**Guide to writing a research protocol / QA project plan**

A well written and comprehensive protocol is essential for a high quality research project. A study protocol generally follows a conventional layout. There are several templates already available, although most are developed for commercially-sponsored randomised controlled studies. This research protocol guidance document aims to offer Mater researchers a generic guide suitable for a broad range of research studies.

**This document is designed to be used as a quick reference guide if clarification on any sections is required after reviewing the associated Research Protocol Template. It is also recommended for novice researchers that completion of the Research Protocol is done in consultation with an experienced researcher.**

All research studies, including low and negligible risk studies, require a protocol. It is also advisable that all clinical audits should have a formal written project plan. This document is separated into three guidance sections:

* All research
* Clinical audits / quality improvement projects.
* Qualitative research

The preparation of a protocol is an important first step in the research process for the following reasons:

1. It states the research question you aim to answer;
2. It provides a structured, written working plan of the study;
3. It encourages adequate consideration and planning of project detail *before* you begin;
4. It provides co-investigators or peers with a living and dynamic document for contribution and early review prior to its completion;
5. It allows research staff, whether at the same location or at multiple locations (in the case of a multi-centre study), to carry out the study in exactly the same way;
6. It acts as a record and reminder for the research team and collaborators of the initial project aims, stated procedures and researchers’ duties and responsibilities;
7. It enables stakeholders to monitor the progress of the project;
8. It provides the basis for funding and/or human research ethics applications (including budgetary information); and
9. It provides a framework for resulting publications.

It is recommended that the protocol should always be developed prior to the completion of a National Ethics Application Form (NEAF) or Low and Negligible Risk (LNR) Research application form. The protocol will then guide the answers to the NEAF and LNR Research application questions.

**ACKNOWLEDGEMENTS**

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Some sections of the guidance document have been extracted, with permission, from the research protocol templates of the Royal Children’s Hospital, Melbourne.

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# SUGGESTED **FRONT PAGE – ALL RESEARCH STUDIES**

**FULL STUDY TITLE**

A well-constructed study title is important as it is the first opportunity to attract the attention of the reader. The study title should be descriptive, although clearly and concisely indicating the subject of inquiry. Having a refined research question can assist in constructing a title. This will ensure that your study title reflects (if appropriate) the patient population, intervention (e.g. medicinal product or device), comparator (e.g. another intervention, placebo or usual care) and outcome. You might also consider incorporating the design type (e.g. a randomized controlled study, case-control study, or retrospective cohort study) as is recommended to improve the reporting of health research (e.g. Consolidated Standards of Reporting Studies, or CONSORT)”.

**SHORT TITLE OR ACRONYM**

You can also include a ‘lay’ (short ‘public’ or ‘simplified’) title easily understood by non-medical or interdisciplinary persons and/or an acronym.

**LAY DESCRIPTION OF THE PROJECT (2-3 LINES ONLY)**

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.

**WORDING TO STATE STUDY WILL BE CONDUCTED IN COMPLIANCE RELEVANT LEGISLATION AND GUIDANCE DOCUMENTS**

As a researcher, you are obligated to conduct your research in such a way that, at all times, it complies with:

* Your respective professional Code/s of Conduct, e.g. Australian Medical Association Code of Conduct for Medical Practitioners. If you are a specialist, for example a pathologist, you may have more than one professional Code of Conduct;
* Any requirements as defined by your Board/s of professional registration e.g. Australian Health Practitioner Regulation Agency;
* Catholic Health Australia (2001). Code of Ethical Standards for Catholic Health and Aged Care Services in Australia
* Current best practices in the field or discipline of your study, including offering best current clinical practices and treatments in all arms of your study;
* Current best practice in ethics including abiding by the *National Statement* and all other relevant NHMRC standards;
* Relevant State and Commonwealth Acts and legislations; and
* Relevant Institutional policies and procedures (available on Mater DocuCube).

As part of your study design, you would have illuminated relevant issues, for example, data gathering and storage, and you would have researched and addressed how you will manage these issues in compliance with the relevant Codes of Conduct, policies and legislations, and institutional requirements. Under Common law, ignorance is not a defense and it is important to ensure you are conducting your research in a lawful and ethical way.

**STUDY INVESTIGATOR(S)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Phone** | **Email** | **Institution** | **Study Role (e.g. Principal Investigator)** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

## **SUGGESTED RESEARCH PROTOCOL TEMPLATE HEADINGS (delete those not applicable)**

## **INTRODUCTION**

## **BACKGROUND**

## **AIM(S) OF STUDY**

### Primary Aim(s)

### Secondary Aim(s)

## **OBJECTIVE(S)**

### Primary Objective(s)

### Secondary Objective(s)

## **HYPOTHESI(E)S**

### Primary Hypothesi(e)s

### Secondary Hypothesi(e)s

## **STUDY DESIGN**

## **STUDY SETTING/LOCATION(S)**

## **STUDY DURATION**

## **STUDY POPULATION**

### Recruitment Process

### Inclusion criteria

### Exclusion criteria

### Potential for Risk, burdens and benefits

## **STUDY OUTCOMES**

### Primary Outcome

### Secondary Outcome(s)

## **STUDY PROCEDURES**

### Recruitment and consent of participants

### Withdrawal of participants from a study

#### 12.2.1 Participant withdrawal from study procedures

#### 12.2.2 Participant withdrawal from a study

### Randomisation

### Measurement tools used

### Study involvement by participants

### Data management

### Safety considerations/Patient safety

### Data monitoring

## **SAMPLE SIZE AND DATA ANALYSIS**

### Sample size and statistical power

### Data analysis plan

## **ETHICAL CONSIDERATIONS**

## **DISSEMINATION OF RESULTS AND PUBLICATIONS**

## **OUTCOMES AND SIGNIFICANCE**

## **BUDGET**

## **GLOSSARY OF ABBREVIATIONS**

## **REFERENCES**

# GUIDANCE RELEVANT TO ALL RESEARCH

## **INTRODUCTION** *(the Introduction and Background sections are sometimes combined into one section depending on the complexity of the study)*

The introduction is a very brief overview of study (~250 words). The introduction should be concise but sufficient to orientate the reader to the main purpose of the study, how it will be conducted and its expected benefits. It is a structured sketch of the study that will provide an overview before examining the details. It is placed at the head of the protocol but is often written after the protocol itself is completed.

## **BACKGROUND** *(see also specific guidance regarding clinical audits and qualitative research)*

The most important aspect of a research proposal is the clarity of the research problem. This is an opportunity to 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 key points may be used as a guide:

* Conduct a comprehensive literature search using databases such as Cochrane, Medline and Embase. A comprehensive literature review should include aspects such as the magnitude, frequency, affected geographical areas, ethnic and gender considerations of the problem and should be followed by a brief description of the most relevant studies published on the subject. The UQ/Mater McAuley Library is a valuable resource for researchers on campus for assistance or advice on developing an optimal search strategy. The library also offers a literature search service for staff registered to use library services. The literature review should logically lead to the statement of the aims of the proposed project.
* Discuss the importance of the topic (public health and/or clinical importance and impact on individuals/community, 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 study worth doing).
* Indicate how the research question has emerged and fits logically with the above.
* Explain how your study will contribute to existing research and benefit other individuals or the wider community.

## **AIM(S) OF STUDY** *(see also specific guidance regarding clinical audits)*

Aims are broad but concise statements of what the research study hopes to accomplish. They create a setting for the remainder of the research protocol. Your aim(s) should arise from your literature review and state what the study hopes to accomplish.

## **OBJECTIVE(S)** (*see also specific guidance regarding clinical audits and qualitative research)*

Your focused research question needs to be further refined into one or more study objectives that relate to your aim. Specific objectives are statements of the research question(s). The study objective(s) should be single and measurable/quantifiable statement(s) that will allow you to answer your research question. There is usually only one primary objective. Ensure that the text supports the chosen study endpoints and that it is specific (not nebulous, open-ended or otherwise not assessable) and objective. Avoid biased statements that might suggest the author has prejudiced the outcome*.*

### Primary Objective(s)

The primary objective reflects the main clinically relevant goal of the study. Every study must have a primary objective. Define the primary objective in terms of what will be measured in a single, clear and concise statement.

### Secondary Objective(s)

A study may or may not have secondary objectives. Delete this heading if there are no secondary objectives. Secondary objectives may or may not be hypothesis-driven and may include more general non-experimental objectives (e.g. to develop a registry, to collect natural history data).

The number of objectives should be kept low as too many objectives may make the study logistically difficult to perform. Also consider that the sample size calculation is based on the primary objective and it may not be possible to satisfy other objectives with this number. The objectives should be stated in clear, concise and specific statements.

## **HYPOTHESI(E)S** *(Quantitative research only – not relevant to clinical audits and qualitative research)*

Hypotheses are more specific than objectives and are amenable to statistical evaluation. Research hypotheses are the specific testable statements made about the independent and dependent variables in the study. The hypothesis translates the research question into an evaluation of the expected outcomes.

### Primary Hypothesi(e)s

Your primary hypothesis is your statement of the hypothesised effect of the primary outcome measure. A hypothesis is worded very simply and written as ‘testable’ statements. Your experimental results will prove or disprove your hypothesis.

### Secondary Hypothesi(e)s

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** *(see also specific guidance regarding qualitative research)*

State the methodology and design of the research (e.g. randomised controlled study, cross-sectional survey, prospective or retrospective cohort/case-control). 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). The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology.

The same study can be described in several ways, and as complete a description of the study as possible should be provided. For example, a study may be described as being basic science research, epidemiologic or social science research, it may also be described as observational or interventional; if observational, it may be either descriptive or analytic, if analytic it could either be cross-sectional or longitudinal etc. If experimental, it may be described as a controlled or a non-controlled study.

An appropriate and well thought out methodology is important.The potential for future benefit/s to knowledge and society is dependent on the scientific integrity of your study, and this is the ethical justification for embarking on projects that create burden and impose risk on researchparticipants.

|  |
| --- |
| **KEY QUESTIONS:**  1. Is my aim clear and concise?  2. Do my objectives clearly relate to my aim?  3. Does my hypothesis relate to my aim?  4. Have I designed the study in a way that will enable me to achieve my aim and prove or disprove my hypothesis? |

## **STUDY SETTING/LOCATION(S)**

The location(s) of where the study will be conducted. 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) and who is the coordinating centre. It is important to be mindful of other studies being conducted in the same location or among the same population as your study and to address any potential issues arising from this including limited staff resources.

## **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 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. You should justify your inclusion and exclusion criteria in this section. Note: Lack of research funding and time limitations are not valid reasons for excluding Indigenous and Torres Strait Islander populations, and English as Second Language (EASL) persons from participating in a research study.

### Inclusion criteria

Inclusion criteria are the ‘characteristics’ that clearly describe the study population that are required for a participant to be included in the study. The criteria may be based on factors such as age, gender, the type and stage of a disease, previous treatment history, and co-morbid medical conditions. If certain criteria will be assessed using existing clinical tools these should also be stated. They may state appropriate criteria for admitting special ‘at-risk’ populations such as women of reproductive age, children or patients with disease states or organ impairment.

### Exclusion criteria

Provide details of participants that 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 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).

### Potential for risk, burdens and benefits to participants

Identify and address any issues relating to any potential risk or burdens to participants. This includes managing risks and burdens relating to the protection of their data and privacy, and the potential future impact of being involved in this study (e.g. potential for surreptitious results to be revealed during studies involving DNA).

|  |
| --- |
| **KEY QUESTIONS:**  1. What other ongoing projects are being conducted in the population I would like to study? Are there enough potential participants for recruitment to my project to be successful?  2. Who will approach potential participants, and are they professionally registered and employed by MHS or Mater Research?  3. Can I adequately justify my inclusion criteria (i.e. scientific, practicality, limited resources)?  4. Can I adequately justify my exclusion criteria (i.e. scientific, practicality, limited resources)? |

## **STUDY OUTCOME(S)** *(see also specific guidance regarding qualitative research)*

### Primary Outcome(s)

The primary outcome should be the most important and clinically relevant outcome (e.g. clinical, psychological, economic, other) of the study. This is the measure used to answer your research question, and should relate directly to your primary aim(s) and objective(s). However, it is also the outcome used to calculate study sample size and power and test the primary research hypothesis. Generally, no more than 1-2 primary outcome measures are pre-specified, as the greater the number of primary outcome measures, generally the higher the number of participants required. Primary outcome measures may be measured in various ways such as: binary (e.g. caesarean/no caesarean, blood loss ≥500mL/blood loss <500mL); continuous (e.g. weight - kg, blood loss - mL); ordinal (e.g. pain - mild, moderate, severe); time to event (e.g. survival), and counts (e.g. number of infections, number of events occurring).

### 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 (e.g. treatment related side effects/adverse events). However, as these endpoints are not used to calculate study power and sample size it is often not possible to draw robust conclusions from the results.

## **STUDY PROCEDURES**

This section should describe exactly what is going to happen during conduct of the study. It is preferable to use the active voice and state in the future tense (e.g. “We will randomly allocate participants to…”).

### Recruitment and consent of participants *(see also specific guidance regarding clinical audits)*

The process of informing and consenting participants is very important. For consent to be considered valid, potential participants must be given enough information, in a way they can understand, about the potential risks and benefits of being involved in clinical research. Successful informed consent transactions are recognition that a participant has waived their right to specific ethical, legal and social rights. Properly used, informed consent can render actions permissible that would otherwise be actionable under Tort law, including negligence, battery, trespass, false imprisonment, and assault among others.

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 will be obtained. 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.

Consent may be written, oral or implied (e.g. returning a questionnaire or completing an online questionnaire). Information on how informed consent is to be obtained should be included. This may need to include allowances for special population groups (e.g. children, Aboriginal and Torres Strait Islander) where applicable. If the research involves more than one group of individuals, for example healthcare users and healthcare providers, a separate specifically tailored informed consent form must be developed for each group and included as appendices.

Will all adult participants have capacity to give informed consent? If not, describe the likely range of impairment and explain how and by whom their capacity to consent will be determined. Individuals who lack capacity to consent may take part in research only if consent is given on their behalf by a legally authorised representative or if a waiver of consent has been granted by the reviewing HREC.

If applicable provide information regarding consent/assent forms that will be used in the research, e.g. adult consent form, youth or adolescent consent form (13-17 years) and child assent form (7-12 years).

If consent is not being sought, the rationale for not obtaining consent needs to be explained and if a waiver of consent from the Human ResearchEthics Committee is required. Please refer to the as *National Statement on Ethical Conduct in Human Research Chapter,* Section 2.3 for information about justifying any requests for waiving consent.

### Withdrawal of participants from a study

For all interventional studies and some observational studies, depending on the data being collected, a ‘Withdrawal of Consent’ form should be developed.

#### 11.2.1 Participant withdrawal from study procedures

If a participant withdraws from the interventional study procedures but not from the study itself then the participant data collected up to the time of withdrawal from the study procedures should still be considered in the data analysis. This must be explained in the participant information sheet. A study’s reliability may be compromised when participants withdraw their data (e.g. because they are unhappy with their experience, they failed to obtain a desired effect or suffered an adverse event). Loss of these participants’ data could greatly distort effectiveness results and could hide important safety information (e.g. toxicity) of a poorly tolerated treatment.

If possible, data collection should continue, if this does not overburden the participant (e.g. continue to collect participant data from the medical records, patient outcome data). The investigator must obtain the participant’s informed consent for this limited participation in the study.

#### 11.2.2 Participant withdrawal from a study

Data collected on study participants up to the time of withdrawal must remain in the study database in order for the study to be scientifically valid. This must be explained in the participant information sheet. If a participant withdraws from a study, removal of already collected data would undermine the scientific, and therefore the ethical, integrity of the research.

|  |
| --- |
| **KEY QUESTIONS:**  1. Who will be procuring consent, and are they an appropriate person? Will it be me, or will it be a third party, e.g. a clinical trial nurse?  2. Have I ensured that the principles of informed consent have been adhered to?  3. Is my documentation written in such a way that potential participants will easily understand what they are consenting too?  4. Have I tested the documents on my peers for readability?  5. Have I ensured that information is being presented to participants in an unbiased way so that they may make an informed choice?  6. Have I considered the potential for participants to feel coerced into being involved in my research project, for example, if we have an unequal relationships (junior staff-manager, student-teacher), or if I am their treating health practitioner? How have I addressed these concerns (i.e. nominated another person to approach or consent participants)? |

### Randomisation *(randomised studies only)*

Include the method (including any software) used to generate the random allocation sequence. Describe the type of randomisation performed, ratio of assignment to groups, block size permutation and stratification if applicable. Explain the methods used to conceal group allocation until assignment. Also, include information on who will generate the allocation sequence and who will assign participants into their groups.

This section should also discuss if participants, the investigator, and those assessing/analysing the outcome(s) will be blinded (or masked) to group assignment or if the study will be an open-label study (investigators and participants know their assigned group).

### Measurement tools used *(see also specific guidance re qualitative research)*

It is essential to state how the data will be collected to assess the primary and secondary outcome(s) of the study (e.g. patient questionnaire, medical charts, routinely collected hospital/research database, biological specimens). 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. 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).

Explain in detail your procedure for data collection. Describe the kind of data you will collect (e.g. field notes from memory, audio tapes, video tapes, transcripts of conversations, examination of existing documents).

Develop a data collection form based on the information you want to collect. Only collect what is absolutely necessary. The data collected should relate to the objectives of the study:

* To ensure that the data collected are precise, and that only essential data are collected, the details of what is to be collected must be established from the outset.

Informally pilot the data collection form with colleagues to make sure that it is giving you the data you need to know.

### Study involvement by participants

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, when they will be randomised, the frequency and duration of visits, 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 treatment(s)/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 treatment schedule. 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.

Describe plans to compensate participants for their time, transport and other expenses. Indicate whether payment will be prorated and whether it will be in cash or kind. If participants will not be compensated, this must be stated in the informed consent form.

**Clinical trials:** Describe what plans are in place to manage participants at the end of the study; in particular indicate if the investigational drug, if shown to be safe and efficacious, will be offered to participants when the study ends and under what circumstances.

### Data management and storage

The protocol should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification. The protocol should explain:

* Who will collect the data?
* Where will you get the data from?
* What time period will you use? (i.e. start date and finish date)
* How will the data be collected and stored: non-identifiable, de-identified or re-identifiable?
* The actual plan for storing your data. This may involve designing a coding system for your data. The data must be stored in such a way that it is both secure and conforms to legal requirements (for further information see Mater policy MHS-HRES-CRSU-1.05).
* How and when will the data be disposed of at the completion of the study? (for further information see Materpolicy MHS-IM-HIS-2.51)

### Safety considerations/Patient safety *(see also specific guidance regarding qualitative research)*

The wellbeing and safety of participants in research, including patients who participate in research, are the paramount considerations at all times. The protection of research participants takes precedence above all other consideration including the potential for your study to contribute to new knowledge in your field. If you are also a registered clinical or health practitioner, the utmost importance afforded to your protecting and promoting the wellbeing of your patients (your ‘*Duty of Care’*) is defined and supported in the relevant Codes of Conduct, policies and duties of your respective registering boards. This may extend to the reporting of any notifiable conditions and illegal activities that you uncover in conducting your research project. You will need to provide adequate information on how the safety of research participants will be ensured. This can include procedures for recording and reporting adverse events (AEs), serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSAR) and their follow-up (mandatory requirement for studies involving intervention or treatments including device trials). Details should include the definition of an AE and SAE and the reporting timeframes.

Remember that even administering a research questionnaire may have adverse psychological effects on susceptible individuals. For example, in the case of interviewing victims of violence, the interview may trigger painful experiences and the participant may become distressed during the interview. How will this be addressed? The interview may open new risks to both researchers and participants. Researchers may be required by law to report information about child or elder abuse, drug traffic, or crimes. How will these be addressed?

You will need to consider and articulate how the quality of the technical aspects have been assured, the potential risks and proposed benefits of the project 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 project and how the participants are informed of the project.

In the event that your study incurs an AE or a SAE, you will need to ensure that you report the incident as per institutional requirements. For the most recent information about what is required by Mater, please refer to the Research Ethics and Governance pages on the Mater website. Adverse events and serious adverse events are categorised according to following:

**Pharmacology Studies**

An SAE is defined as any **unexpected** medical occurrence that:

* results in death;
* is life-threatening;
* requires in-patient hospitalisation or prolongation of existing hospitalisation;
* results in a persistent or significant disability/incapacity;
* is a congenital anomaly/birth defect; or
* is a medically important event or reaction.

An event should be considered **unexpected** if the nature, severity or frequency of that event is not consistent with the information in the Investigator’s Brochure, if the product or device being trialled is unapproved, or if it is not documented in the current Australian Product Information if the product is approved for marketing.

For more information on adverse events or serious adverse events reporting relating to therapeutic products, please refer to the NHMRC website: <http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf>

**Medical Devices**

Medical device adverse incidents (AE) involving actual harm caused to a patient/caregiver, or that could have resulted in harm should be notified to the facility's Research Governance Office who should coordinate reporting to external organisations, such as the supplier of the device and the TGA. These events should be investigated as quickly as possible.

Typical causes of AEs with medical devices include:

* multifactorial causes
* mechanical or material failure
* design issues
* labelling, packaging or manufacturing errors
* software deficiencies
* device interactions
* user/systemic errors

For more information on reporting adverse events or incidents related to the use of medical devices, please refer to the TGA website: <http://www.tga.gov.au/hp/problem-device-reporting-incidents.htm>

|  |
| --- |
| **KEY QUESTIONS:**  1. During my literature review, what medical or clinical indications were noted or caused attrition or withdrawals in other studies? Have I included these as possible adverse events in my study?  2. During my literature review, what adverse events, and serious adverse events occurred in other studies? Have I clearly accounted for their potential in this study? Have I devised a plan to survey, manage and report if any of these events, or others arsing, occur during my study?  3. Have I included my/Principal Investigator contact details for participants to use in the event that they experience an adverse events, or serious adverse event? |

### Data monitoring

This section includes information on the personnel and processes of the Data and Safety Monitoring Committee or the use of study monitors to audit study conduct. This should include, at a minimum, any pre-specified stopping and discontinuation rules, committee membership and frequency of meetings.

## **SAMPLE SIZE AND DATA ANALYSIS**

### Sample size and statistical power *(see also specific guidance regarding clinical audits and qualitative research)*

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. This number is calculated by specifying the magnitude of the effects that are expected (i.e. informed and clinically significant), variability of the measurements and the acceptable degree of type I and II errors. You need to specify the assumptions made for the calculation. It is recommended that you consult with a statistician for this section. Also keep in mind the estimated recruitment rate and whether you need to adjust for anticipated non-responders and losses to follow up.

### Data analysis plan *(see also specific guidance regarding clinical audits and qualitative research)*

The statistical methods used for the study objectives/hypotheses (e.g. t-test, chi-squared, multivariate modeling) must be sufficiently detailed, and relate to your study aims and objectives. If conducting a randomized controlled study, you should state whether methods will include an “intention to treat” (ITT) analysis, per protocol analysis, or both. An ITT analysis is preferred as it compares all participants in the groups to which they were originally randomly assigned (despite withdrawal, treatment failure or cross-over). 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. Consultation with a statistician is strongly recommended.

## **ETHICAL CONSIDERATIONS** *(delete this section if you have included all relevant aspects in other sections)*

In the preceding sections you will have considered and articulated:

* Relevant professional, ethical, legal and institutional requirements;
* How the quality of the technical aspects have been assured;
* The potential risks and proposed benefits of the study procedures;
* Responsibility for liability of injury during the study;
* The priority of the participants’ interests over those of science or of society and how those interests will be safeguarded; and
* How they give voluntary consent to participate.

These ethical considerations can be transposed into your ethics application. In the application you are effectively stating that your study will be conducted in full conformance with the principles of the National Statement on Ethical Conduct in Human Research, and all other relevant guidance documents and within the laws and regulations of the country in which the research is conducted.

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. For further information see the *National Statement on Ethical Conduct in Human Research* and see the Mater Human Research Ethics Coordinator for advice and guidance on your particular study.

*Additional information regarding Participant Information Sheet and Consent Forms (PICF) birth control wording.*

This wording is not required to be inserted in the protocol and is inserted here for information only. The following wording complies with the Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001) wording for Participant Information Sheet and Consent Forms (PICF) used in research studies regarding birth control.

**Section #. Pregnancy**

Because of the [known/unknown] effects of the [trial/study medication], women must not become pregnant [and/or breastfeed] during the course of this trial/study. You should discuss with your GP/treating doctor or trial/study doctor about the need to avoid pregnancy, if you choose to participate in this trial/study.

If you become pregnant while participating in this trial/study you should notify your treating doctor/GP and the trial/study doctor immediately. Your treating doctor/GP or trial/study doctor will withdraw you from the trial/study and advise you on further medical treatment should this be necessary.

The PICF may also include the following paragraph if relevant:

**Section #. Fathering a child**

Because of the [known/unknown] effects of the [trial/study medication], men must not father a baby during the course of this trial/study and should inform their partner about this requirement.

You should discuss this requirement to avoid pregnancy with your treating doctor/GP or trial/study doctor. You must advise your treating doctor and the trial/study doctor if your partner is currently pregnant, or becomes pregnant while you are participating in this trial/study.

## **DISSEMINATION OF RESULTS AND PUBLICATIONS** *(see also specific guidance regarding clinical audits)*

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. Refer to the International Committee of Medical Journal Editors requirements for authorship: <http://www.icmje.org/ethical_1author.html>.

## **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.

The protocol should indicate how the study will contribute to advancement of knowledge, how the results will be utilised, not only in publications but also how they will likely affect health care, health systems, or health policies.

## **BUDGET**

The budget section should contain a detailed item-wise breakdown of the funds required to successfully complete the study, including details of any funds requested, along with a justification for each item.

## **GLOSSARY OF ABBREVIATIONS**

All abbreviations used in the project plan, including appendices, should be listed with an explanation of each abbreviation. Accepted international medical abbreviations should be used. Project specific abbreviations should be standardised within the project plan. All abbreviations should be spelled out when first used in the text, followed by the abbreviation in parentheses.

## **REFERENCES**

Include all references used throughout the application.

# ADDITIONAL GUIDANCE RELEVANT TO CLINICAL AUDITS

## **INTRODUCTION**

See general guidelines

## **BACKGROUND**

The background gives the information on why you are conducting the project e.g. assessing your clinical practice. If you are looking critically at clinical care you need to identify evidence of good clinical practice standards on which to base your assessment. A literature review can ascertain if there are any recommended standards on which to base your clinical practice and to find out about any previous projects which have been conducted on your specific topic to help you in designing your audit, especially the method of data collection. The literature review may give guidance regarding the estimated sample size and is it large enough to achieve the aims of the project and is representative of the audit population as a whole?

Clinical audits relate specifically to reviewing current standards, systems or processes of care with the aim of improving outcomes for patients or improving service delivery. Clinical audits do not usually involve assessing new interventions, new treatments or new methods of service delivery; this is usually considered research (National Statement Chapter 3.3). A clinical audit may be undertaken to provide data for the development of a research project. Note: HREC approval would be required in order to use the data from the clinical audit in the research project.

## **AIM(S) OF STUDY**

The project may be conducted to provide data to inform the development of clinical standards and guidelines, especially if no higher level evidence is available, or to guide further review of clinical practice.

## **OBJECTIVES**

Having decided on the topic area it is helpful to clearly define your clinical audit objectives, why you are doing the project and what you are hoping to achieve as a result. This will facilitate the setting of standards and development of data collection methods at a later stage. Targets should be set at realistic and attainable levels, while not being set too low. When setting targets the following factors should be considered:

• Clinical importance

• Practicability

• Acceptability.

## **HYPOTHESIS** *(heading can be deleted)*

Clinical audits, because of their limited nature, should not state a hypothesis. The information from clinical audits can be used to generate hypotheses for research studies.

## **STUDY DESIGN**

See general guidelines

## **STUDY SETTING/LOCATION**

See general guidelines

## **STUDY DURATION**

See general guidelines

## **STUDY POPULATION**

See general guidelines

## **STUDY OUTCOMES**

See general guidelines

## **STUDY PROCEDURES**

### Recruitment and consent of participants

If consent is not being sought, the rationale for not obtaining consent needs to be explained. Generally, a clinical audit can be undertaken without consent of the patients if:

* The project carries only low or negligible risk;
* It is impractical to obtain consent;
* The project follows the National Privacy Principles (in particular National Privacy Principle 2.1 a): http://www.privacy.gov.au/materials/types/infosheets/view/6583; **AND**
* The activity does not seek to gather information about the patient beyond that collected in routine clinical care.

### Withdrawal from study *(heading can be deleted)*

Not relevant to clinical audits

### Randomisation *(heading can be deleted)*

Not relevant to clinical audits

### Measurement tools used

See general guidelines

### Study involvement by participants

See general guidelines

### Data management

See general guidelines

### Safety considerations/Patient safety

See general guidelines especially in relation to questionnaires

### Data monitoring (heading can be deleted)

Not relevant to clinical audits

## **SAMPLE SIZE AND DATA ANALYSIS**

### Sample size and statistical power

* How will you select your sample? (How many participants do you need?) Sample size should be based on your primary outcome measure.
  + You need to be sure that the information you collect from auditing your sample is similar to what you would collect from auditing your whole population. Therefore, you need to ensure that your sample size is large enough and is representative of your audit population.
  + There is no ideal number as to exactly how many participants should be included and it will depend on the intervention being audited, the amount of information being collected, how easy it will be to obtain that information and the resources available.
* It is necessary first to define the population to which the project applies; for example, all patients presenting with urinary retention during a specific year.
* It may be impractical to collect data on every patient in the population, so other sampling methods may be used instead. Methods may include:
  + A time frame: e.g. all women referred to the breast clinic in a one-month period.
  + A consecutive sample: Choose the first agreed number of participants after an agreed start date, e.g. the last 100 referrals.
  + Random sampling: Assumes your audit population will remain the same throughout the audit period and that each participant will have an equal chance of being chosen, e.g. every 8th patient presenting at the clinic.
  + Interval Sampling: Assumes your audit population will change over the period of the audit. In these circumstances, the audit sample is often determined by a period of time, e.g. all donors deferred during May and June.
  + Convenience Sampling: a non-scientific method of sampling where you take the convenient sample available, e.g. if you were interviewing blood donors, you would just pick donors from those available at the time when you are interviewing.

If you are unsure of the most appropriate method of sampling for your study it is recommended to consult with a statistician.

### Data analysis plan

When analysing your data you will generally want to try to reach conclusions about:

* The general pattern of actual practice;
* The degree to which actual practice (results of audit) is meeting the standards set;
* Those cases for which it is clinically acceptable for the standards not to be met; and
* The limitations of the project.

Analysing audit data does not usually require complex statistical tests, although these may be necessary in certain situations. The type of data you have collected will determine the type of analysis employed. The following approaches may be used in analysing your data:

* **Descriptive Statistics.** This is where the data are described numerically. You may wish to calculate:
  + The frequency of certain events/values occurring (i.e. rates and percentages);
  + Estimates of the central point of your data, such as the mean or the median; and
  + Estimates of the variability of your data, such as the standard deviation, interquartile range or range.
* **Statistical Tests.** These may be used:
  + When conducting an outcome audit, for example comparing ‘before’ and ‘after’ results on questionnaires to find out whether there has been a statistically significant improvement in the client symptom scores; or
  + When wanting to show whether the results you have obtained can be attributed to chance variation.

Where open-ended questions have been asked as part of the clinical audit project, qualitative data will be obtained. There are a number of ways of analysing qualitative data. It may be possible, for example, to conduct a content analysis of the major recurring themes and a frequency count may then be performed.

## **ETHICAL CONSIDERATIONS**

If the clinical audit involves more than assessing or comparing current, existing practices it is categorised as research and would require an ethics review. Other ethical considerations include:

* Does the proposed activity pose any risk, burden or inconvenience for patients beyond that experienced or imposed as part of their routine clinical care?
* Does the proposed activity pose any risk to maintaining patient confidentiality and privacy?
* Is the proposed activity to be conducted by a person who does not normally have access to the patient records for clinical care or a directly related secondary purpose?

At the Mater Health Services, quality improvement / clinical audit exercises within a department may usually be undertaken by departmental staff without formal ethical review if:

* The exercise is directly related to the functionality of the department and
* Is undertaken by staff who would normally have access to the information / patients through normal clinical care and
* The information will be used solely for  internal departmental use and
* The project is using routinely collected data and
* The project is assessed as per the [National Statement on Ethical Conduct in Human Research](http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_0.pdf)  by a departmental head who has a thorough working knowledge of the National Statement.

The primary focus must, of course, always be the assessment of risk and protection of participants as per Section 2 of the National Statement.

## **DISSEMINATION OF RESULTS AND PUBLICATIONS**

Discussing the results of the clinical audit project with key stakeholders is an essential exercise through which areas of practice which need to be changed can be identified and agreed. What actions will be taken for an action plan to be developed after this project results have been finalised?

## **OUTCOMES AND SIGNIFICANCE**

See general guidelines

## **BUDGET**

See general guidelines

## **GLOSSARY OF ABBREVIATIONS**

See general guidelines

## **REFERENCES**

See general guidelines

# ADDITIONAL GUIDANCE RELEVANT TO QUALITATIVE RESEARCH

## **INTRODUCTION**

See general guidelines

## **BACKGROUND**

Broadly speaking, describe what you intend to accomplish through this research (e.g., expanding a knowledge base, developing a grounded theory, emancipating informants, establishing the trustworthiness of a theory, investigate how communities and individuals interpret and make sense of their experiences etc.).

## **AIM(S) OF STUDY**

See general guidelines

## **OBJECTIVES**

A good qualitative study will address a problem / issue through a clearly formulated question.

## **HYPOTHESIS** *(heading can be deleted)*

Qualitative research studies generally do not state a hypothesis and therefore this heading can usually be deleted for qualitative research studies. Qualitative research usually begins with an intention to explore a particular area, collects “data” (observations and interviews), and then may generate ideas from these data largely through what is known as inductive reasoning.

## **STUDY DESIGN**

Qualitative researchers may use different research paradigms to answer the research questions including critical theories, post-modernist, feminist approaches, constructivism, grounded theory, classical ethnography, phenomenology. Qualitative methods are also loosely present in other methodological approaches, such as action research or actor-network theory. Use specific language to name and describe your research paradigm, and justify the use of the chosen paradigm. Explain the type of relationship that the researcher will have with the informants (e.g. unobtrusive observer, participant observer, collaborator, emancipation).

## **STUDY SETTING/LOCATION**

See general guidelines

## **STUDY DURATION**

See general guidelines

## **STUDY POPULATION**

See general guidelines

## **STUDY OUTCOMES**

The research questions often evolve as the study does, because the researcher wants to know “what is happening” and may not want to bias the study by focusing the investigation too narrowly.

## **STUDY PROCEDURES**

### Recruitment and consent of participants

See general guidelines

### Withdrawal from study

See general guidelines

### Randomisation

Not relevant

### Measurement tools used

The strength of qualitative research lies in validity (closeness to the truth) - that is, good qualitative research, using a selection of data collection methods, really should touch the core of what is going on rather than just skimming the surface. The validity of qualitative methods is greatly improved by using a combination of research methods, a process known as triangulation, and by independent analysis of the data by more than one researcher. Forms of the data collected can include interviews and group discussions, observation and reflection field notes, various texts, pictures, and other materials. Some distinctive qualitative methods are the use of focus groups and key informant interviews.

**Interview & focus group questions**

Briefly explain the purpose of the interview, relate to the qualitative tradition and research design. If possible, provide a list of interview questions or the format of the focus group.

**Questionnaire & interview considerations**

* Describe interview methodology (i.e. open-ended questions, semi-closed questions).
* Describe development or selection of questionnaire.
* Describe any literacy or foreign language concerns or accommodations.
* Indicate whether questionnaire is validated.
* Describe how questionnaire will be tested (e.g., piloted).
* Describe how missing or incomplete information will be handled in analysis.

**Focus group considerations**

* Describe qualifications of facilitator or individual supervising facilitation. Expectations include:
  + Prior experience facilitating groups
  + Adequate knowledge of the topic
  + Understands the purpose of group
* Provide script or discussion questions that will be used in focus group.
* Describe any literacy or foreign language concerns or accommodations.
* Describe how information will be captured.
* Describe how information from focus group will be presented and used.
* How will focus group responses be summarized and integrated?
* How will contradictory responses be handled?
* Will there be thematic or qualitative coding of transcribed discussions?
* Will focus group responses be used to guide the development of education materials, measures, interventions or other research procedures, publication, or inform study design?
* Describe whether information drawn from focus group will be shared with group participants.
* Describe what will be done with any audio, image, video or digital records after the study is completed.

### Study involvement by participants

See general guidelines

### Data management

See general guidelines

### Safety considerations/Patient safety

Although qualitative research methods make it difficult to predict how data will be collected through interviews or observation, researchers have the obligation to anticipate the possible outcomes of an interview and to weigh both benefits and potential harm.

### Data monitoring

See general guidelines

## **SAMPLE SIZE AND DATA ANALYSIS**

### Sample size and statistical power

Describe the purpose of the sampling, characteristics of potential types of persons, events, or processes to be sampled, how decisions about sampling are made, if applicable sample size estimates provided based on previous experience, pilot work, etc. For example: the use of purposeful sampling with explanation and rationale behind the sampling methodology: extreme or deviant case sampling; typical case sampling; maximum variation sampling; snowball or chain sampling; confirming or disconfirming case sampling; politically important case sampling or convenience sampling.

Define guidelines for when the data collection process with be stopped. For example: exhaustion of resources, emergence of regularities or overextension, or going too far beyond the boundaries of the research. The decision to stop sampling must take into account the research goals, the need to achieve depth through triangulation of data sources, and the possibility of greater breadth through examination of a variety of sampling sites

### Data analysis

Whilst it is not necessary to generalise the results, analysis of the data should be done using explicit, systematic, and reproducible methods. The most common analysis of qualitative data is observer impression. That is, expert or bystander observers examine the data, interpret it via forming an impression and report their impression in a structured and sometimes quantitative form. Description of critical themes may be used.

In the conventional view, qualitative methods produce information only on the particular cases studied, and any more general conclusions are only propositions (informed assertions).

Some types of problems that may affect the analysis of qualitative studies are the researcher/participant relationship, the researcher’s subjective interpretations of data, and the design itself.

## **ETHICAL CONSIDERATIONS**

See general guidelines

## **DISSEMINATION OF RESULTS AND PUBLICATIONS**

See general guidelines

## **OUTCOMES AND SIGNIFICANCE**

See general guidelines

## **GLOSSARY OF ABBREVIATIONS**

See general guidelines

## **BUDGET**

See general guidelines

## **REFERENCES**

See general guidelines