**Note to Users**

This study template is not to be used for clinical trials (e.g., clinical trial of a drug, device, treatment etc.) If you are unsure if this template is suitable for your research, please contact WM\_Research@health.qld.gov.au.

This study template is designed to be generic. Some subsections and suggestions may not be appropriate for your specific study. You can tailor the contents to meet the specific requirements of your study. Only include the sections pertinent to your study, you can omit irrelevant sections.

You are reminded that this template should be a standalone document. A completed Human Research Ethics Application (HREA) will be required in addition to the template. While the HREA ensures that all ethical requirements in the National Statement are satisfied, information provided in the study template should provide a detailed description of every aspect of your project, therefore the two documents meet different requirements.

**[Please delete this page prior to submission]**

# Research StudyPROTOCOL

**<Insert Full Study Title>**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
Version Number: <insert>
Date: DD/MM/YYY

**Statement of Compliance**

This document provides details of a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC *National Statement on Ethical Conduct in Human Research (2023)*, NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2018).*

|  |  |
| --- | --- |
| **STUDY INVESTIGATORS:** | **CONTACT DETAILS** |
| Principle Investigator: | Institution:Department:Address:Telephone:Email: |
| Co-Investigator: | Institution:Department:Address:Telephone:Email: |
| Co-Investigator: | Institution:Department:Address:Telephone:Email: |
| Co-Investigator: | Institution:Department:Address:Telephone:Email: |
| Co-Investigator: | Institution:Department:Address:Telephone:Email: |

**STUDY SYNOPSIS**

**(please provide brief information summarising information provided in the Protocol)**

|  |  |
| --- | --- |
| Title: |  |
| Short Title: |  |
| Study sites where project will take place: |  |
| Study Objectives: |  |
| Study Design: |  |
| Study Data / Measures: |  |
| Study group/s: |  |
| Number of participants in group/s: |  |
| Briefly state how findings may be used to change clinical practice / service delivery: |  |
| Key Ethical and Safety considerations: |  |

## Glossary of Abbreviations, Terms, and Acronyms

|  |  |
| --- | --- |
| **Abbreviation, Term, Acronym** | **Definition (using lay language)** |
|  |  |
|  |  |
|  |  |

## Background

* + *Introduce the reader to the topic of the study and provide the context for the research. Carefully describe the disease, condition, or topic of interest. Give an overview of the disease, condition, or topic of research noting such things as prevalence, economic or social burden, or other importance. Critically appraise the relevant literature identifying both areas of consensus and gaps in knowledge.*
	+ *Provide justification for conducting the study. Indicate how the research question has emerged and fits logically with the evidence presented.*
	+ *Explain how your study will contribute to existing research and benefit your target population.*

## Study Aims / Objectives

### Aim

### *The aim refers to the main goal or purpose of the study. The sentence(s) describing the aim of a study are usually brief and to the point.*

### Objective

### *The objectives are more specific than your research aim. These indicate the specific ways you will address the aim. They break down the research aims into smaller, more manageable components and describe what you want to achieve.*

### Hypothesis may or may not be required dependent on the aim of the study. e.g., it is hypothesised/expected that variable A is positively related to variable B; that the new intervention Y is more efficacious than existing treatment Z

## Methods

### Study Design

* *Specify the type of study e.g., Qualitative or quantitative.*
* *Qualitative studies may include, interviews, focus groups, participant observation, etc.*
* *Quantitative studies may include Cohort-study (retrospective or prospective), case-control study, cross-sectional study. If the project is made up of components or will be delivered via a number of phases, describe each component/phase and time frame for its delivery. For example: patient recruitment, baseline assessments, intervention, evaluation of intervention, and translation plan.*
* *Specify if this study will be a single-centre or multi-centre, national or international, study.*
* *State if this study will be used towards a student project, and if so, state what course and degree the student will undertake.*

### Study Setting

*Specify all locations and settings at which the study will be conducted. If the study requires home visits, specify the home visit policy and procedures that will be applied.*

### Study Group

* *Define the group/s to be included in the study in terms of demographics, disease/condition, risk factors and comorbidity.*
* *Specify inclusion criteria (e.g. age range, gender, specific diagnosis and stage of disease, previous treatment history) and exclusion criteria (eg. an inability to give informed consent, or understand English, contraindications of the study treatment and/or procedures, conditions that will hinder the interpretation of results from the study, or participant’s inability to comply with the study protocol).*
* *Explain how participants will be recruited. You should make a distinction between how you will recruit control subjects compared to other groups (if performing a comparative intervention).*
* *Recruitment methods may vary with type of study, for example…:*
* *Cohort Studies: Describe sources and methods that will be employed in the identification and recruitment of potential participants e.g., clinics, referring doctors, advertisements etc…*
* *Cross-sectional Studies: Describe the sources and methods that will be employed in the identification and recruitment of participants (e.g., clinics, referring doctors, advertisements etc…) or of historical data (e.g., medical records, registries, databases etc...).*
* *Case-Controlled studies: Describe how controls will be identified and recruited (e.g., advertisements, letters from GP’s, family members etc...), and describe if and how they will be matched. Describe how the case population will be identified and recruited. Describe measures taken to avoid bias.*

### Consent

* + - *Discuss whether individual consent will be obtained or if a waiver of consent will be required, or if consent is not required. Please refer to:* [*National Statement on Ethical Conduct in Human Research (2023)*](https://www.nhmrc.gov.au/guidelines-publications/e72) *sub-sections 2.1, 2.2 and 2.3.*
			* *If requesting a waiver of consent, please be sure to address the requirements in sub-section 2.3.10 of the* [*National Statement on Ethical Conduct in Human Research (2023)*](https://www.nhmrc.gov.au/guidelines-publications/e72)
		- *Stipulate if consent from participants is for this research project only, for future related projects, or if consent is unspecified.*

### Participant confidentiality

* *Describe how participants’ privacy and confidentiality will be protected via:*
* *Storage of participant information and consent forms.*
* *Storage of patient specific data (paper and electronic)*
* *Whether patient data will be identified, de-identified, or potentially re-identifiable.*

### Data storage and management

* *Describe your data storage and management plan:*
* *How will the data or information be stored and disposed of?*
* *How long will the data be stored to meet NHMRC guidelines? All records should be kept for a minimum of 5 years post study closure.*
* *What are the risks associated with the collection, use, management and storage of the data and how can they be minimised?*
* *Will the data be used for any subsequent research activities or made available to anyone outside the current research team? (e.g., future research, data sharing on a repository)*
	+ - * *If yes, how will data be shared, e.g., in what format, how long will it be kept for, who can access it?*
* *A summary of this information should be included in the Participant Information and Consent Form*
	+ - **Participant Safety**
		- *Identify all situations where participant safety may be compromised. Such examples may include, but are not limited to, exposure to radiation and invoking psychological or physical distress. Provide evidence of planning to mitigate safety concerns.*

### Participant withdrawal from a study

* + - *Participants may withdraw from the study by choice, a protocol violation may have occurred, or the participant has experienced an adverse event. Describe the procedures to be followed when a participant is withdrawn from the study. This should include what happens to all collected data (e.g., blood samples, scans, photos, etc…) that have already been collected, if the participant needs to have any follow-up, and all administrative requirements to withdraw a subject adhered to, to ensure their information isn’t inappropriately used after their withdrawal from the study.*

### Study Procedure

* + - *Provide a detailed description of how the study is intended to proceed. Include sites and relative timing of procedures and data collection. Identify the personnel to perform each task. Give details of how each task is to be performed, e.g. Blood collection. Note any logistical problems and their anticipated solution. A flow chart may be a useful inclusion.*

*Specifically note any tissue samples taken or interviews or any other procedures performed on Participants. For tissue samples, how long do you intend to store each sample, where and in what format will the samples be stored? State if any samples will be used for genetic testing. Will samples be entered into a biobank?*

### Outcome Measures

* + - *Specify the primary and any secondary outcomes. Distinguish between specific, measurable outcomes and implied general outcomes.*

### Data Collection

* *Describe how you will collect and store all types of data collected to measure each specific outcome. Specifically, how will blood tests, tissue samples, MRI’s, results from genetic testing, videos, photos, questionnaires, interviews and other observations associated with an intervention or application be recorded as data. How often will data be collected, by whom and in what format. Discuss any specific coding of raw data to be undertaken that is intended to facilitate data analysis.*

### Data Analysis

* *Discuss the methods by which you intend to describe and analyse your data. Relate these analyses to answering the actual research questions. Note any statistical software to be used.*
* *Specify the estimated sample size and justify how this sample size will ensure that your study will identify with statistical significance a clinically relevant difference or have sufficiently precise (narrow) confidence intervals. Consulting a biostatistician is recommended for this requirement.*
* *Specify how missing data will be handled or allowed for.*

### Translation to Changes in Clinical Practice

* *Applicants should clearly define the anticipated changes in clinical practice that are likely to result from the research. Examples of possible changes are listed and described in Appendix 1. Note; some specific changes may follow on from more fundamental changes. Give an estimate of the likely extent of the changes, e.g. hospital wide, national, international.*
* *Applicants should outline measures to be taken to translate study outcomes to changes in clinical practice. For example:*
	+ *How new knowledge generated by the project will be disseminated to relevant stakeholders such as clinicians, patients, community groups, policy makers and other researchers.*
	+ *How novel practices or procedures validated by the research will be introduced into clinical practice.*
	+ *How the researchers are placed to influence policy and practice change.*

### Timeline

* *Provide a timeline of activities described in this protocol.*

### Funding

* *Give details of any funding received or sought for this project. Name the funding organization, the size of the grant, period of funding, nature of peer review, and date of application.*

### References

* *Provide relevant references in a standard format.*

**Appendix 1.**

**Translation of Study Outcomes to Changes in Clinical Practice.**

|  |  |
| --- | --- |
| **Change in Clinical Practice** | **Example** |
| Knowledge of Practitioners | “Speech pathologists will understand the importance of considering XYZ when treating patients who stutter” |
| More applied clinical research or quality improvement activity | “Generalizability of our findings will follow from the likely implementation and reporting of our intervention in various clinical settings” |
| Clinical Process | “This research is likely to change anaesthetic triage by….” |
| Treatments/Lifestyle Interventions | “Demonstration of the effectiveness of drug X for dementia will lead to a change in treatment strategy for the condition”. |
| Techniques | “If we demonstrate that the “under-over” technique is superior to the “over-under” technique we expect that this will become the definitive treatment”. |
| Medical Practice/Guidelines | “…will change the way clinicians fundamentally view and recommend the use of vitamin T”. “…approach to the treatment and prevention of Disease X” |
| Other Indicators of Tangible Change | “…legislative changes are likely to ensue”  |