Quality Assurance//Negligible Risk Research: Notes to users and Protocol Guidelines

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| **Version Notes:** | **QUALITY ASSURANCE PROJECT PLAN GUIDANCE**   |  | | --- | | **Version 1.0**  **Dated 1 August 2020** |   This guidance has been 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, and modified for use at Melbourne Children’s. |
| **Why do you need a project plan?** | A project plan describes in detail the organisation for conducting your quality improvement project, and is essential to ensure the quality of conduct, review, reporting, and interpretation of any clinical audits and quality assurance.  All quality assurance projects should have a formal written project plan. |
| **Why use this guidance?** | This guidance is appropriate for projects where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation, which can be known as **clinical audits**\*, quality assurance, quality activities, quality improvement, et al. These terms are often used interchangeably.  \* Definition of clinical audit  The Health Victoria definition of a **clinical audit**  as “The systematic review of elements of clinical care against predetermined criteria, with the aim of identifying areas for improvement and then developing, implementing and evaluating strategies intended to achieve that improvement.”.  QA, evaluation and research exist on a continuum of activity, and work that begins as one form of activity can evolve into another over time. If you are unsure, please contact [Research Ethics and Governance.](mailto:rch.ethics@rch.org.au) Note that on the [CRDO website](http://www.mcri.edu.au/research/core-facilities/clinical-research-development-office/other-research-resources/) you will also find protocol templates for use in the following research:   * + [Clinical trial using a drug, biologic or device intervention](https://www.mcri.edu.au/sites/default/files/media/crdo/template_clinical_trial_imp_annotated_prot.docx)   + [Clinical trial not using a drug, biologic or device intervention](https://www.mcri.edu.au/sites/default/files/media/crdo/template_non_drug_intervention_trial_annotated_prot.docx)   + [Research not involving an intervention](https://www.mcri.edu.au/sites/default/files/media/crdo/template_obs_study_annotated_prot.docx) |
| **How to use this Guidance:** | This document provides the recommended contents heading, and each section is explained underneath the relevant heading. You will need to input project specific information under each heading, and remove explanatory information.  Please delete any sections that are not relevant to your project.  It is not necessary to include text under a major numbered heading (e.g., 1, 2) that is immediately followed by numbered subheadings, (e.g., 2.1, 2.2). That is because certain numbered headings are used only for organisational purposes. Text should be entered under all numbered subheadings.  **It is always recommended that completion of the project plan is done in consultation with a person experienced in quality improvement projects.** Please contact [Research Ethics and Governance](mailto:rch.ethics@rch.org.au) for assistance. |

**Bibliography** (all links current as at 30/5/2019)

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* NHMRC. Ethical considerations in quality assurance and evaluation activities. <https://nhmrc.gov.au/about-us/publications/ethical-considerations-quality-assurance-and-evaluation-activities#block-views-block-file-attachments-content-block-1>
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project plan

[Insert Title/ Identifier]

The title should be kept brief but descriptive, mentioning the design the subject of enquiry

[Version # and date]

**OUTLINE:**

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 project.

**DOCUMENT HISTORY:**

Table each change made to the protocol, with the most recent at the top of the table. The protocol may be updated due to queries raised by an ethics committee, or changes may be required during the life of the project.

A version date must always be present on every page (header or footer) of the draft and final protocols. The version date of an approved protocol should reflect the date of the last changes prior to an ethics submission.

| **Version Number and Date** | **Summary of changes** |
| --- | --- |
|  | Include here a simple reason for why the change was made, for example "updated post HREC review" |
|  |  |

**CONFIDENTIAL**

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**STATEMENT OF COMPLIANCE**

As 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
* Relevant State and Commonwealth Acts and legislations; and
* Relevant Institutional policies and procedures

**PROJECT TEAM MEMBERS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Phone** | **Email** | **Institution** | **Project Role** |
|  |  |  |  |  |
|  |  |  |  |  |

## **Before you start read the** [NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities.](https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities)

## **INTRODUCTION**

## The Introduction and Background sections may be 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 project plan but is often written after the project plan itself is completed.

## **BACKGROUND**

The background gives the information on why you are conducting the project e.g. assessing your clinical practice. If you are looking critically at clinical care you need to identify evidence of good clinical practice standards on which to base your assessment. A literature review can ascertain if there are any recommended standards on which to base your clinical practice and to find out about any previous projects which have been conducted on your specific topic to help you in designing your audit, especially the method of data collection. The literature review may give guidance regarding the estimated sample size and 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 research or non-research (e.g quality audit or quality improvement project), consult the HREC Office prior to submitting your application for review.**

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

Aims and objectives may be combined, depending on the complexity of your project.

**Aim(s):** 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.

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

• Clinical importance

• Practicability

• Acceptability.

## **PROJECT DESIGN**

State the design of the project. 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.

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.

**TIP: Contact** [**CEBU**](mailto:cebu@mcri.edu.au) **for advice as they can provide support to assist you designing your project.**

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

The location(s) of where the project will be conducted / data collected from.

## **PROJECT POPULATION**

Defining your project group population provides the context for which the project has relevance. This section also describes how one can ascertain if the results can be generalised to a larger 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 for their data to be included in your project. It also gives the data custodian a clear direction on which population group you are wanting to extract data from.

### 6.1 Inclusion criteria

Inclusion criteria are the ‘characteristics’ that clearly describe the attributes that are required for population group / and or data 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.

### 6.2 Exclusion criteria

Exclusion criteria are the ‘characteristics’ that clearly describe the attributes that make a population group ineligible for the project.

## **PROJECT OUTCOME(S)**

### 7.1 Primary Outcome(s)

The primary outcome should be the most important relevant outcome (e.g. clinical, psychological, economic, other) of the project.

### 7.2 Secondary Outcome(s)

Secondary outcome(s) are measures of additional or less important interest.

## **PROJECT PROCEDURES**

### 8.1 Consent of the population group

If consent is not being sought, the rationale for not obtaining consent needs to be explained. In many cases a non-research project can be undertaken without consent of the population group 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.

You may also use implied consent e.g if you ask someone to complete a questionnaire either in person or online and they complete the questionnaire.

**SEEK ADVICE FROM THE HREC CO-ORDINATOR REGARDING CONSENT**

### 8.2 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, and routinely collected hospital/research database). Describe at what point(s) of the project data collection will occur.

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.

### 8.3 Project involvement by population group

### If undertaking non research projects which involve patient / staff etc participation e.g completing a questionnaire etc, you need to clearly and comprehensively describe exactly what their involvement will be.

### 8.4 Data management and storage

The plan should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification. The project 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 project?

### 8.5 Safety considerations

## Identify and address any issues relating to any potential risk or burdens regarding the project. For non research projects the main potential risk is privacy and confidentiality breaches.

## **SAMPLE SIZE AND DATA ANALYSIS**

### 9.1 Sample size and statistical power

* How will you select your sample? (How many do you need?)
  + 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 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 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 babies and infants in the neonatal ward 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. you could just pick patients 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.

### 9.2 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 Royal Children’s Hospital, 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 non research, 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 the NHMRC National Statement on Ethical Conduct in Human Research and NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities.

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

## **DISSEMINATION OF RESULTS AND PUBLICATIONS**

Discussing the results of the 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**

It may be of value to reiterate the potential benefits of 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 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.

## **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.