Research Protocol

**Metro North Health**

#### Research project title (full)

The research study title should be descriptive, while clearly and concisely indicating the subject of inquiry. The title should be consistent across all related documents (including regulatory documents).

#### Research project title (short)

You might also like to include a ‘lay’ (‘simplified’) title easily understood by non-medical or interdisciplinary persons and/or an acronym

#### Study investigators

It is important to list the investigator affiliations to ensure reviewers are aware of the organisations involved, as this may have implications for data transfer, privacy, and confidentiality. Keep a study delegation log of all Associate Investigators they do not need to be on the protocol.

|  |  |
| --- | --- |
| Principal Investigator:  *(for single site studies)*  *OR*  Coordinating Principal Investigator:  *(for multi-centre studies) & the* Principal Investigator for each site | For example:  Dr Jane Smith  Staff Specialist Surgical Unit  Metro North Health    Ph: 07  Email: Jane.Smith@health.qld.gov.au |
| Study Coordinator/Contact person:  *(if applicable)* |  |
| Co-investigator’s |  |

#### Study sponsor

The sponsor is an individual, company, institution or organisation that takes responsibility for the initiation, management and/or financing of the research. For investigator-initiated projects, the sponsor is usually the lead site where the Chief/Coordinating Principal Investigator is from but may be also be the organisation administering the funding for the project. If the project is for a research higher degree, the study sponsor is the university institution.

#### Funding

Sources and types of financial, material and other support. For investigator-initiated studies, the funding body may be different to the sponsor.

### Version history

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Change date | Section changed | Summary of changes |
| V1 | DD/MM/YYYY | NA | First version |
|  |  |  |  |

### List of abbreviations

|  |  |
| --- | --- |
| MNH | Metro North Health |
| PICF | Participant Information and Consent Form |
|  |  |

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1. Introduction

The introduction is a brief overview of the research project (~250 words). The introduction should be concise but sufficient to orientate the reader to the main purpose of the research, how it will be conducted and its expected benefits. It is a structured sketch of the research project that will provide an overview before examining the details. It should be written using lay language.

1. Background

The background is an important aspect of a research protocol. In this section, the research problem should be described in the context of a literature review. A literature review involves finding, reviewing and forming conclusions about the published literature to provide clarity of the research problem. This is an opportunity to outline why the research needs to be done.

The following key points may be used as a guide:

* Conduct a comprehensive literature search (PubMed, EMBASE, CINAHL, and Cochrane Library and other databases relevant to your area of research).
* Discuss the importance of the topic (public health, clinical importance, impact on individuals/community including incidence, prevalence, mortality and morbidity).
* Critically appraise the relevant literature and discuss the state of current knowledge on the topic (including deficiencies in knowledge or gaps that make the research worth doing).
* Indicate how the research question has emerged.
* Explain how your research will contribute to existing research and benefit individuals or the wider community.
* The literature review should be concise and present only key references. The literature review should logically lead to the statement of the aims of the proposed research.

1. Aim(s) and objectives

The aim(s) should be developed from the literature review and state what the research hopes to accomplish (both primary and secondary).

The research aim(s) needs to be further refined to one or more research objectives. The research objective(s) are usually quantifiable statement(s) that will provide answers to the research problem.

**Hypothesis (if applicable)**

Hypotheses are more specific than objectives and amenable to statistical evaluation. Your primary hypothesis is the statement of the hypothesised effect on the primary outcome measure. A hypothesis is worded very simply and written as a ‘testable’ statement. The experimental results will prove or disprove the hypothesis. Hypotheses are generally stated in the null form (Ho) as they have their basis in inferential statistics. Rejecting the null hypothesis increases confidence, with a given level of probability, that there is a relationship between the variables being studied. However, a classic scientific hypothesis includes both a null and alternative (Ha) hypothesis.

1. Methods

The scientific integrity of the research project and the credibility of the data from the study depend substantially on the study design, therefore it is important that the study will be conducted using robust methodology .

* 1. Study type/design

Describe the design of the research (eg cross-sectional survey, cohort study, case-control study, qualitative research methods, focus groups). Ensure that a clear description of the proposed design is provided. You need to justify the particular research design that has been chosen.

* 1. Setting/sites

Identify the location(s)/organisations where the research will be conducted and state whether the research is going to be single-site or a multi-site research. If multi-site, describe each site where the research will be undertaken, who is providing oversight for the research at that site and the research activities that will be undertaken at each site.

1. Participants

This section should describe the target population, target number of participants as well as the inclusion and exclusion criteria to identify appropriate participants for the study.

* 1. Inclusion criteria

Inclusion criteria are the ‘characteristics’ that clearly describe the research population that are required for a participant to be included in the research. The criteria may be based on factors such as age, gender, sex, the type and stage of a disease, previous treatment history, and co-morbid medical conditions.

* 1. Exclusion criteria

Provide details of participants who will be considered ineligible to participate and justification for their exclusion. These criteria are not always clinical in nature, aiming principally to accommodate participants in a safe and ethical manner. 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 research 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).

1. Research outcomes
   1. Primary outcome

The primary outcome should be the most important and relevant measurable outcome (eg clinical, psychological, economic, or other) of the research. This is the measure used to address the primary research aim. However, it is also the outcome used to calculate sample size and statistical power and test the primary research hypothesis. Generally, no more than 1-2 primary outcome measures are pre-specified. Primary outcome measures may be measured in various ways such as: binary (eg caesarean/no caesarean, blood loss ≥500mL/blood loss <500mL); continuous (eg weight - kg, blood loss - mL); ordinal (eg pain - mild, moderate, severe); time to event (eg survival), and counts (eg number of infections, number of events occurring).

* 1. Secondary outcome(s)

Secondary outcome(s) are measures of additional or less important research interest. They may include additional clinical, psychological, economic, or safety outcomes (eg treatment related side effects/adverse events). However, as these endpoints are not used to calculate research power and sample size it is often not possible to draw robust conclusions from the results.

1. Procedures/assessments/Intervention

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

In this section you need to clearly and comprehensively describe exactly what will happen to participants once they are enrolled in your study. Depending on the study it might include how potential participants will be approached, 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).

You should include precise details of the intervention(s) intended for each group/participant You should also provide details of any follow-up schedule (i.e. time between visits) and consider how you will monitor participants’ adherence with the intervention. You might also describe under which circumstances participants may be withdrawn and how this will occur. A schematic diagram or flow chart may be useful for this section.

For drugs and devices that are commercially available, the protocol must state their proprietary names, manufacturer, chemical composition, dose, duration and frequency of administration. Please note that a clinical trial protocol needs to be even more robust than what is described here. For further guidance please consult the **ICH Guideline for Good Clinical Practice (annotated with Therapeutic Goods Administration comments)**. Please also be aware that for drugs and devices that are still in the experimental stage (or commercially available and used for a different indication or mode of administration), an Investigators Brochure (IB) is a required accompanying document to the protocol. The IB is a compilation of clinical and non-clinical data, available pre-clinical experiments in animals and/or results of Phase I/II clinical studies available on the experimental products intended for use in the study in question. It provides study investigators and staff with an understanding of the rationale of the study in order to inform their compliance with the protocol requirements. In these cases, the approval of the TGA will be required prior to commencing the study. Refer to the TGA website for further information on submission requirements – [www.tga.gov.au](http://www.tga.gov.au)

* 1. Recruitment of participants

This section should describe how potential participants will be identified and selected for recruitment (eg at the outpatient clinic), how they will be approached/invited to participate (e.g. by principal investigator at a clinic visit), and how informed consent will be obtained. Be specific in naming which members of the research team (and their affiliation) will be involved in each step of the recruitment process (e.g., a researcher from MNH, a researcher from the University). If there are any members of staff from the institution who are not part of the research team, but will be involved in recruitment, please list them.

You need to outline the estimated time schedule and feasibility for recruitment of participants and any strategies for achieving the target sample size.

* 1. Consent

Consent is the process by which a participant voluntarily confirms their willingness to participate in a research study. Before enrolment into the research, each potential participant should be given a full explanation of the study. Once the essential information has been provided to the potential participant, and the researcher is sure that the individual understands the implications of participating in the study, the participant should be asked to sign the consent form.

Information on how informed consent is to be obtained should be included in the protocol, such as which members of the research team will perform this task and when this will occur.

If a waiver of consent is being requested from the HREC, justification must be given in the **ethical considerations section**, citing the National Statement section 2.3.10.

If seeking a waiver of consent for use of health information held by a commonwealth agency, please provide further justification citing section 95 of the Privacy Act 1988 **ethical considerations section.**

1. Methods of data collection

It is essential to state how data will be collected to assess the outcome(s) of the study (eg patient questionnaire, interview, focus group, medical charts, routinely collected hospital case notes, datasets/databases, biological specimens).

Describe at what point(s) study data collection will occur. You should make statements that justify the validity of the study measure/instrument and/or whether there will be audio recordings. If not, you will have to verify how you will ensure the validity and quality of data being collected.

* 1. Surveys

Provide details of any surveys that will be administered during the study. Justify the validity of any research instruments being administered and describe how the surveys will be administered, e.g., in hard copy or online.

* 1. Access to existing data and data linkage

Further Detail can be described in the data management section of the protocol or your data management plan.

This section includes more detailed information data being collected from databases or existing datasets, specifically the organisation holding the data, the data custodian, and the data variables. The data management section should clearly address additional details related to storage, access, etc.

Data linkage allows for the identification of distinct entities between datasets. If data linkage is occurring in your study, specific detail is required on how the linkage will occur, including who will conduct the linkage and how participants’ privacy and confidentiality will be protected, if not already described elsewhere.

1. Data analysis
   1. Sample size and statistical power

A sample size or power calculation and any other relevant statistical details should be included. A sample size calculation provides an estimate of the number of participants required to achieve the study aim or research hypothesis with an accepted level of statistical power. Conversely, it also allows an estimation of the power that can be achieved with a limited number of participants, for example a convenience sample. This number is calculated by specifying the magnitude of the effect that is expected (informed and clinically significant), variability of the measurements and the acceptable degree of type I and II errors. Specify the assumptions made for the calculation. It is recommended to consult with a statistician for this section. Also keep in mind the estimated recruitment rate and whether the sample size will need to be adjusted for anticipated non-responders and losses to follow up.

* 1. Statistical methods

This section should detail the statistical methods used to analyse the data in accordance with the research objectives/hypotheses (eg t-test, chi-squared, multivariate modelling) must be sufficiently detailed. Include the timing of any planned interim analysis and the level of significance to be used.

* 1. Qualitative

The analysis strategy adopted in qualitative research will relate to the type of study being conducted and the theoretical framework guiding the study. In this section you should describe briefly your guidelines for managing data, your analytical framework and how you will identify patterns and themes in your data.

1. Data management
   1. Data storage, retention and disposal

This section addresses the storage, retention, disposal, sharing and re-use of data or information. It should address the following questions:

* How and by whom will the data or information be generated, collected and/or accessed?
* Will the data or information be disclosed or shared and, if so, with whom, and how?
* What type of data are you collecting? [Is-it-personal-information-20181031.pdf (health.qld.gov.au)](https://qheps.health.qld.gov.au/__data/assets/pdf_file/0027/451890/Is-it-personal-information-20181031.pdf)
* What format will the data be stored (e.g., identifiable, re-identifiable or non-identifiable)?
  + Identifiable: data that can uniquely identify an individual. Examples of direct identifiers include name, address, driver’s licence number, patient UR number and Medicare number.
  + Re-identifiable: data, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.
    - Will a master data key be generated -how? Who will hold the Master key?
  + Non-identifiable: data which have never been labelled with individual identifiers for the purposes of research.

For more information on data characteristics (personal, sensitive or health information) see [*Queensland Health’s fact sheet*](https://qheps.health.qld.gov.au/__data/assets/pdf_file/0027/451890/Is-it-personal-information-20181031.pdf)

* Research records/data are kept in a secure location (hard copy or electronic), backed up and only accessible by the research team
* Research records/data are retained for appropriate timeframe (from publication or end of research) consistent with institutional policy and relevant Queensland Health Disposal Registers.
  1. Privacy and confidentiality

Confidentiality of patient’s personal data must be protected in accordance with the relevant national data protection and confidentiality laws/acts, as applicable. Please identify:

* What protected health information will be collected from patients
* Who will have access to that information and why
* Who will use or disclose that information
* What measures are in place to protect participant confidentiality (eg only a unique study number and initials will identify participants together with the date of birth, will be used in the database for participant identification, participant names or addresses will not be entered in the database, no material bearing a participant’s name will be shared with external stakeholders.
* Participants must be informed of their rights within the Participant Information Sheet and Consent Form.
  1. Monitoring, auditing and inspecting

Provide information regarding the monitoring, quality audits, data checks; data verification and inspections by government regulatory authorities, or if applicable the Sponsor (eg source documents, regulatory documents, data collection instruments, case report forms).

1. Ethical considerations

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 2023, the NHMRC Australian Code for the Responsible Conduct of Research (2018) and applicable organisational Policies and Procedures.

The safety of research participants is foremost. Where applicable for a clinical research, state that the research project will be conducted in full conformance with principles of the World Medical Association Declaration of Helsinki, Good Clinical Practice (ICH-GCP) and in accordance with the applicable legislation and regulations. State that the study will be conducted in compliance with the protocol an consider and articulate how the quality of the technical aspects have been assured, the potential risks and proposed benefits of the research 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 research, how the participants are informed of the research, and how they give voluntary consent to participate.

* 1. Risk assessment

The researcher should assess the level of risk for participants involved in this study to determine if this study meets the criteria to be submitted for review as a Low Risk study or Greater than Low Risk Study.

A risk is a potential for harm or discomfort. It involves:

* the likelihood that a harm or discomfort will occur, and
* the severity or magnitude of the harm or discomfort, including their consequences.

While discussion of the risk of harm or discomfort applies to risk to an individual research participant, it can also apply to groups or communities as well as to non-participants such as family members. Risk can be associated with the conduct of research or the proposed outcomes of the research.

Risk in research exists on a continuum with the risk profile of an individual research project falling somewhere along this continuum.

Low risk research describes research in which the only foreseeable risk is no greater than discomfort. Accordingly, research in which the risk for participants or others is greater than discomfort is not low risk research. Research in this category is considered higher risk research and carries risk of harm.

Reference: National Statement on Ethical Conduct in Human Research (2023). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra

Include information to indicate that a comprehensive and centralised filing system of all study-related (essential) documentation, will be maintained and will be suitable for inspection at any time by representatives from the Sponsor if applicable and/or applicable regulatory authorities.

Study documentation must be retained by the Principal Investigator and organisation for as long as necessary to comply with national and international regulations.

* 1. Justification of Waiver of Consent

If seeking a justification for a wavier of consent, you must details and justify each statement below in accordance with National Statement.

1. Involvement in the research carries no more than low risk – insert justification.
2. The benefits from the research justify any risks of harm associated with not seeking consent - insert justification.
3. It is impracticable to obtain consent - insert justification.
4. There is no known or likely reason for thinking that participants would not have consented if they had been asked. insert justification.
5. There is sufficient protection of their privacy - insert justification.
6. There is an adequate plan to protect the confidentiality of data – insert justification.
7. In case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them - insert justification.
8. The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled - insert justification.
9. The waiver is not prohibited by State, federal, or international law - insert justification.
   1. Declaration of interests

State any perceived or actual conflicts of interest.

1. Impact and dissemination

Explain the wider relevance of science to the community and/or MNH, how to build support for future research and innovation funding and ensure the uptake of results within the scientific community and open up potential opportunities.

1. References

Include references to support your protocol.

1. Appendices

List additional study tools such as study specific forms or logs etc.