**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, reorder and add sections as needed.

Once you feel you have completed all elements of the protocol that applies to your study, right click on the contents page and select “update field”, this will automatically update the page and section numbers that have change. Please also ensure you have deleted all of the annotations and added the version number and document date in the footer.

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| protocol  |
| [Insert Full study Title] |
| Version: #Date: DD/MM/YYYY |
| **Protocol Author/s:****Sponsor/s:** |
| **CONFIDENTIAL**This document is confidential and the property of GV Health. No part of it may be transmitted, reproduced, published, or used without prior written authorisation from the institution.**Statement of Compliance**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 2018) and the Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2), dated 9 November 2016 annotated with TGA comments.**STUDY INVESTIGATOR(S)****Principal Investigator**

|  |  |
| --- | --- |
| Title and Name |  |
| Position |  |
| Department |  |
| Qualifications |  |
| Phone |  |
| Email |  |

**Associate Investigator**

|  |  |
| --- | --- |
| Title and Name |  |
| Position |  |
| Department |  |
| Qualifications |  |
| Phone |  |
| Email |  |

*Note: Copy table and repeat for each additional associate investigator or delete table if there are no associate investigators.* |

**LIST OF ABBREVIATIONS**

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# INTRODUCTION/BACKGROUND INFORMATION

### LAY SUMMARY

[A lay description differs from a formal scientific description. It must be written in such a way that a lay person or consumer can easily understand your research question, and how you will answer it. Limit this section to 2-3 lines only.]

### INTRODUCTION

[The introduction is a very brief overview of the study (~250 words). The introduction should be concise but sufficient to orientate the reader to the main purpose of the study and how it will be conducted and its expected benefits. It should include details on (1) what the research question is, (2) how the proposed study will fill a gap in the literature, and (3) provide an understanding that this study is novel].

### BACKGROUND INFORMATION

[This section should give clarity on the research question being addressed. The information should convince the reader (or reviewer) of why the study needs to be done (and deserves funding or ethical approval). The background should also include the rationale which specifies the reasons for conducting the research in light of current knowledge. It should include a well-documented statement of the need/problem that is the basis of the project, the cause of this problem and its possible solutions. Discussion should be clear and logical that demonstrates you are fully conversant with the ideas presented and can grasp their methodological implications. Keep this brief and to the point (no longer than two A4 pages). The following points may be used as a guide:

* Conduct a comprehensive literature search. The GV Health Library is a valuable resource for researchers on campus for assistance or advice on developing an optimal search strategy.
* Critically appraise the relevant literature and discuss the current knowledge on the topic (include deficiencies). If applicable, discuss the current treatment options and the associated issues risks and benefits.
* Discuss the importance of the topic (e.g., public health, clinical importance, impact on individuals/community, incidence, prevalence, mortality and morbidity).
* Indicate how the research question has emerged and fits logically with the evidence detailed above.
* Explain how your study will contribute to existing research and benefit your target population, other individuals, or the wider community.
* Outline your approach to address the research question.]

# AIM

[An aim is a broad but concise statement of what the research study hopes to accomplish. It creates a setting for the remainder of the research protocol. Your aim should arise from your literature review and state what the study hopes to accomplish.]

# OBJECTIVES

[Research objectives indicate in more detail the specific research topics or issues the project plans to investigate, building on the main theme stated in the research aim. The study objective(s) should be single and measurable/quantifiable statement(s) that will allow you to answer your research question. Ensure that the text supports the chosen study endpoints and that it is clear, concise, specific (not nebulous, open-ended or otherwise not assessable), and objective. The number of objectives should be kept low as too many objectives may make the study logistically difficult to perform.]

### PRIMARY OBJECTIVE

[The primary objective reflects the main clinically relevant goal of the study. Every study must have a primary objective. This objective generally drives statistical planning for the study. Define the primary objective in terms of the population, intervention, comparator and outcome that will be measured in a single clear and concise statement.]

*Example text: “The primary objective is to evaluate the impact of <intervention> on time to resolution of <condition> in <type of participants> compared with <placebo>”*

### SECONDARY OBJECTIVE(S)

[Secondary objectives are other constructs being tested by the study that could clarify findings from the primary objective or show potential additional effects.]

*Example text: “The secondary objectives of this trial are:*

1. *To determine the safety and tolerability of <intervention> in <type of participants> with <condition>.*
2. *To determine the impact of <intervention> on healthcare utilisation in <type of participants> with <condition>.”*

# HYPOTHESIS

[A hypothesis states your predictions about what your research will find. It is a tentative answer to your research question that has not yet been tested. Hypotheses are more specific than objectives and are amenable to statistical evaluation. Your experimental results will prove or disprove your hypothesis.]

### PRIMARY HYPOTHESIS

[Your primary hypothesis is your statement of the hypothesised effect of the primary outcome measure.]

### SECONDARY HYPOTHESIS

[Although a study is usually based around a primary hypothesis, secondary hypotheses may also be pre-specified although based on outcomes of lesser importance or additional interest. As the primary hypothesis is usually the basis for statistical power calculations, secondary hypotheses with insufficient power will generally not lead to statistically robust conclusions.]

# STUDY DESIGN

[State the design of the research (e.g. randomised controlled study, cross-sectional study, prospective or retrospective cohort, case-controlled study). Whatever the study design, you need to ensure that you provide the reader with a clear statement and description of your proposed design. You may also explain why the particular study design has been chosen in preference to other possible designs (i.e. justification for choice of study design).]

# STUDY SETTING/LOCATION

[The location of where the study will be conducted (e.g. Obstetrics & Gynaecology Department, GV Health). You need to mention whether the study is going to be a single-centre study or a multi-centered study (i.e. conducted in more than one location).]

# STUDY DURATION

[The protocol should specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken. If possible, a Gantt chart should be included.]

# STUDY POPULATION

[Defining the group in which the study will be carried out on provides the setting for which the research has relevance. This section also describes how one can be certain that the results from your sample population can be generalised to the target population of interest. This section should describe the target population, including but not limited to:

* Population the participants will be drawn from
* All aspects of participant selection
* The total number and number within any subgroups
* Age range
* Gender.]

### INCLUSION CRITERIA

[Inclusion and exclusion criteria are standards that you have set to determine whether a person may or may not be allowed to enter your study. They are used to identify appropriate participants and to ensure their safety. Clearly describe the study population characteristics that are required for a subject to be included in the study. The criteria may be based on factors such as age, gender, type and stage of disease, previous treatment history, etc. If certain criteria will be assessed using existing clinical tools these should also be stated.]

### EXCLUSION CRITERIA

[Provide details of participants that will be considered ineligible to participate and justify why they have been excluded. Exclusion criteria may include circumstances that interfere with the participant’s ability to give informed consent (diminished understanding or comprehension, or a language other than English spoken and an interpreter unavailable), contraindications to the study treatment(s)/procedure(s), taking certain concomitant medication(s), or conditions that interfere with a patient's ability to comply with all treatment(s)/procedure(s).]

# STUDY OUTCOMES

[The outcomes (also known as endpoints) are the variables which are used to assess the effect of the study intervention and therefore the study objectives. Outcomes should be clearly specified and include:

* A brief explanation (i.e. a justification) should be provided to explain why these outcomes were chosen.
* Their respective outcome measures (i.e. the method for measuring an outcome), such as:
	+ Objective assessments (e.g. mortality rates);
	+ Subjective clinical assessments (e.g. validated rating scales);
	+ Measurements of various physiological functions (e.g. blood pressure);
	+ Anatomical or histological assessments (e.g. tumour measurements)
	+ Biomarkers or biochemical markers (e.g. tumour markers, liver function tests); or
	+ Pharmacokinetic tests.
* Description of the metric used to characterise the measure (e.g., change from baseline, final value, time to event, maximum).
* The timeframe (i.e., total duration of the time period, specific time points) over which the measurement will be assessed.]

### PRIMARY OUTCOME

[The primary outcome is the basis for concluding whether or not the study has met its primary objective. There should be just one primary outcome that will provide a clinically relevant, valid, and reliable measure of the primary objective. However, sometimes researchers will propose more than one primary end point if several outcome measures are of equal therapeutic importance. In a study designed to establish efficacy, a primary endpoint should measure a clinically meaningful therapeutic effect or should have demonstrated ability to predict clinical benefit.]

### SECONDARY OUTCOME(S)

[Secondary outcome measures, also known as secondary endpoints, may provide information on therapeutic effects of secondary importance, side effects, or tolerability. Secondary outcome(s) may or may not be related to the primary objective and are generally based on the secondary objectives.]

# STUDY PROCEDURES

[This section should describe exactly what is going to happen during conduct of the study.]

### RECRUITMENT AND CONSENT OF PARTICIPANTS

[This section should describe how potential participants will be identified/selected for recruitment (e.g. via outpatient clinic, medical records search), how they will be approached/invited to participate, and how consent (if required) will be obtained. Also describe who will approach potential participants and who will procure consent. Detail types of recruitment strategies planned (e.g. patient advocacy groups, national newspaper, local flyers; social media) and if the study requires long-term participation, describe procedures that will be used to enhance participant retention (e.g., multiple methods for contacting participants, visit reminders, incentives for visit attendance). You may need to justify the feasibility of recruiting the required number of participants and estimate the proportion that you would expect will agree to participate. Finally, the period of time expected to recruit the required number of participants should be stated here. Include all documents to be used in the recruitment process as separate documents, e.g. letters, brochures, participant information and consent forms (PICFs).]

### PARTICIPANT WITHDRAWAL

[Participants may withdraw from the study for the following reasons: participant has chosen to withdraw from the study, protocol violation, or 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, all administrative requirements to withdraw a subject to ensure their information isn’t inappropriately used after their withdrawal from the study].

### RANDOMISATION

[Include a description on how your participants will be randomised, include any software that will be used. Where applicable, a description of the type of randomisation performed, ratio of assignment to group and stratification should be included. An explanation on the method used to conceal group allocations 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].

### STUDY SCHEDULE

[In this section, provide a clear and comprehensive description of exactly what will happen to participants once they are enrolled in the study. Depending on the study it might include how potential participants will be approached, when they will be randomised, the frequency and duration of visits or whether they are expected to self-complete a daily diary at home, the duration of the study or follow-up, and any measurements taken at each visit (e.g. questionnaires, physical measurements, biological samples). Include precise details of the treatment(s)/intervention(s) intended for each group/participant. Also provide details of any follow-up schedule. Consider how you will monitor participants’ adherence with the treatment/intervention schedule (if applicable). A schematic diagram or flow chart and/or table may be useful for this section.]

### DATA COLLECTION

[Explain procedures for data collection in detail. State what data will be collected e.g., blood tests, MRI’s, genetic testing, videos, photos, questionnaires, etc. Describe at what point(s) of the study data collection will occur. You should make statements that justify the validity of the study measure/instrument. If not, you will have to verify how you will ensure the validity and quality of data being collected. If you are using standardised surveys, questionnaires or other test please attach a copy of each of these tests to the appendix of the protocol. Also, mention here if you are going to have one or more assessors to collect data, their level of training/experience (or how they will be trained), and if you are planning to assess inter-rater reliability (if applicable).]

### DATA MANAGEMENT AND STORAGE

[Provide details on:

* Where records will be kept and how long will they be stored for.
* Form of stored data (specify if the data collected will be identifiable, re-identifiable or non-identifiable).
* The personnel who will have access to the data and how that access will be granted (password, key, code etc.).
* Disclosure of information.
* The use/re-use and transfer of data (if applicable).
* Method of destruction of data.]

### SAFETY CONSIDERATIONS

[The safety of research participants is foremost. Provide adequate information on how the safety of research participants will be ensured. This can include procedures for recording and reporting adverse events (and serious adverse events) and their follow-up (mandatory requirement for studies involving intervention or treatments). Remember that even administering a research questionnaire may have adverse psychological effects on susceptible individuals.]

# STATISTICAL CONSIDERATIONS AND DATA ANALYSIS

[Consultation with a statistician is strongly recommended for this section.]

### SAMPLE SIZE AND STATISTICAL POWER

[A sample size or power calculation should be performed. This calculation is used to estimate the number of participants required to measure the primary outcome with an accepted power, allowing you to draw a robust conclusion from your data. Conversely, it also allows you to estimate what power can be achieved with a limited number of participants. You need to specify the assumptions made for the calculation. Also keep in mind the estimated recruitment rate and whether you need to adjust for anticipated non-responders and losses to follow up].

### STATISTICAL METHODS/DATA ANALYSIS PLAN

[Describe the statistical methods that will be undertaken for this study. A description of all statistical methods to be employed should be outlined. Procedures for accounting for missing, unused, and spurious data and reporting any deviation(s) from the original statistical plan should be described and justified.]

# ETHICAL CONSIDERATIONS

[The protocol should have a description of ethical considerations relating to the study. This should not be limited to providing information on how or from whom the ethics approval will be taken, but this section should document the issues that are likely to raise ethical concerns. You must state that the study will be conducted in full conformance with the NHMRC National Statement on Ethical Conduct in Human Research (2007 and updates), World Medical Association Declaration of Helsinki (2013 and updates), Good Clinical Practice (GCP), and within the laws and regulations of the state and country in which the research is conducted. Consider and articulate how the quality of the technical aspects have been assured, the potential risks and proposed benefits of the study procedures, the priority of the participants’ interests over those of science or of society and how those interests will be safeguarded, responsibility for liability of injury during the study, how the participants are informed of the study, and how they give voluntary consent to participate.]

# DISSEMINATION OF RESULTS AND PUBLICATIONS

[The protocol should specify not only dissemination of results in the scientific media, but also to the community and/or the participants, and consider dissemination to the policy makers where relevant. Publication policy should be clearly discussed - for example who will take the lead in publication and who will be acknowledged in publications. Describe the plan for publication. To the extent possible, roles and responsibilities of each research team member should be determined in advance. Additionally, if the research study will be published, there should be an additional plan that describes assignment of authorship and the contributions of each author.]

# OUTCOMES AND SIGNIFICANCE

[It may be of value to reiterate the potential benefits of answering the research question and conducting the project. This section restates the justification for the study in terms of the anticipated results. It may be important to specify the implications of the potential results and how the results of this study may inform future research or policy makers and also how they will likely affect health care, health systems, or health policies.]

# REFERENCES

# APPENDICES

[Include a list of appendices (e.g. questionnaires, surveys, interview scripts, phone scripts, data collection forms, assessment forms, rating scales, PICFs). Provide the appendices as separate documents and any documents to be provided to participants should be presented in the form that they will be provided to the participant.]

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