**Note to Users**

This Protocol Template is designed to be generic. Some subsections and suggestions will not be appropriate for your specific study. You must tailor the protocol contents to meet the needs of your study. Only include sections pertinent to the study, omit irrelevant sections.

You are reminded that a protocol should be a standalone document. The HREA does need to be filled out in addition to the protocol, however the HREA ensures that all ethical requirements in the National Statement are satisfied, whereas a protocol should be 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 is a protocol for 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 (2007) – Updated May 2015*, NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2007)* and the *Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)*.

|  |  |
| --- | --- |
| **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 Outcome Measures: |  |
| Study Population: |  |
| Number of participants: |  |
| Translation to Change in Clinical Practice: |  |
| Key Ethical and Safety considerations: |  |

## Glossary of Abbreviations, Terms, and Acronyms

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

## Background

* + *Introduce the reader to the main topic of the study and provide the context for the research. Carefully define the disease, condition, or topic of interest. Critically appraise the relevant literature identifying both areas of consensus and gaps in knowledge. Give an overview of the disease, condition, or topic of research noting such things as prevalence, economic or social burden, or other importance.*
	+ *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 Objectives

### Aim e.g., To determine if socioeconomic status is associated with childhood asthma in children attending Gold Coast State Schools; To determine if new intervention A influences outcome B once known covariates are accounted for.

### 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., 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 protocol 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 in which the study will be conducted. If the study requires home visits, specify the home visit policy and procedures that will be applied.*

### Study Population

* *Define the group in which the study will be carried out on 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…:*
* *Clinical Trials: Include a description of how your participants will be randomized and note any software that will be used. A description of the type of randomisation performed, should be included noting, for example, block sizes and stratification. An explanation on the method used to conceal group allocations, such as envelopes, should be included and who will assign participants to their groups. This section should also discuss if the participants and/or investigators will be blinded to group allocations or if the study will be unblinded to the participants and/or investigators.*
* *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

* + - *Describe if individual consent will be obtained or if a waiver of consent is required, or if no consent is required. Please refer to:* [*National Statement on Ethical Conduct in Human Research (2007) - Updated May 2015*](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 participants have given unspecified consent.*

### Participant confidentiality

* *Describe how participants’ privacy and confidentiality will be protected:*
* *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.*
* *How long the data will be stored to meet NHMRC guidelines (all records should be kept for a minimum of 5 years post study closure. If your study contains a clinical trial notification (CTN) device, then records must be kept for a minimum of 15 years.*
	+ - **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. Note the personnel to perform each task. Give details of how each task is to be performed; eg. 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, for example, 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 described 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 outcomes of this 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, eg. 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 time line 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”  |