**Low Negligible Risk (LNR) or Quality Assurance (QA) Protocol Template**

# Introduction

There are many ways to improve healthcare services and outcomes. Across the domains of research, quality assurance (QA) and quality improvement (QI), a well written and complete plan is essential for the success of any project. This template is designed to be completed by CHQ staff who are planning to undertake a project or initiative which is considered Low Negligible Risk (LNR) research, QA or QI in nature and you plan to publish any part of this work. It is recommended that you complete this template if you are considering publishing your project or initiative, even if you will do it in the future as it is not feasible to get permission retrospectively.

The function of the template is to:

1. Encourage and guide the planning of project details before you commence the project
2. Clearly articulate the aims of your project
3. Act as a comprehensive record and reminder for you and your co-investigator(s), co-worker or supervisor/sponsor of the initial project aims and stated procedures
4. Enables you to monitor progress
5. Provide the basis for funding or human research ethics applications, including where waivers or exemptions may apply, such as for QA activities
6. Provide the basis for reporting requirements through the appropriate governance channels, which will vary depending if the project is predominantly research, QA or QI in nature.

# The research and quality continuum

It can be difficult to decide if your project is research (including LNR), QA or QI as these approaches have much in common - they share a rigorous approach to methodology in terms of design, procedure or process, analysis and interpretation of data. Below are some points to consider when trying to decide where your project sits:

**Research:**

Research usually asks the question “What …?” Research may be used to compare treatments or interventions and often involves the generation of new knowledge. Research may be stratified into low and negligible risk or standard risk. Research is considered *low or negligible risk* where the only foreseeable risk is one of discomfort. A *standard risk* application is, by virtue of its form and content, an activity which constitutes something more than discomfort (emotional, physical, spiritual pr psychological) or inconvenience for study participants. For more information go to the following site: (<https://www.childrens.health.qld.gov.au/research/for-researchers/human-research-ethics-committee/new-applications/>)

**Quality Assurance (QA) and Quality Improvement (QI):**

An activity that primarily involves monitoring, auditing or evaluation is likely to be considered QA. An activity that is primarily to improve a service, process or experience is likely to be considered QI. These terms can often be used interchangeably which can cause confusion. This is because QA, QI and research are on a continuum rather than being distinct entities. It is helpful however, to consider which of these terms most closely aligns with the project you are undertaking as each will require different levels of accountability, require you to follow different processes and each have distinct governance requirements. If you are unsure if your project is Quality Improvement, low risk research or QA this CHQ designed navigation tool may help to clarify your thinking [Improvement-Navigation-Tool\_FINAL\_54349.pdf](https://healthqld.sharepoint.com/:b:/t/ImprovementandInnovationCommunity/ERzq_xNIMzNLjDPzGZTleOsB5aw_6vZB5jG30drj2YnQwQ?e=CXoO7X).

“Irrespective of whether an activity is called research or QA or evaluation, those conducting the activity must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy.” (National Health and Medical Research Council (NHMRC) ([Ethical considerations in quality assurance and evaluation activities | NHMRC](https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities)).

This template contains a broad outline of sections usually expected in a research protocol. It is a guide to the information conventionally required rather than aiming to be definitive. Not all sections will be relevant for every project and may be modified or deleted as applicable. The information included in the boxes are designed to provide instruction and guidance – please enter your project details in the form where indicated.

We recommend that you review the [EQUATOR Network guidelines](https://www.equator-network.org/) to inform the development of your protocol. These will provide a detailed guide on how best to write up your project to support its publication, across the varying methodological approaches. Key resources include:

* For QI studies: [Standards for Quality Improvement Reporting Excellence](https://www.equator-network.org/reporting-guidelines/squire/) (SQUIRE)
* For Observational studies: [Strengthening the Reporting of Observational Studies in Epidemiology](https://www.equator-network.org/reporting-guidelines/strobe/) (STROBE) including [cohort](https://www.equator-network.org/wp-content/uploads/2015/10/STROBE_checklist_cohort.docx), [case-control](https://www.equator-network.org/wp-content/uploads/2015/10/STROBE_checklist_case-control.doc) and [cross-sectional](https://www.equator-network.org/wp-content/uploads/2015/10/STROBE_checklist_cross-sectional.docx) approaches
* For Qualitative research: [Standards for reporting qualitative research](https://www.equator-network.org/reporting-guidelines/srqr/) (SRQR).

*This is not an exhaustive list, there may be other relevant guidelines depending on the methodology you are using for your project.*

**Full project title**

**Version #:**

**Date:** Click or tap to enter a date.

##### Click on the arrow to the left of this line for some helpful information on creating a well-constructed project title

A well-constructed study or project title is important as it is the first opportunity to attract the attention of the reader. The title should be descriptive, although clearly and concisely indicating the subject of inquiry. Having a refined research question can assist in constructing a title. This will ensure that your title reflects (if appropriate) the patient population, intervention (e.g. medicinal product or device), comparator (e.g. another intervention, placebo or usual care) and outcome. You might also consider incorporating the design type (e.g. a randomized controlled study, case-control study, or retrospective cohort study, quality assurance, quality improvement or service development) as is recommended to improve the *reporting* of health research (e.g. Consolidated Standards of Reporting Studies). In the first instance, your initial title will only be a working title that would usually be revised as your study becomes more refined. The final title should be consistent across all related documents (including regulatory documents if applicable). You might also like to include a ‘lay’ (‘public’ or ‘simplified’) title easily understood by non-medical or interdisciplinary persons. These are sometimes asked for in funding applications, Human Research Ethics Committee (HREC) submissions, and clinical study registries.

*e.g. ‘A cross-sectional survey of clinician knowledge, skills and attitudes of telemedicine in regional communities’.*

**Statement of Compliance**

This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research and the Note for Good Clinical Practice.

**Study Investigator(s)**

Principal Investigator (A)1: Name:

Phone: **3068**

Email:

Principal Investigator (B)2:

Co-Investigator (A):

Co-Investigator (B):

1. *Institution, street, suburb, city, state, country, etc.*

2. *Institution, street, suburb, city, state, country, etc.*

It is important to highlight that good research and quality improvement are most often a collaborative effort, with many contributors. It is recommended that you bring together people with a diverse set of skills and expertise, including those with data, methodological and clinical knowledge.

## 1. Introduction and Background

The most important aspect of a proposal is the clarity of the problem.

This is an opportunity to convince the reader (or reviewer) why the study needs to be done (and deserves funding, ethical approval or completion). Keep this brief and to the point (approximately two A4 pages).

The following key points may be used as a guide:

* Conduct a comprehensive literature search (Cochrane, Medline, Embase and other databases relevant to your area of study).
* Discuss the importance of the topic (public health and/or clinical importance and impact on individuals/community; incidence, prevalence, mortality and morbidity).
* Critically appraise the relevant literature and discuss the state of current knowledge on the topic (including deficiencies in knowledge or gaps that make the study worth doing).
* Indicate how the research question has emerged and fits logically with the above.
* Outline your approach to address the question.
* Explain how your study will contribute to existing research and benefit other individuals or the wider community.

Discussion should be clear and logical that demonstrates you are fully conversant with the ideas presented and can grasp their methodological implications. Aim to be concise and present only key sources rather than an exhaustive list of cited references (limit to approximately 20-25 key papers). The literature review should logically lead to the statement of the aims of the proposed project.

## 2. Aim(s) of Project

Your aim(s) should arise from your literature review and state what the project hopes to accomplish (the purpose).

## 3. Objectives

Your focused question needs to be further refined into one or more study objectives. The study objective(s) should be single and quantifiable statement(s) that will allow you to answer your research questions.

e.g. *The objective of this study is to describe the use of mHealth technologies in paediatric healthcare.*

## 4. Project Design

State the design of the research or quality activity (e.g. cross-sectional survey, pre-post evaluation, prospective or retrospective cohort, point prevalence audit). Whatever the study design, you need to ensure that you provide the reader with a clear statement and description of your proposed design. You may also explain why the particular design has been chosen in preference to other possible designs (i.e. justification for choice of study design).

## 5. Project Setting/Location

The location of where the project will be conducted (e.g. Respiratory Department, Queensland Children’s Hospital). You need to mention whether it is going to be a single-centre or a multi-centered project (i.e. conducted in more than one location). Include relevant dates, including periods of recruitment, exposure, follow-up, and data collection.

## 6. Project Population

Defining the group in which the project will be carried out on provides the setting for which the research has relevance. This section also describes how one can be certain that the results from your sample population can be generalized to the target population of interest. This section should describe the target population, including:

* Population the subjects will be drawn from - for example, children admitted to hospital, staff cohorts, families in the Emergency Department etc.
* All aspects of subject selection, such as age groups, medical specialty, specific diagnosis, or treatment groups etc.

## 7. ELIGIBILITY CRITERIA

## 7a. Inclusion Criteria

Inclusion criteria are the ‘characteristics’ that clearly describe the population that are required for a subject to be included as a participant. The criteria may be based on factors such as age, gender, the type and stage of a disease, previous treatment history, co-morbid medical conditions or staff cohorts such as junior medical workforce. They may state appropriate criteria for admitting special ‘at-risk’ populations such as infants or school-aged children, patients with specific disease states or organ impairment.

## 7b. Exclusion Criteria

These describe the details of individuals that would be considered ineligible to participate and justification for their exclusion. These 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 (e.g. diminished understanding or comprehension), contraindications to the study treatment(s)/procedure(s), taking certain concomitant medication(s), or conditions that interfere with a patient’s ability to comply with all treatment(s)/procedure(s).

## 8. Project Intention/Focus (Intervention)

The focus or intention of your project would be considered to be the independent variable – it is the specific thing you want to test and find out what changes when you do it. This may be an intervention or the implementation of a change in process or procedure that may affect the outcomes you will measure in your project. It may already exist as part of a process or procedure, or it may be something that the researches manipulate, change or introduce to see how it affects the outcomes. The project focus should be outlined in this section. Describe how it will be implemented for studies with an intervention, or identified for observational studies, retrospective studies and quality activities.

## 9. PROJECT OUTCOMES

## 9a. Primary Outcome

The primary outcome should be the most important and clinically relevant outcome (e.g. clinical, psychological, economic or other) of the project. This is the measure used to answer your aim. However, it is also the outcome used to calculate the sample size and power and to test the primary research hypothesis. Generally, no more than 1-2 primary outcome measures are pre-specified. Primary outcome measures may be measured in various ways such as: binary (two possible outcomes to a certain situation); continuous (measurement on a numerical scale); ordinal (variables have natural, ordered categories and the distances between the categories is not known); time to event, and counts of.

## 9b. Secondary Outcome(s)

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

## 9c. Variables

Some descriptive study designs (e.g. cross-sectional surveys) have multiple variables in addition to the main outcomes being measured. These can include exposures, predictors, potential confounders and effect modifiers. These should be chosen and defined.

## 10. PROJECT PROCEDURES

*This section should describe exactly what is going to happen during conduct of the project. If there are participants involved this section should outline the process or steps to be implemented exactly.* ***Note:*** *It is preferable to use the active voice and state in the future tense (e.g. ‘We will survey via…’).*

## 10a. Recruitment of Participants

Not all LNR, QI or QA projects will require recruitment of participants. However, if there is participation, either by a clinician, parent or child, this section should describe which potential participants will be identified/selected for recruitment (e.g. via outpatient clinic, medical records search), how they will be approached/asked to participate if applicable, and how consent will be obtained if it is required. You may need to justify the feasibility of recruiting the required number of subjects and estimate the proportion that you would expect will agree to participate. Finally, you will need to identify the period of time expected to recruit the required number of participants.

## 10b. Project Procedure

In this section you need to comprehensively describe what will happen to participants once they are enrolled in your project. In this section, the reader should know exactly what will happen at each time point in the study. This might include how, when and by whom potential participants will be approached, when they will be randomized, the frequency and duration of visits or what activities/measurements (e.g. questionnaires, physical measurements, biological samples) they will be expected to complete at each time point and the duration of the study or follow-up.

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 flowchart may be useful for this section. Include any implementation framework you choose to use here also.

## 10c. 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). Describe at what point(s) the data collection will occur. You should make statements that justify the validity of the study measurement/instrument. If not, you will have to verify how you will ensure the validity, reliability and quality of data being collected, Also, you should 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).

## 10d. Safety Considerations / Patient Safety

This is a quality improvement activity, there is no risk or safety concerns identified for the clients or participants. Implemented to improve the referral pathway and care for patients.

## 10e. Data Management & Storage

This should include the data management systems, confidentiality and security of data, details of where records will be kept, who will have access to them, and how long they will be stored/archived or re-used.

## 11. Data Analysis

This section should describe how data collected as part of the project will be analysed. If you are using quantitative data the statistical method used for the study objectives (e.g. t-test, chi-squared, multivariate modelling) must be sufficiently detailed. Consultation with a statistician is strongly recommended.

If you are using qualitative data you will need to outline the steps involved in analysing the data.

If not using statistical analysis, it is still important to clearly articulate the data metrics you will use to evaluate your project including any cost-benefit, utilization and/or any staff or patient experience measures.

The data you collect and how it will be analysed must be planned for carefully from the outset of any project.

## 12. Ethical Considerations

You must state that the study will be conducted in full conformance with principles of the ‘Declaration of Helsinki’, Good Clinical Practice (GCP) and within the laws and regulations of the country in which the research is conducted. You will need to consider and articulate how the quality of the technical aspects have been assured, the potential risks and proposed benefits of the study procedures, the priority of the participants’ interests over those of science or of society and how those interests will be safeguarded, responsibility for liability of injury during the study, how the participants are informed of the study, and how they (or parent/guardian) give voluntary consent to participate.

If consent will be required to participate, information should be included on how informed consent will be obtained. If consent will not be obtained, reasons for waiving the consent process should be provided. For example, if a survey is to be used, state your process for providing information on participation and the consequence of completing the survey

You will also need to adequately detail methods of data extraction (non-identifiable, de-identified or re-identifiable), and data management, storage and security storage (of paper hardcopies and/or electronic files).

For further information see the National Statement of Ethical Conduct in Human Research (NHMRC, 2007) and liaise with the Children’s Health Queensland Research Ethics Coordinator for advice and guidance on your particular study.

## 13. Outcomes and Significance

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

## 14. References

[World Medical Association Declaration of Helsinki](http://www.who.int/bulletin/archives/79(4)373.pdf) (1964)

[Note for guidance on good clinical practice (CPMP/ICH/135/95 - Annotated with TGA comments)](http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf)

[National Statement on Ethical Conduct in Human Research](http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e72-jul09.pdf) (2007)