Queensland Government

Guide to writing a study plan for a Quality Assurance (QA) activity

A study plan is a document which describes in detail the plan for conducting a quality assurance (QA) activity. The terms study and project are often used interchangeably.

A well written and comprehensive plan is essential for a high-quality QA activity. A study plan generally follows a conventional layout. This study plan guidance document aims to offer investigators a generic guide and suitable template for a broad range of QA activities.

All QA activities conducted on staff, patients, and/or data, whereby the findings are to be disseminated external to the organization, require a study plan.

The preparation of a study plan is an important first step in the QA project process for the following reasons:

- It states the question you aim to answer;
- It provides a structured, written working plan of the QA activity;
- It encourages adequate consideration and planning of the QA activities in detail *before* you begin;
- It provides the principal investigator (PI) and associate investigators (AI) or peers with a dynamic document for contribution and early review prior to its completion;
- It allows investigators to carry out the QA activity in a consistent, standardised way;
- It acts as a record and reminder for the investigator team and collaborators of the initial QA activity aims, stated procedures and investigator duties and responsibilities;
- It enables stakeholders to monitor the progress of the QA activity;
- It provides the basis for funding and/or human research ethics applications (including budgetary information); and
- It provides a framework for any resulting publications and/or presentations.

It is recommended that the study plan should always be developed prior to the completion of a QLD Exemption Form in the ERM system. The study plan will then guide the answers to the QLD Exemption Form questions in the ERM system.

The *National Statement on Ethical Conduct in Human Research (2007) – updated 2018 (paragraph 5.1.22 and 5.1.23)* defines research that can be exempted from ethics review as negligible risk research that involves the use of existing collections of data or records that contain only non-identifiable data about human beings. A QA activity is an activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation.

For novice investigators, it is always recommended that completion of the QA activity study plan is done in consultation with an experienced investigator.

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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 QA STUDY PLAN

FULL QA ACTIVITY STUDY 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 the QA activity. Having a refined question can assist in constructing a title. This will ensure that your title reflects (if appropriate) the patient population and outcome. You might also consider incorporating the design type (e.g. retrospective cohort study) as is recommended to improve the reporting of health project findings.

SHORT TITLE OR ACRONYM

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

LAY DESCRIPTION OF THE STUDY (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 QA activity question, and how you will answer it.

WORDING TO STATE THE QA ACTIVITY WILL BE CONDUCTED IN COMPLIANCE WITH RELEVANT LEGISLATION AND GUIDANCE DOCUMENTS

As an investigator or a person undertaking a QA activity, 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 project, including offering best current clinical practices and treatments in all arms of your study;
- Current best practice in ethics including abiding by the National Statement 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.

STUDY INVESTIGATORS

Please ensure only one Principal Investigator (PI) is listed within this section. This person is the investigator responsible for the overall conduct of the QA activity study at an individual site. Please list all members of the QA activity 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 QA 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 QA activity in a lawful and ethical way.

ADDITIONAL GUIDANCE RELEVANT TO QA ACTIVITIES

1. INTRODUCTION

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 study plan but is often written after the study plan itself is completed.

2. BACKGROUND

The background gives the information on why you are conducting the project e.g. assessing your clinical practice. If you are looking critically at clinical care, you need to identify evidence of good clinical practice standards on which to base your assessment. A literature review can ascertain if there are any recommended standards on which to base your clinical practice and to find out about any previous projects which have been conducted on your specific topic to help you in designing your project, 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 falling within the ethics review exemption category 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 is not comparing 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.* 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 (National Statement Chapter 3.3). A clinical audit may be undertaken to provide data for the development of a research project.
Note: HREC approval would be required in order to use the data from the clinical audit in the research project.

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

3. AIM(S) OF QA ACTIVITY

Ethics review exemptions are typically the assessment of current practice to see whether it is working, or, measuring current practice against a procedure, standard or guideline in order to identify / eliminate gaps in a current service, with the aim of improving service delivery. The study may also be conducted to provide data to inform the development of clinical standards and guidelines, especially if no higher-level evidence is available.

4. OBJECTIVE(S)

Having decided on the topic, it is helpful to clearly define your clinical audit objectives, for example 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

5. HYPOTHESIS *(heading can be deleted if not applicable)*

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

6. QA DESIGN AND METHODOLOGY

State the methodology and design of the QA activity (e.g., prospective, or retrospective cohort / chart review / survey / interviews). Whatever the study design, you need to ensure that you provide the reader with a clear statement and description of your proposed design. You may also explain why the study design has been chosen in preference to other possible designs (i.e., justification for choice of project design). The scientific integrity of the study and the credibility of the data depend substantially on the QA activity design and methodology.

The same study can be described in several ways, and as complete a description of the QA activity as possible should be provided. For example, a study may be described as being a basic science study, epidemiologic or social science study.

An appropriate and well thought out study design is important. The potential for future benefit/s to knowledge, society and practice is dependent on the scientific integrity of your study, including the ethical justification for embarking on studies that create burden and impose risk on research participants.

KEY QUESTIONS TO ASK YOURSELF:

1. Are my QA activity's aim(s) clear and concise?
2. Do my objectives clearly relate to my aim(s)?
3. Have I designed the study in a way that will enable me to achieve my aim with realistic outcomes?

7. QA SETTING(S) / SITE(S)

The site(s) where the study will be conducted. You need to mention whether the study is going to be a single-site QA activity or a multi-site QA activity (i.e., conducted in more than one location) and identify which is the coordinating site. QA activities are Health Service Specific, in that, each Health Service involved requires a separate application. It is important to be mindful of other studies being conducted in the same location or

among the same population as your QA activity and to address any potential issues arising from this including the potential for limited staff resources.

8. QA DURATION / TIMELINE

The QA activity study plan should specify the time that each phase of the study 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 QA activity on time.

9. QA POPULATION

Defining your study group population (i.e., the study participants) provides the context for which the QA activity 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 study. They are used to identify appropriate participants and to ensure their safety. You should justify your inclusion and exclusion criteria in this section. Note: Lack of study funding and time limitations are not valid reasons for excluding Aboriginal and Torres Strait Islander populations, and/or primary language other than English persons from participating in a project.

9.1 Inclusion criteria

Inclusion criteria are the 'characteristics' that clearly describe the attributes that are required for a participant to be included in the study. 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.

9.2 Exclusion criteria

Exclusion criteria are the 'characteristics' that clearly describe the attributes that make a participant ineligible to participate in the study. 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).

9.3 Potential for risk, burdens and benefits to participants

Identify and address any issues relating to any potential risk or burdens to participants. This includes managing risks and burdens relating to the protection of their data and privacy, and the potential future impact of being involved in this study.

KEY QUESTIONS TO ASK YOURSELF:

1. What other ongoing studies are being conducted in the population I would like to study? 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) / Aboriginal Community Controlled Health Organisation (ACCHO)?
3. Can I adequately justify my inclusion criteria (i.e. scientific, practicality, limited resources)?
4. Can I adequately justify my exclusion criteria (i.e. scientific, practicality, limited resources)?

10. QA OUTCOMES

10.1 Primary outcome(s)

The primary outcome should be the most important relevant outcome (e.g. clinical, psychological, economic, other) of the study. This primary outcome is the measure used to answer your study question and should relate directly to your primary aim(s) and objective(s). For quantitative studies, the primary outcome is also the outcome used to calculate appropriate sample size. Generally, no more than 1-2 primary outcome measures are pre-specified, as the greater the number of primary outcome measures, 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).

10.2 Secondary outcome(s)

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

11. QA PROCEDURES

This section should describe exactly what will happen during conduct of the study. It is preferable to use the active voice and state in the future tense.

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 studies. 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 project 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.

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 the project only if consent is given on their behalf by a legally authorised representative.

If applicable provide information regarding consent / assent forms that will be used in the study, 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. If you are a Queensland Health employee, you can access cohort (patient) information as a *Designated person under the Hospital and Health Boards Act 2011*.

Generally, a clinical audit can be undertaken without consent of the patients if:

- The study carries only low or negligible risk;
- It is impractical to obtain consent;
- The study follows the Australian Privacy Principles: http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles ; **AND**

- The QA activity does not seek to gather information about the patient beyond that collected in routine clinical care.

11.2 Withdrawal from a study *(heading can be deleted if not applicable)*

A 'Withdrawal of Consent' form should be developed for consenting participants. If a participant withdraws from the study, then the participant data collected up to the time of withdrawal from the study procedures should still be considered in the data analysis unless stated otherwise in the patient 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 information.

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.

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 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 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)?

11.3 Randomisation *(heading can be deleted if not applicable)*

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 study (e.g., patient questionnaire, medical charts, routinely collected hospital data, biological specimens). Describe at what point(s) of the project data collection will occur. You should make statements that justify the validity of the study 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 study:

- To ensure that the data collected is precise, and that only essential data is 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 your form is giving you the data you require.

11.5 Study involvement by participants

In this section you need to clearly and comprehensively describe exactly what will happen to participants once they are enrolled in your study. Depending on the 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 study plan should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification. The study plan 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 study?

11.7 Safety considerations / Patient safety

The wellbeing and safety of participants in studies, including patients who participate, are always the paramount considerations. The protection of study 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 project. You will need to provide adequate information on how the safety of participants will be ensured.

Remember that even administering a 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 investigators and participants. Investigators may be required by law to report information about child or elder abuse, drug trafficking, 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 study and how the participants are informed of the project.

12. SAMPLE SIZE AND DATA ANALYSIS

12.1 Sample size and statistical power

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.

- 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 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 to first define the population to which the study 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 would just pick donors from those available at the time when you are interviewing.
  - If you are unsure of the most appropriate method of sampling for your project, it is recommended to consult with a statistician.

12.2 Data analysis plan

The statistical methods used for the study objectives (e.g. t-test, chi-squared, descriptive, multivariate modeling) must be sufficiently detailed, and relate to your project aims and objectives. 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.

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.

13. ETHICAL CONSIDERATIONS

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

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

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

- The exercise is directly related to the functionality of the department; and
- Is undertaken by staff who would normally have access to the information / patients through normal clinical care; and
- The information will be used solely for internal departmental use; and
- The study is using routinely collected data; and
- The study is assessed as per the *National Statement on Ethical Conduct in Human Research* by a departmental head who has a thorough working knowledge of the National Statement.

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

TIP: If a clinical audit assessing current practice or identifying service gaps is to be presented in a public forum or published it is recommended that, prior to the clinical audit being undertaken, the study plan for the clinical audit be submitted to the FNQ HREC with a request for an exemption of formal ethics review on the basis that the clinical audit is not research.

14. DISSEMINATION OF RESULTS AND PUBLICATIONS

Discussing the results of the clinical audit study 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 the study results have been finalised?

15. OUTCOMES AND SIGNIFICANCE

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

The study plan 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 study plan, including appendices, should be listed with an explanation of each abbreviation. Accepted international medical abbreviations should be used. Study specific abbreviations should be standardised within the study 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.