

Guide to writing a Research Protocol

A research protocol also known as a research proposal, study plan and/or project plan is a document which describes in detail the plan for conducting a research study. The terms study and project are often used interchangeably.

A well written and comprehensive research protocol is essential for a high-quality research project. A research protocol generally follows a conventional layout. There are several templates already available, although most are developed for commercially sponsored randomised controlled studies. This generic guide and research protocol template will assist researchers in the preparation of a well-designed research protocol for a broad range of research studies. All research projects require a research protocol.

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 associate 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 if applicable); and
- It provides a framework for resulting publications.

It is recommended that the protocol should always be developed prior to the completion of a Human Research Ethics Application (HREA) form in the Ethics Review Manager (ERM) system. The protocol will then guide the answers to the HREA questions in ERM.

For novice researchers, it is always recommended that completion of the research protocol is done in consultation with an experienced researcher.

ACKNOWLEDGEMENTS

This document has been adapted with permission, from the Townsville Hospital and Health Service (THHS) 'Guide to writing a research protocol or quality assurance (QA) or clinical audit project plan' developed by Sue Jenkins-Marsh and Nikola Stepanov in consultation with the Townsville HHS Human Research Ethics Committee Office, Research Governance Office and local researchers. Special thanks to Wendy Smyth and Jenny Kelly. Some of this guidance document has been extracted from the research protocol templates of the Royal Children's Hospital, Melbourne and the Mater Research - UQ Brisbane.

The content of this document has been endorsed by the Membership of the Far North Queensland Human Research Ethics Committee (FNQ HREC).

DISCLAIMER

The Authors do not accept any liability for any injury, loss or damage incurred by use of or reliance on the information in this guide. The authors have developed this document based on the best of evidence available at the time of compiling the guide. However, they cannot guarantee and assume no responsibility or legal liability for the currency and completeness of the information.

SUGGESTED FRONT PAGE OF RESEARCH PROTOCOL

FULL 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 research 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 study design type (e.g. case-control study, or retrospective cohort study). Including the study design is recommended to improve the reporting of health research (e.g. Consolidated Standards of Reporting Trials (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 THE PROJECT WILL BE CONDUCTED IN COMPLIANCE WITH RELEVANT LEGISLATION AND GUIDANCE DOCUMENTS IS RECOMMENDED HERE

As a researcher or a person undertaking a research project, you are obligated to conduct your study 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 (AHPRA);
- Current best practices in the field or discipline of your study, including offering best current clinical practices and treatments in all arms of your project;

- Current best practice in ethics including abiding by the *National Statement on Ethical Conduction in Human Research* and all other relevant National Health and Medical Research Council (NHMRC) standards;
- Relevant State and Commonwealth Acts and legislations; and
- Relevant Institutional policies and procedures.

PROJECT INVESTIGATOR(S)

Please ensure only one Principal Investigator (PI) is listed within this section. This person is the investigator responsible for the overall conduct of the research study at an individual site. Please list all members of the research study team designated and supervised by the PI at an individual site. These people are known as Associate Investigators (AI) or Associate Researchers.

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.

SUGGESTED TEMPLATE HEADINGS AND GUIDANCE RELEVANT TO ALL RESEARCH *(delete those not applicable)*

1. 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.

2. BACKGROUND *(see also additional specific guidance regarding 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 (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, 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 literature review should logically lead to the statement of the aims of the proposed project.
- Critically appraise the relevant literature and discuss the state of current 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 literature and research and improve practice and benefit individuals and/or the wider community (e.g. resolve an important theoretical issue, address a major gap in the literature)

3. AIM(S) OF PROJECT *(see also specific guidance regarding qualitative research)*

Aims are broad statements of what the research project hopes to accomplish, and they provide a framework for researchers. 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.

If appropriate, using a framework (e.g. PICO, SPICE, ECLIPSE) may assist you in identifying important concepts in your research aim(s) and/or question(s). The PICO framework is a technique used in research for formulating a clinical research aim(s) and/or question(s) using the following concept model: 1) population / patient / problem, 2) intervention / exposure / indicator, 3) comparison / control (if applicable) and 4) outcome.

4. OBJECTIVE(S)

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 objective 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.

4.1 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.

4.2 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.

5. HYPOTHESIS (HYPOTHESES) *(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.

5.1 Primary hypothesis (hypotheses)

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 (alternative hypothesis) or reject your hypothesis (null hypothesis).

5.2 Secondary hypothesis (hypotheses)

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.

6. PROJECT DESIGN AND METHODOLOGY *(see also specific guidance regarding qualitative research)*

State the methodology and design of the research (e.g. 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 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. A research design should be systematic, empirical, ethical and replicable.

The same project can be described in several ways, and a detailed description of the project 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 study design is important as it explains how you plan to tackle your research problem. The potential for future benefit/s to knowledge, society and practice is dependent on the scientific integrity of your project, including the ethical justification for embarking on projects that create burden and impose risk on research participants.

KEY QUESTIONS TO ASK YOURSELF:

1. Are my research aim(s) and question(s) clear and concise?
2. Do my objectives clearly relate to my aim(s)?
3. Does my hypothesis (hypotheses) relate to my research aim(s) and questions(s)?
4. Have I designed the project in a way that will enable me to achieve my aim and prove or disprove my hypothesis?

7. PROJECT SITE(S) / LOCATION(S)

The site(s) where the project will be conducted. You need to mention whether the project is going to be a single-site project or a multi-site project (i.e., conducted in more than one site) and identify which site is the coordinating site for multi-site projects. 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.

8. PROJECT DURATION / TIMELINE

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. This will also help monitor the progress to be able to complete the research on time.

9. PROJECT POPULATION

9.1 Recruitment process

Defining your study group population (e.g. 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. 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 populations, and primary language other than English persons from participating in a research project.

If the research project is **focused** at Aboriginal and Torres Strait Islander persons or will compare Aboriginal and Torres Strait Islander persons with non-indigenous persons, then the project is considered high risk and is noted at **Question 1.19** of the Human Research Ethics Application (HREA) in ERM.

The six core values listed in **Chapter 4.7** of the National Statement on the Ethical Conduct of Human Research will need to be addressed in Question P8.1 of the HREA.

Below is the link to information regarding the National Statement on the National Health and Medical Research Council (NHMRC) website:

<https://www.nhmrc.gov.au/guidelines-publications/e72>

The National Statement can be downloaded via the link at the bottom of the page.

The six core values as listed in the National Statement are:

Reciprocity is the concept of exchange for mutual benefit.

Respect is about the due regard for the feelings, wishes and rights of others. It is about how the ATSI people feel about the study.

Equality is the concept of being of equal status in rights and opportunities. This important concept is about recognizing that ATSI people are not regarded or treated as second-class citizens. This is not about equality of the data. It is about the way the people are treated and regarded.

Responsibility is the concept of control, i.e. the acknowledgement that the researchers have a duty to the ATSI people in the study to responsibly conduct the study.

Survival and protection is the concept of ensuring the continuation of culture and values that are important to ATSI people.

Spirit and Integrity is about maintaining intangible qualities and values ensuring that these values remain whole and undivided.

Please also review the below two publications from the NHMRC for additional information:

[Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities.](#)

[Keeping research on track II.](#)

Below is a link to the Aboriginal and Torres Strait Islander Health page for the Cairns and Hinterland Hospital and Health Service.

http://gheps.health.qld.gov.au/cairns/html/atsi_hmu_home.htm

Below are links for the Torres and Cape Hospital and Health Service.

<https://gheps.health.qld.gov.au/torres-cape/html/cultural-practice>

<https://gheps.health.qld.gov.au/torres-cape/html/traditional-owners>

<https://www.health.qld.gov.au/torres-cape>

Please note: *If your research is **FOCUSED** at Aboriginal and Torres Strait Islander people or plans to compare Aboriginal and Torres Strait Islander participants against non-Indigenous persons, letters of support from relevant Aboriginal and Torres Strait Islander bodies and communities must be provided with your application.*

9.2 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.

9.3 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).

9.4 Potential for risk, burdens, and benefits

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).

KEY QUESTIONS TO ASK YOURSELF:

1. What other ongoing projects are being conducted in the population I would like to research? Are there enough potential participants for recruitment to my project to ensure its success?
2. Who will approach potential participants, and are they professionally registered and employed by the Hospital and Health Service (HHS) Research?
3. Can I adequately justify my inclusion criteria (e.g., scientific, practicality, limited resources)?
4. Can I adequately justify my exclusion criteria (e.g., scientific, practicality, limited resources)?

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

10.1 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 $\geq 500\text{mL}$ /blood loss $< 500\text{mL}$); 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).

10.2 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.

11. 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...”).

11.1 Recruitment and consent of participants

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, 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.

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 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 HREC is required. Please refer to the *National Statement on Ethical Conduct in Human Research Chapter*, Section 2.3 for information about justifying any requests for waiving consent.

If undertaking research which involves Aboriginal and Torres Strait Islander peoples', researchers should refer to the NHMRC guideline document: *Values and Ethics: Guidelines for Ethical Conduct in Health Research* when writing their protocol.

11.2 Withdrawal of participants from a project

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

- *Participant withdrawal from project 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.

- *Participant withdrawal from a project*

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 TO ASK YOURSELF:

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 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 understand what is required from them and what they are consenting to?
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 unequal relationships (junior staff-manager, student-teacher), or if

I am their treating health practitioner? How have I addressed these concerns (e.g., nominated another person to approach or consent participants)?

11.3 Randomisation

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).

11.4 Measurement tools used

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 and reliability of the findings. 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 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.

11.5 Project involvement by participants

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.

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 informed consent form.

11.6 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 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?

11.7 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 always the paramount considerations. 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 is afforded to 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, for example what are the potential risks and proposed benefits of the project procedures, has the priority of the participants’ interests over those of science or of society been assured and how those interests will be safeguarded including responsibility for liability of injury during the project and how the participants are informed of the project.

If 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, please refer to the Research Ethics and Governance website.

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

KEY QUESTIONS TO ASK YOURSELF:

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 for participants to use if they experience an adverse event, or serious adverse event?

11.8 Data monitoring

This section includes information on the 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.

12. SAMPLE SIZE AND DATA ANALYSIS

12.1 Sample size and statistical power *(see also specific guidance regarding 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.

12.2 Data analysis plan *(see also specific guidance regarding qualitative research)*

The statistical methods used for the project objectives / hypotheses (e.g., t-test, chi-squared, descriptive multivariate modeling) must be sufficiently detailed, and relate to your project aims and objectives. This section should include a list of the independent, dependent, and confounding (if applicable) variables of the study. 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.

13. 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 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. Any protocol should also include how the researchers have reviewed and reflected on the NHMRC: *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*.

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 Ethics Coordinator for advice and guidance on your particular study.

14. DISSEMINATION OF RESULTS AND PUBLICATIONS

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 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 project 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.

15. 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.

16. 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.

17. REFERENCES

Include all references used throughout the application.

18. ADDITIONAL GUIDANCE RELEVANT TO QUALITATIVE RESEARCH

18.1 Introduction

See general guidelines

18.2 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.).

18.3 Aim(s) of Project

See general guidelines

18.4 Objectives

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

18.5 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.

18.6 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).

18.7 Project Setting/Location

See general guidelines

18.8 Project Duration

See general guidelines

18.9 Project Population

See general guidelines

18.10 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.

18.11 Project Procedures

18.11.1 Recruitment and consent of participants

See general guidelines

18.11.2 Withdrawal from project

See general guidelines

18.11.3 Randomisation

Not relevant

18.11.4 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.

18.11.5 Project involvement by participants

See general guidelines

18.11.6 Data management

See general guidelines

18.11.7 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.

18.11.8 Data monitoring

See general guidelines

19 SAMPLE SIZE AND DATA ANALYSIS

19.1 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 chainsampling; 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 datasources, and the possibility of greater breadth through examination of a variety of sampling sites.

19.2 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.

20 ETHICAL CONSIDERATIONS

See general guidelines

21 DISSEMINATION OF RESULTS AND PUBLICATIONS

See general guidelines

22 OUTCOMES AND SIGNIFICANCE

See general guidelines

23 GLOSSARY OF ABBREVIATIONS

See general guidelines

24 BUDGET

See general guidelines

25 REFERENCES

See general guidelines