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***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 Research Protocol and HREA***

*In Queensland Health, the Human Research Ethics Application (HREA) needs to be submitted with the protocol. The role of the HREA is to ensure that all ethical requirements in the* [NHMRC National Statement](https://www.nhmrc.gov.au/guidelines-publications/e72) *are satisfied, whereas a protocol should be a detailed description of every aspect of a project, therefore the two documents meet different requirements.*

*The recommended approach to avoid redundancy across the two documents is to refer to sections of the protocol in the HREA application. An example is below.*

* *HREA Q2.2.1 Indicate the relevant section/s of your*[Project Description /Protocol](https://au.forms.ethicalreviewmanager.com/Personalisation/DisplayPage/9#ProjectDescription)*that address/es consent.*
* *Please reference section 3e. of the research protocol.*

***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.*

*Feedback on the protocol or questions about research, including methodological and statistical questions, can be directed to* [GCHResearchDevelopment@health.qld.gov.au](mailto:GCHResearchDevelopment@health.qld.gov.au)

*Questions on the HREA or ethics submissions can be directed to* [GCHEthics@health.qld.gov.au](mailto:GCHEthics@health.qld.gov.au)

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| --- |
| INSERT INSTITUTIONAL LOGO HERE  **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 INVESTIGATORS**

*Please add rows and edit the investigator titles as desired (e.g. Principal Investigator A, Associate Investigator). If this study will be used as part of a student project/course requirement, note this in “Role in Study” in the table below. Include what course and degree the student will undertake.*

|  |  |
| --- | --- |
| Principal Investigator: | Name:  Institution:  Department:  Address:  Tel:  Email:  Role in Study: |
| Co-Investigator: | Name:  Institution:  Department:  Address:  Tel:  Email:  Role in Study: |
| Co-Investigator: | Name:  Institution:  Department:  Address:  Tel:  Email:  Role in Study: |
| Co-Investigator: | Name:  Institution:  Department:  Address:  Tel:  Email:  Role in Study: |

**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) |
|  |  |
|  |  |
|  |  |

## 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. You may wish to reference this section in the benefits section of the HREA.*
  + *Typically, this section references 10-20 key sources and spans 1-2 pages.*
  + *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 Aims/objectives

* *Provide the research question and/or aims/objectives. It may be helpful to use the PICOT method (Population, Intervention, Comparator, Outcome, Time).*
* *Example aims- 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

* *A hypothesis may or may not be required dependent on the aims 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). A hypothesis is usually amenable to statistical evaluation.*

## Methods

### Methodological Approach

* *Describe the research methods to be used in the study. Note, data collection and data analysis methods will be addressed later. It should be clear how the design and methods will adequately address the research question and aims. The EQUATOR network publishes guidelines which, although they are designed for reporting, can help as guidance on the type of information to include here. Refer to* <https://www.equator-network.org/toolkits/selecting-the-appropriate-reporting-guideline/> *to pick a guideline which matches your study. 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, as for example in a mixed methods study, describe each component/phase and time frame for its delivery.*
* *For projects where the later stages are informed by the preceding stages (e.g. Knowledge Translation research), make clear the implications for ethics approval and whether amendments or separate submissions will be made for each stage.*
* *Be aware that in the Methods section of the HREA you must categorise your study as consisting of one or more (or none) of the research methods listed in the table (reproduced here as an Appendix). This is not necessary in the protocol.*
* *Help with methodology is available for Gold Coast Health staff, contact* [GCHResearchDevelopment@health.qld.gov.au](mailto:GCHResearchDevelopment@health.qld.gov.au)*.*

### Study Sites/Settings

* *Specify if this study will be a single-centre or multi-centre, national or international study. Please specify the study sites and provide a short justification of the selection of the site/s with reference to the methodology (e.g. will sites be compared?).*
* *If applicable, specify all 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 (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’s inability to comply with the study protocol)*

### Recruitment/ Selection

* *Explain how participants will be recruited (e.g. for trials) or data will be selected (e.g. for retrospective chart audits). Describe sources and methods that will be employed in the identification and recruitment/selection of potential participants (e.g., clinics, referring doctors, advertisements, time periods) or of historical data (e.g., medical records, registries, databases). You should make a distinction between how you will recruit/select control subjects compared to other groups if performing a comparative intervention.*
* *Recruitment or selection 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 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.*
* *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.*

### Consent

* + - *Describe if individual consent will be sought. For studies which will consent participants, describe the consent process, including who will consent participants, time set aside for consenting and time for the participant to consider.*
    - *Some studies may need to provide information about multiple methods for consent, renegotiation of consent, staged/tiered information, limitations on/consequences of withdrawal of consent.*
    - *Will consent be specific (for this study only), extended (for use of data and/or tissue in future research that is an extension of, or closely related to this study, or in the same general field), or unspecified (use of data and/or tissue in any future research).*
    - *If the study is not seeking individual participant consent, a waiver of consent should be requested under the* [National Statement on Ethical Conduct in Human Research (2007) - Updated 2018](https://www.nhmrc.gov.au/_files_nhmrc/file/publications/national-statement-2018.pdf)*, addressing the requirements of section 2.3.10.*

### Risk Mitigation Procedures

* *Identify any risks to participants taking part in the study, including physical, mental, emotional and other risks. Describe procedures that will be followed to mitigate these risks. This can include procedures for recording and reporting adverse events and their follow up.*

### Participant Withdrawal Procedures

* + - *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) 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?*
    - *Please also note the timeline of participant involvement, including any screening and follow up requirements. It may be of use to include a table like the below to display this information.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | * Baseline visit | * Post-intervention visit | * Follow up visit |
| * Blood collection | * x | * x |  |
| * Measure A | * x | * x | * x |
| * Questionnaire A | * x | * x | * x |
| * Questionnaire B | * 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 and store all types of data collected to be used in measuring each specific outcome. Specifically, for example, how blood tests, tissue samples, MRIs, results from genetic testing, videos, photos, questionnaires, interviews and other observations be recorded as data. Describe how often data will be collected, by whom and in what format. Discuss any specific coding of raw data to be undertaken to facilitate data analysis.*

### Data Storage and 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).*
* *The identifiability of the information (i.e. whether participant data will be individually identifiable, re-identifiable (or potentially re-identifiable) or non-identifiable). If applicable, please outline how data identifiers will be removed, by who, and whether a list of identifiers will be kept and where that will be stored.*
* *Whether any data will be sent to other sites, including internationally.*
* *Note if there are circumstances in which data may be reported to relevant authorities.*
* *Note whether participants will be able to access or request their own data.*
* *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.*
* *Describe any plans for secondary use of data or information (e.g. data banking/sharing).*

### 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).*
* *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 determined, which may discuss data saturation, reference to previous studies, alignment with objectives and practical considerations.*
* *Specify how missing data will be handled or allowed for.*
* *Please identify if a statistician has been consulted.*
* *Services of a biostatistician are available to Gold Coast Health staff, contact* [GCHResearchDevelopment@health.qld.gov.au](mailto:GCHResearchDevelopment@health.qld.gov.au)*.*

## 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 timeline of activities described in this protocol.*

## Funding and Resources

* *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 any standard format (e.g. APA).*

**Appendix 1. HREA Methods**

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| **Q1.17.** **From the list below, select all the research methods that will be used in the research project.** |
| • Your answer to this question will have a significant impact on the subsequent questions in this HREA.  • One or more of these methods may be used for research across many academic fields and research categories, including arts, social and behavioural sciences, education and health.  • Research may employ more than one method. Select all that apply.  • Consider the description of each method provided below. |
| |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | |  |  | | --- | --- | | Action research | • [National Statement 3.1](https://www.nhmrc.gov.au/book/chapter-3-1-qualitative-methods?) states that action research “is often community- or organisation-based and is carried out in the field. This approach involves testing ideas in practice as a means of improving social, economic or environmental conditions and increasing knowledge. Action research proceeds in a spiral of steps consisting of planning, action, and evaluation. It provides a basis for further planning of critically informed action.”  • This method includes design and implementation research and ‘rapid appraisal’ research. | | Biospecimen analysis research | • [National Statement 3.4](https://www.nhmrc.gov.au/book/chapter-3-4-human-biospecimens-laboratory-based-research?) describes biospecimens as, “any biological material obtained from a person including tissue, blood, urine, sputum and any derivative from these including cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person.”  • Biospecimen analysis includes potential genetic or genomic investigations. | | Data linkage research | • The [International Population Data Linkage Network](http://www.ipdln.org/) describes data linkage as, “Secondary use of linked administrative data… often referred to as ‘data linkage,’ ‘record linkage,’ or ‘linked data.’ This is typically population based longitudinal data that has originally been collected for another purpose. Linkage may take place across data sets in a single domain (i.e. health) or across domains (i.e. health, education, environment, early childhood, etc.)”  • **Note:** The character of and planned activities related to data will be addressed in Section 3 of the HREA for *all* projects, irrespective of the methods selected. | | Ethnographic research | • Ethnographic research is a qualitative, iterative research method used to engage with a group, community, population or society that is aimed at description of everyday life and practice and the interpretation of cultural meanings, patterns and systems emphasising an ‘insider’s point of view’.  • Ethnographic research is usually based on fieldwork using a model of participant-observation and the research questions are often developed in collaboration with research participants. The result is an account of the people, place or institution with whom or with which the researchers have interacted. | | Epidemiological research | • The [World Health Organization](http://www.who.int/topics/epidemiology/en/) describes epidemiology as “the study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems. Various methods can be used to carry out epidemiological investigations: surveillance and descriptive studies can be used to study distribution; analytical studies are used to study determinants.” | | Interventional/Clinical Trials research | • Interventional research is the use of one or more substances, devices, treatments, therapies, techniques or processes in a defined cohort of participants to determine the impact or effect on individuals. Interventions can be physical, behavioural, psychological or informational and can be used in clinical, educational or other contexts.  • Interventional research may or may not:        o Be comparative,        o Randomise the participants,        o Include an experimental arm, and/or        o Include a placebo arm.  • The [World Health Organization](http://www.who.int/topics/clinical_trials/en/) defines a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes". | | Observational research | • [National Statement 3.1](https://www.nhmrc.gov.au/book/chapter-3-1-qualitative-methods?) states that observational research “involves the researcher observing participant/s in their own environment, or in the environment being studied. Data collection through observation can be structured or unstructured, with the observer as a collaborative participant (participant observation) or external to the environment.” | | Survey/Interview/Focus Group research | • [National Statement 3.1](https://www.nhmrc.gov.au/book/chapter-3-1-qualitative-methods?) states that interviews “involve researchers talking to one or more participants, where the categories of response are focused but not necessarily pre-determined. Interviews are usually recorded by audio- or video-tape, or notes. These records are research data in themselves, but also may be transcribed. Interviews are usually conducted in locations mutually acceptable to participants and interviewers.”  • [National Statement 3.1](https://www.nhmrc.gov.au/book/chapter-3-1-qualitative-methods?) states that “focus groups of participants discuss a set of research questions or topics. This may entail the researcher acting as a moderator for the discussion.”  • This method includes research using oral history. | | Textual analysis research | • This method may involve evaluation of texts including film, television, photographs, magazines, advertisements, clothes, graffiti and other media.  • This method may include the study of content or specific language and its frequency (e.g. hermeneutics or linguistic analysis). | | |

**Appendix 2: Translation of Study Outcomes to Changes in Clinical Practice**

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| **Change in Clinical Practice** | **Example** |
| Knowledge of Practitioners | “Speech pathologists will better understand the lived experience and psychosocial impacts of stuttering” |
| 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” |