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

**Collaborative Research Grant Scheme 2020**

***What is a Research Protocol?***

*The preparation of a research protocol is an important first step in the research process. The development of a written protocol ensures that research activities are well-planned from the outset, and that a clear record is available for investigators to refer to throughout the project, especially when there are changes in investigators.*

*The protocol also provides a living document to inform grant applications, peer-review, manuscript preparation and ethics applications*

***The Protocol Template***

*This Protocol Template is designed to be generic. Some subsections and suggestions will not be appropriate for your specific study and can be deleted/modified. In this scientific protocol you should include background information that provides a rationale for your study, study objectives, study design, and information on data collection and analysis.*

***The study protocol is to be no longer than 3000-words, excluding references, and can include 2 tables of no more than 1 page each. Numerical referencing is encouraged.***

*Information from this protocol template can be used for Section A of the ethical review protocol. Section B of the ethical review protocol will prompt you to consider ethical and safety issues. The full protocol is available at;* <https://www.goldcoast.health.qld.gov.au/publications/research-protocol-template>

*Questions about research, including methodological and statistical questions, can be directed to* [ResearchGoldCoast@health.qld.gov.au](mailto:ResearchGoldCoast@health.qld.gov.au)

|  |
| --- |
| **protocol** |
| [Insert Full Study Title] |
| Version Number: INSERT  Date: DD/MM/YYYY |
|  |
|  |
| **Statement of Compliance**  This document is a protocol for a research project. This study will be conducted in compliance with all stipulations 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 NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2018)*. If the project is a clinical trial, it will comply withthe *Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)*. |

**STUDY SYNOPSIS**

*Please provide a brief summary of the information provided in the protocol.*

|  |  |
| --- | --- |
| Title: |  |
| Short title: |  |
| Study sites: |  |
| Study aims/objectives/hypothesis: |  |
| Study design: |  |
| Study outcome measures: |  |
| Study population: |  |
| Number of participants: |  |
| Translation to clinical practice: |  |
| Key ethical and safety considerations: |  |

## Glossary of Abbreviations, Terms, and Acronyms

## Please add rows as needed.

|  |  |
| --- | --- |
| Abbreviation, term, acronym | Definition (using lay language) |
|  |  |
|  |  |
|  |  |

# SECTION A:

## 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 noting such things as prevalence, economic or social burden, or other aspects of importance.*
  + *Present and critically appraise the relevant literature and demonstrate that a comprehensive literature search has been conducted. The CASP Appraisal checklists may assist (*<https://casp-uk.net/casp-tools-checklists/>*).*
  + *With reference to the literature, identify both areas of consensus and gaps in knowledge. Indicate how the research question has emerged and fits logically with the evidence presented.*
  + *Justify why this research is worth pursuing, including how it contributes to existing research and benefits your target population.*
  + *The Gold Coast Health Research Office offers a literature search service, submit a request at* <http://gchlibrary.snapforms.com.au/form/literature-search-request>*.*

## Study Objectives

### Research Question and/or Aims/objectives

### *Provide the research question and/or aims/objectives. It may be helpful to use the PICOT method (Population, Intervention, Comparator, Outcome, Time), or another method appropriate to your study design http://library.nd.edu.au/evidencebasedpractice/ask/question.*

### *Example aims- To determine if socioeconomic status is associated with childhood asthma in children attending Gold Coast State Schools; To explore parents’ perceptions of managing their children’s asthma; To determine if new intervention A influences outcome B, accounting for covariates.*

### Hypothesis

### *A hypothesis may or may not be required dependent on the study objectives (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). A hypothesis is usually amenable to statistical evaluation.*

## Methods

### Study design

* *Describe the study design to be used in the study. Note, data collection and data analysis methods will be addressed later. It should be clear how the design will adequately address the research question and/or aims/objectives. The EQUATOR network publishes guidelines which, although they are designed for reporting, can provide guidance on the type of information to include here. Refer to* <https://www.equator-network.org/toolkits/selecting-the-appropriate-reporting-guideline/> *to identify a guideline relevant to your study design. Information provided by the Centre for Evidence Based Medicine may also assist novices with study design nomenclature* <https://www.cebm.net/2014/04/study-designs/>*.*
* *If the project is made up of components or will be delivered via several phases, for example in a mixed methods study, describe the approach used for each phase.*
* *Help with study design is available for Gold Coast Health staff, contact* [ResearchGoldCoast@health.qld.gov.au](mailto:ResearchGoldCoast@health.qld.gov.au)*.*

### Study Sites/Settings

* *Specify if this study will be a single-centre or multi-centre, national or international study.*
* *Specify the study sites and provide a short justification of the selection of the site/s with reference to the study design (e.g. will sites be compared?).*
* *If applicable, specify all settings in which the study will be conducted.*

### Sample

* *Define the proposed sample including 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 (e.g. 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 inability to comply with the study protocol)* .
* *If applicable, specify the estimated sample size and justify how this sample size will ensure that your study will identify a clinically relevant difference with statistical significance or have sufficiently precise (narrow) confidence intervals. Consulting a biostatistician is recommended for this requirement. For qualitative studies, comment on how sample size will be determined, which may discuss data saturation, reference to previous studies, alignment with objectives and practical considerations.*
* *Sampling methods vary with type of study, but may include some description of:*

*Sampling: Describe how participants will be sampled (e.g. random, consecutive, purposive, convenience sampling).*

*Randomisation: Include a description of how your participants will be randomised 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.*

*Blinding and allocation concealment: An explanation of 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.*

### Intervention (if any)

* + - *Provide evidence-based rationale for the intervention. If the intervention has been pilot tested provide brief description.*
    - *Describe the intervention. See the TIDieR checklist:* [*https://www.equator-network.org/reporting-guidelines/tidier/*](https://www.equator-network.org/reporting-guidelines/tidier/) *for items that should be described for interventions including, but not limited to, what are the intervention materials, what is the procedure for delivering the intervention, who delivers the intervention.*
    - *For complex interventions a flow chart or table may be a useful, for example:*

|  |  |  |  |
| --- | --- | --- | --- |
|  | On admission | Within 48h of admission | Prior to hospital discharge |
| Patient receives face-to-face education session from healthcare professional | x |  |  |
| Patients watches education video administered by Research Assistant |  | x |  |
| Patient sets goals with healthcare professional |  |  | x |

### 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 all types of data being used to measure each specific outcome.*
* *Describe how often data will be collected, by whom and in what format. It may be helpful to include a table like the below to display this information.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Baseline | Post-intervention | Follow up |
| Blood collection | x | x |  |
| Measure A | x | x | x |
| Questionnaire A | x | x | x |
| Questionnaire B | x |  |  |

### Data Analysis and Statistical Considerations

* *Discuss the methods by which you intend to describe and analyse your data. Relate these analyses to addressing the research question/hypotheses. Note any software to be used (e.g. STATA, NVivo).*
* *Specify how missing data will be allowed for or handled.*
* *Discuss any specific coding of raw data to be undertaken to facilitate data analysis.*
* *Please identify if a statistician has been consulted.*
* *Services of a biostatistician are available to Gold Coast Health staff, contact* [ResearchGoldCoast@health.qld.gov.au](mailto:ResearchGoldCoast@health.qld.gov.au)*.*

### Timeline

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