential participants?

How will potential participants be approached/invited to participate?

How will consent be obtained?

Sampling techniques.

Feasibility of recruiting required number. Time period required for recruitment.

#### Study Interventions / Procedures

What will happen to participants after they enrol?

Describe all interventions and additional tests or diagnostic procedures that are required. Note any questionnaires, surveys or interviews that participants will complete.

What study visits are required? When must they occur? What happens at each visit?

Tables and flow charts are often helpful.

#### Data collection and analysis

May be split into subsections depending on study design.

What are the outcomes of interest?

How will the data be collected? (e.g. patient questionnaire, analysis of biological specimens)

When will data or tissue samples be collected?

What demographic information you will collect about participants? Provide a list in the protocol (or an appendix).

NEAC advises that “All researchers conducting health research in New Zealand must collect good-quality ethnicity data” (see 9.20 - 9.21 of the NEAC Guidelines).

Do you need access to participant’s medical records? What health information you will collect from participants medical records? Provide a list in the protocol (or an appendix).

Does a particular instrument need to be used to ensure valid data collection?

Who will be responsible for data collection? Do they need any specific training or experience (if multiple people)?

Who will be present at study visits, interviews, or focus groups?

For qualitative data collection, how and by whom data will be (for example) transcribed, coded, de-identified, stored/transferred, accessed, or archived? Will focus groups or interviews be recorded?

#### Withdrawal

What are the options for participants who choose to leave the study? How will their data be handled?

### Statistical Considerations

Do you need to consult a statistician?

#### Sample size and statistical power

If appropriate perform a sample size or power calculation. If not, explain why.

Will you need to adjust for anticipated non-responders or participants lost to follow up?

#### Statistical methods

### Data management

#### Data storage and security

How will you collect/extract data (identifiable, non- identifiable, de-identified or re-identifiable)?

How will you manage and store data (of paper hardcopies and/or electronic files)?

How will you ensure privacy and confidentiality during the study?

What will be done with the data at the end of the study?

Data storage, governance and management may also be described in a separate data management plan. HDEC has data (and tissue management plan (DMP or DTMP) templates, which should be used for all studies requiring HDEC review.

Māori Data Sovereignty (e.g. Te Mana Raraunga – Principles of Māori Data Sovereignty <https://www.temanararaunga.maori.nz/>

FAIR Principles: <https://research-hub.auckland.ac.nz/guide-to-managing-research-data/ethics-integrity-and-compliance/fair-principles-for-research-data>

CARE Principles: <https://www.gida-global.org/care>

### Safety considerations

Patient safety/Researcher safety

### Ethical Considerations

Describe the ethical risks and considerations, and how you plan to deal with them.

For medical research involving human participants, you should state that the study will be conducted in full conformance with principles of the “Declaration of Helsinki”, Good Clinical Practice (GCP) and within the laws and regulations of the country in which the research is conducted.

The National Ethics Advisory Committee – Kāhui Matatika o te Motu (NEAC) issues the National Ethical Standards for Health and Disability Research and Quality Improvement. All health and disability research and quality improvement activities conducted in Aotearoa New Zealand must meet or exceed the ethical requirements set out in the National Ethical Standards.

Topics considered here may include:

* Conflicts of interest
* Anticipated benefits vs Risks associated with participation in the study.
* Informed consent
* Privacy and confidentiality

Declaration of Helsinki <https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/>

Privacy Act 2020: <https://www.privacy.org.nz/privacy-act-2020/privacy-principles/>

Health Information Privacy Code 2020: <https://www.privacy.org.nz/privacy-act-2020/codes-of-practice/hipc2020/>

National Ethical Standards: <https://neac.health.govt.nz/national-ethical-standards>

### Equity Considerations

#### Māori Health Advancement

#### Māori Consultation and Engagement

Describe any consultation undertaken and how it has influenced the research design.

What are your plans for Māori consultation, partnership or engagement before, during and after the study?

#### Other equity considerations

Describe any consultation with other involved or interested groups that you have undertaken or planned. (e.g. other ethnic groups, patients groups or public).

### Study Impact and Significance

Do you want to reiterate the potential benefits of successfully answering your research questions?

How might the results inform future research, clinical practice or policy makers?

### References

### Appendices

Questionnaires to be completed by participants

Interview questions

Data collection forms (or list of variables to be collected)

## Additional study documents

Participant Information Sheet(s) and Consent form (s) - PISCF

Consider different populations (e.g. health professionals, patients).

HDEC usually require optional aspects of a project (e.g. Future Unspecified Research, or a substudy) to be addressed and consented to using a separate PISCF.

Participant Information Sheets and Assent forms,

In addition to parent/caregiver PISCF, if your research involves children under 16.

More than one may be required to present the information appropriately for different age groups.

Data (and Tissue) Management Plan

If submitting to HDEC, use their template.

# Resources

National Ethical Standards https://neac.health.govt.nz/national-ethical-standards

Māori Data Sovereignty (e.g. Te Mana Raraunga – Principles of Māori Data Sovereignty <https://www.temanararaunga.maori.nz/>

Declaration of Helsinki https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/

Privacy Act 2020 https://www.privacy.org.nz/privacy-act-2020/privacy-principles/

FAIR Principles: <https://research-hub.auckland.ac.nz/guide-to-managing-research-data/ethics-integrity-and-compliance/fair-principles-for-research-data>

CARE Principles: <https://www.gida-global.org/care>

For interventional trials consider the SPIRIT Statement and Checklist (Standard Protocol Items: Recommendations for Interventional Trials) <https://spirit-statement.org>

Health and Disability Ethics Committee

Standard Operating Procedures <https://ethics.health.govt.nz/operating-procedures>

Templates and guidelines <https://ethics.health.govt.nz/guides-templates-and-forms>

Top 10 tips for getting your application right the first time <https://ethics.health.govt.nz/guides-templates-and-forms/gettingapplicationright>

**For further support, resources and databases. Contact your librarian.**

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* + - <https://southerndhb.ovidds.com>
		- email: library@southerdhb.govt.nz
		- Their services include literature search for staff.

University of Otago library

* + - <http://www.otago.ac.nz/library>
1. <https://bestpractice.bmj.com/info/toolkit/learn-ebm/how-to-clarify-a-clinical-question/> [↑](#footnote-ref-1)
2. <https://en.wikipedia.org/wiki/PICO_process> [↑](#footnote-ref-2)