**Townsville Hospital and Health Service**

**Guide to writing a research protocol or quality assurance (QA) or clinical audit project plan**

**Guide to writing a research protocol or quality assurance or clinical audit project plan**

A study protocol / project plan is a document which describes in detail the organisation for conducting a research study or quality improvement project. 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 / project plan guidance document aims to offer Townsville HHS researchers and people undertaking QA and clinical audit projects a generic guide suitable for a broad range of research studies, QA and clinical audit for projects being conducted in Queensland. All research studies, including low and negligible risk studies, require a protocol. It is also advisable that all clinical audits / quality assurance projects should have a formal written project plan.

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

* It states the research question you aim to answer;
* It provides a structured, written working plan of the project;
* It encourages adequate consideration and planning of project detail *before* you begin;
* It provides co-investigators or peers with a dynamic document for contribution and early review prior to its completion;
* It allows research staff, whether at the same location or at multiple locations (in the case of a multi-centre project), to carry out the project in a consistent, standardised way;
* 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;
* It enables stakeholders to monitor the progress of the project;
* It provides the basis for funding and/or human research ethics applications (including budgetary information); and
* It provides a framework for resulting publications, including authorship

It is strongly advised that you refer to the NHMRC National Statement on Ethical Conduct in Human Research, 2007 (Updated 2018) and in particular Section 3: *Ethical Considerations in the Design, Development, Review and Conduct of Research* when writing your protocol. Seven elements are covered in Section 3:

Element 1 – Research Scope, Aims, Themes, Questions and Methods

Element 2 – Recruitment

Element 3 – Consent

Element 4 – Collection, Use and Management of Data and Information

Element 5 – Communication of Research Findings or Results to Participants

Element 6 – Dissemination of Research Outputs and Outcomes

Element 7 – After the Project

For research studies, it is recommended that the protocol should always be developed prior to the completion of a Human Research Ethics Application (HREA) form. The protocol will then guide the answer to the questions on the HREA form.

**For novice researchers it is always recommended that completion of the Research Protocol / project plan is done in consultation with an experienced researcher.**

**TIP: Contact the THHS Research Education, Support and Administration (TRESA) Unit:** [**TSV-ResearchSupportUnit@health.qld.gov.au**](mailto:TSV-ResearchSupportUnit@health.qld.gov.au) **for advice, as they can provide support to assist you designing your study and writing your protocol, or visit the TRESA website:** <https://www.health.qld.gov.au/townsville/tresa/index>

**ACKNOWLEDGEMENTS**

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**DISCLAIMER**

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# SUGGESTED **FRONT PAGE OF PROTOCOL / PROJECT PLAN**

**FULL STUDY / PROJECT TITLE**

A well-constructed title is important as it is the first opportunity to attract the attention of the reader. The title should be descriptive, clear and concise, indicating the subject of inquiry. Having a refined question can assist in constructing a title. This will ensure that your 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 randomised controlled study, case-control study, or retrospective cohort study) as is recommended to improve the reporting of health research.

**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 PROJECT WILL BE CONDUCTED IN COMPLIANCE WITH RELEVANT LEGISLATION AND GUIDANCE DOCUMENTS**

As a researcher or a person undertaking a QA or clinical audit project, you are obligated to conduct your project in such a way that, at all times, it complies with:

* Your respective professional Code/s of Conduct
* Any requirements as defined by your Board/s of professional registration e.g. Australian Health Practitioner Regulation Agency
* Current best practices in the field or discipline of your project, including offering best current clinical practices and treatments in all arms of your project
* Current best practice in ethics, including abiding by the NHMRC *National Statement on Ethical Conduct in Human Research* and all other relevant NHMRC and TGA guidelines
* Relevant State and Commonwealth Acts and legislations; and
* Relevant Institutional policies and procedures

**STUDY INVESTIGATOR(S)** **or** **PROJECT TEAM MEMBERS**

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

## **SUGGESTED RESEARCH PROTOCOL / PROJECT PLAN TEMPLATE HEADINGS**

## (Delete those not applicable)

## **INTRODUCTION**

## **BACKGROUND**

## **AIM(S) OF PROJECT**

### Primary Aim(s)

### Secondary Aim(s)

## **OBJECTIVE(S)**

### Primary Objective(s)

### Secondary Objective(s)

## **HYPOTHESIS (HYPOTHESES)**

### Primary Hypothesis (Hypotheses)

### Secondary Hypothesis (Hypotheses)

## **PROJECT DESIGN**

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

## **PROJECT DURATION / TIME LINE**

## **PROJECT POPULATION**

### Recruitment Process

### Inclusion criteria

### Exclusion criteria

### Potential for Risk, burdens and benefits

## **PROJECT OUTCOMES**

### Primary Outcome

### Secondary Outcome(s)

## **PROJECT PROCEDURES**

### Recruitment and consent of participants

### Withdrawal of participants from a project

#### 12.2.1 Participant withdrawal from project procedures

#### 12.2.2 Participant withdrawal from a project

### Randomisation

### Measurement tools used

### Project 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**

## **GLOSSARY OF ABBREVIATIONS**

## **REFERENCES**

# GUIDANCE RELEVANT TO ALL RESEARCH / QA / CLINICAL AUDIT

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

The introduction is a very brief overview of project (~250 words). The introduction should be concise but sufficient to orientate the reader to the main purpose of the project, how it will be conducted and its expected benefits. It is a structured sketch of the project that will provide an overview before examining the details. It is placed at the beginning 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. The background section is an opportunity to convince the reader (or reviewer) of why the project needs to be done (or 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, CINAHL 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 Townsville HHS Library is a valuable resource for THHS researchers 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.
* Critically appraise the relevant literature and discuss the current state of knowledge on the topic (including deficiencies in knowledge or gaps that make the project worth doing).
* Discuss the importance of the topic (public health and/or clinical importance and impact on individuals/community, incidence, prevalence, mortality and morbidity).
* Indicate how the research question has emerged and fits logically with the above.
* Explain how your project will contribute to existing research and benefit other individuals or the wider community.

**TIP: Consult the THHS library staff to assist you with your literature search**

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

Aims are broad statements of what the research project 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 project 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 project objectives that relate to your aim. Specific objectives are statements of the research question(s). The project 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 project endpoints and that it is specific, objective and assessable. Avoid biased statements that might suggest the author has prejudiced the outcome*.*

### Primary Objective(s)

The primary objective reflects the main aim of the project. Every project 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 project 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 project 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.

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

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

**TIP: Contact the THHS Research Support Unit for advice as they can provide support to assist you defining a testable hypothesis**

### Primary Hypothesi(e)s

Your primary hypothesis is your statement of the anticipated effect of the primary outcome measure. A hypothesis is worded very simply and written as ‘testable’ statements. Your experimental results will lead to accept or reject 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.

## **PROJECT 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 project 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 project design has been chosen in preference to other possible designs (i.e. justification for choice of project design). The scientific integrity of the project and the credibility of the project data depend substantially on the project design and methodology.

The same project can be described in several ways, and as complete a description of the project as possible should be provided. For example, a project 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 design.

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

**TIP: Contact the THHS Research Support Unit for advice as they can provide support to assist you designing your study.**

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| **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 project in a way that will enable me to achieve my aim and prove or disprove my hypothesis? |

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

The location(s) of where the project will be conducted. You need to mention whether the project is going to be a single-centre project or a multi-centered project (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 project and to address any potential issues arising from this, including limited staff resources.

## **PROJECT 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.

## **PROJECT POPULATION**

Defining your study group population (i.e. the study participants) provides the context 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 (quantitative research only). 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 e.g. numbers of Aboriginal and Torres Strait islander peoples
* Age range
* Gender

Inclusion and exclusion criteria are standards that you have set to determine whether a person may or may not be eligible to enter your project. 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 Aboriginal and Torres Strait Islander peoples, and or primary language other than English persons from participating in a research project.

If undertaking research which involves Aboriginal and Torres Strait Islander peoples, researchers should refer to the NHMRC guideline documents: *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and*

*communities: Guidelines for researchers and stakeholders* and *Keeping research on track II* and the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) document: *Best practices for Aboriginal and Torres Strait Islander research* when writing their protocol.

### Inclusion criteria

Inclusion criteria are the ‘characteristics’ that clearly describe the attributes that are required for a participant to be included in the project. The criteria may be based on factors such as age, gender, ethnicity, 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

Exclusion criteria are the ‘characteristics’ that clearly describe the attributes that make a participant ineligible to participate in the project. 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 project 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 project (e.g. potential for surreptitious results to be revealed during studies involving DNA).

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| **KEY QUESTIONS:**   1. What other ongoing projects are being conducted with the population I would like to research? Are there enough potential participants for recruitment to my project to be successful? 2. Can I adequately justify my inclusion and exclusion criteria (i.e. scientific, practicality, limited resources)? 3. Have I clearly articulated the potential risks associated with the research e.g physical, psychological, social, legal, emotional etc and how these can be mitigated? 4. Have I clearly explained how the potential benefits to the research participant and or society outweigh the potential risks inherent in the research? |

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

### Primary Outcome(s)

The primary outcome should be the most important relevant outcome (e.g. clinical, psychological, economic, other) of the project. This primary outcome is the measure used to answer your research question, and should relate directly to your primary aim(s) and objective(s). For quantitative research, the primary outcome is also the outcome used to calculate project sample size 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 project power and sample size it is often not possible to draw robust conclusions from the results.

## **PROJECT PROCEDURES**

This section should describe exactly what will happen during conduct of the project. 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)*

**11.1.1 General guidance**

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 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, who will recruit participants to the study, how these recruiters will be trained 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.

**11.1.2 Consent**

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 information may need to include allowances for different population groups (e.g. children, people with language and/or literacy barriers, 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.

**11.1.2.1 Capacity to consent - adults**

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 Human Research Ethics Committee (HREC).

If undertaking clinical research, as defined under the Guardianship and Administration Act 2000, which involves adult participants who are unable to give consent in their own right Queensland Civil and Administrative Tribunal (QCAT) written approval is required. The Guardianship and Administration Act 2000 (the Act) provides that the Queensland Civil and Administrative Tribunal (the tribunal) may approve clinical research. Clinical research under the Act is:

1. medical research intended to diagnose, maintain or treat a condition affecting the participants in the research, or
2. a trial of drugs or techniques involving the carrying out of health care that may include the giving of placebos to some of the participants in the trial.

A comparative assessment of health care already proven to be beneficial to participants is not medical research as defined by the Act, and does not need approval by QCAT.

Approved clinical research is clinical research approved by the tribunal. The tribunal may approve clinical research, which seeks to include persons with impaired decision-making capacity, only if QCAT is satisfied about the following:

1. the clinical research is approved by an ethics committee
2. any drugs or techniques on trial in the clinical research are intended to diagnose, maintain or treat a condition affecting the participants in the research
3. the research will not involve any known substantial risk to the participants or, if there is existing health care for the particular condition, the research will not involve known material risk to the participants greater than the risk associated with the existing health care
4. the development of any drugs or techniques on trial has reached a stage at which safety and ethical considerations make it appropriate for the drugs or techniques to be made available to the participants despite the participants being unable to consent to participation
5. having regard to the potential benefits and risks of participation, on balance it is not adverse to the interests of the participants to participate.

**11.1.2.2 Capacity to consent - children**

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

QCAT does not need to be consulted on matters of research where children are the participants.

**11.1.2.3 Waiver of consent**

If prospective consent is not being sought, a statement that waiver of consent approval will be sought from the Human ResearchEthics Committee (HREC) should be included in the protocol and justified. Please refer to the as *National Statement on Ethical Conduct in Human Research Chapter,* Section 2.3 for information about justifying any requests for HREC approval of a waiver of consent.

In addition to the HREC approval of a waiver of consent, where a researcher wants to use confidential identifiable or potentially re-identifiable confidential health information for research, without the consent of the patient or a legally authorised representative, there are two ways that this may occur in Queensland:

* Approval under Chapter 6 Part 4 of the Public Health Act 2005
* Permission under Section 150 of the Hospital and Health Boards Act 2011
  + For evaluating, managing, monitoring or planning health services

As well as your protocol stating the justification for seeking HREC approval for a waiver of consent a statement on which Act will be applied, providing a rationale on how the Act applies should be included in this section.

**11.1.2.4 Opt out consent**

Opt out consent is not considered legal consent in Queensland. Please refer to the as National Statement on Ethical Conduct in Human Research Chapter, Section 2.3 for information about justifying any requests for HREC approval of opt out consent.

In addition to the HREC approval of opt out consent, where a researcher wants to use confidential identifiable or potentially re-identifiable confidential health information for research, under an opt out consent process, there are two ways that this may occur in Queensland:

* Approval under Chapter 6 Part 4 of the Public Health Act 2005
* Permission under Section 150 of the Hospital and Health Boards Act 2011
  + For evaluating, managing, monitoring or planning health services

As well as your protocol stating the justification for seeking HREC approval for opt out consent, a statement on which Act will be applied, providing a rationale on how the Act applies should be included in this section.

**11.1.2.5 Deferred or delayed consent**

The concepts of ‘deferred’ or ‘delayed’ consent are not supported by the National Statement or by Queensland Health.

They do not exist in the NHMRC National Statement on Ethical Conduct in Human Research and do not constitute any form of consent. The QH legal opinion is this is because it is not possible to obtain a person's consent to something after that thing has already happened. Accordingly, Queensland Health requires that the terms must not be used by researchers or HRECs operating in Queensland Health.

For some studies a waiver of prospective consent to enrol a participant into a study is appropriate, e.g emergency care research, with subsequent prospective consent to continue the participant in the study and use the data for the purposes of research or for the use of deceased patients’ data. Please also note the requirement for approval under Chapter 6 Part 4 of the Public Health Act 2005 or permission under Section 150 of the Hospital and Health Boards Act 2011 as per protocol section 11.1.2.4.

It is acknowledged that in emergency care research, recruitment into a research project often has to be achieved rapidly. Where the research involves emergency treatment and meets the requirements of National Statement Section 4.4.1, consent for the research may be waived provided the conditions of National Statement paragraph 2.3.10 are satisfied.

### 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. This section should describe how a person can withdraw from a study (advising the investigator, filling out the Withdrawal of Consent form etc.), and what the process is to remove them from the study procedures. Consider what options participants will have to withdraw. For interventional studies will follow up continue after withdrawal?

#### 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 and or they failed to obtain a desired effect and 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

As per 11.2.1 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.

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| **KEY QUESTIONS:**   1. Who will be obtaining consent, and are they an appropriate person? Will it be me, or will it be a third party, e.g. a research assistant? 2. How will these people approaching potential participants and obtaining consent be fully informed and provided education regarding the project? 3. Have I ensured that the principles of informed consent have been adhered to? 4. Have I ensured that information is being presented to participants in an unbiased way so that they may make an informed choice? 5. Have I considered the potential for participants to feel coerced into being involved in my research project, for example, if we have an unequal relationship (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)? 6. Is my protocol consistent with what is written in my other research documentation e.g. the participant information sheet and consent form? |

### Randomisation *(clinical trials 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 project (e.g. patient questionnaire, medical charts, routinely collected hospital/research database, biological specimens). Describe at what point(s) of the project data collection will occur. You should make statements that justify the validity of the project 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 project. 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, or a group similar to the actual study participants, to make sure that it is giving you the data you need to know.

**TIP: If accessing patients’ medical files contact the THHS Clinical Information Service when designing your data collection tool, as they can provide advice if the data you require is available and accessible.**

### Project 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 project. Depending on the project it might include how potential participants will be approached, when they will be randomised, the frequency and duration of contacts, whether they are expected to self-complete a daily diary at home, the duration of the project or follow-up, and any measurements taken at each contact (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 participant information 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 and how you will obtain the data
* What time period you will you use (i.e. start date and finish date)
* How the data will 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
* How and when the data will be disposed of at the completion of the project?

### 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 issues 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.

**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.

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| **KEY QUESTIONS:**   1. During my literature review, what medical and or clinical indications were noted or caused attrition or withdrawals in other studies? Have I included these as possible limitations in my project? 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 project? Have I devised a plan to survey, manage and report if any of these events, or others occur during my project? 3. Have I included my/Principal Investigator and/or other contact details on the participant information sheet in the event that the participant experiences an adverse event? |

### Data monitoring

This section includes information on the processes of the Data and Safety Monitoring Committee (DSMC) or the use of study monitors to audit study conduct. This should include, at a minimum, any pre-specified stopping and discontinuation rules, and for the DSMC the committee membership and frequency of meetings. If a DSMC is required separate DSMC Terms of Reference should be developed.

## **SAMPLE SIZE AND DATA ANALYSIS**

**TIP: Contact the THHS Research Support Unit for advice, as they can provide support to assist you with your sample size calculations and data analysis plan.**

### 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 project objectives/hypotheses (e.g. t-test, chi-squared, multivariate modeling) must be sufficiently detailed, and relate to your project aims and objectives. If conducting a randomised controlled project, 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.

## **STORAGE AND DISPENSING ON STUDY MEDICATION / DEVICE** (*clinical trials only)*

This section should explain how the study medication / device will be stored (e.g. special temperature considerations etc.), dispensed and accounted for. Explain what logs etc. will be kept.

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

As part of your project 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.

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.

In the preceding sections you should 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 the participants give voluntary consent to participate in the research.

If the study may impact on Aboriginal and Torres Strait Islander peoples this section should also describe any liaison / communication with the Aboriginal and Torres Strait Islander peoples that will be undertaken. It is imperative that any discussions commence at the study design stage.

## **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 and authorship 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. There should be a plan that describes assignment of authorship and the contributions of each author.

## **OUTCOMES AND SIGNIFICANCE**

It may be of value to reiterate the potential benefits of answering the research question and conducting the project. This section restates the justification for the project in terms of the anticipated results. It may be important to specify the implications of the potential results and how the results of this project may inform future research or policy makers.

The protocol should indicate how the project 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.

## **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 (Non- research projects)

## **INTRODUCTION**

See general guidelines

## **BACKGROUND**

The background gives the information on why you are conducting the audit 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 determine if it is large enough to achieve the aims of the project and if it is representative of the audit population as a whole?

**Note: 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.** **A retrospective medical chart review, which does not compare the findings against current standards, systems or processes of care is generally considered research, not clinical audit and therefore should be submitted to the HREC as such.** In addition, clinical audits do not usually involve assessing new interventions, new treatments or new methods of service delivery; this is also usually considered research. 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.

**TIP: If in doubt if your project is clinical audit or research, consult the HREC Office prior to submitting your application for review.**

## **AIM(S) OF PROJECT**

To review a local standard of care compared to current recognised standards, systems or processes of care, with the aim of improving outcomes for patients or improving service delivery. The project may also 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 it is helpful to clearly define your clinical audit objectives, why you are doing the audit 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.

## **PROJECT DESIGN**

See general guidelines

## **PROJECT SETTING/LOCATION**

See general guidelines

## **PROJECT DURATION**

See general guidelines

## **PROJECT POPULATION**

See general guidelines

## **PROJECT OUTCOMES**

See general guidelines

## **PROJECT PROCEDURES**

### Recruitment and consent of the patients

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 Australian Privacy Principles; **AND**
* The activity does not seek to gather information about a patient beyond that collected in routine clinical care.

### Withdrawal from project *(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

### Project 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; e.g. 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 within 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 a 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 could 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 project 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 may be categorised as research and, if so, would require ethics review and approval. 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 Townsville HHS Health Services, quality improvement / clinical audit exercises within a department may usually be undertaken by departmental staff without formal ethics 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.

**TIP: If a clinical audit conducted at THHS is to be presented in a public forum or published it is required that, prior to the clinical audit being undertaken, the project plan for the clinical audit is submitted to the THHS HREC, with a request for HREC** **endorsement of a non-research project.**

## **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 PROJECT**

See general guidelines

## **OBJECTIVES**

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

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

Qualitative research studies do not state a hypothesis. Qualitative research usually begins with an intention to explore a particular area, collects “data” (e.g. observations and or interviews), and then may generate ideas from these data largely through what is known as inductive reasoning.

## **PROJECT DESIGN**

Qualitative researchers use different research paradigms /methodologies to answer the research questions including critical theories, post-modernist, feminist approaches, constructivism, grounded theory, classical ethnography, phenomenology. 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).

## **PROJECT SETTING/LOCATION**

See general guidelines

## **PROJECT DURATION**

See general guidelines

## **PROJECT POPULATION**

See general guidelines

## **PROJECT OUTCOMES**

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

## **PROJECT PROCEDURES**

### Recruitment and consent of participants

See general guidelines

### Withdrawal from project

See general guidelines

### Randomisation

Not relevant

### Measurement tools used

The strength of qualitative research lies in validity - 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 focus 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 an interview guide or the format of the focus group.

**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.
* Describe how you will obtain the trust of the participants.

**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 guide with suggested questions that may be used in focus groups.
* 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 opposing responses be handled?
* How will the transcribed discussions be analysed?
* Will focus group responses be used to guide the development of education materials, measures, interventions or other research procedures, publication, and or inform project design?
* Describe whether information drawn from focus groups will be shared with group participants.
* Describe what will be done with any audio, image, video or digital records after the project is completed.

### Project 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, features of characteristics of the 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 will be stopped. For example: exhaustion of resources, emergence of regularities or overextension, data saturation or going too far beyond the boundaries of the research. The decision to stop sampling must take into account the research methodology, 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