**Example Research Protocol Template**

**INTRODUCTION**

* The Protocol is the primary reference document for the conduct of any audit or study and provides detailed, written documentation that outlines how the research study will be performed. It also helps you to clarify what your goals are and how you will achieve them.
* It is written before the study starts – a considered protocol will make the completion of the study approval application forms easier.
* Most Ethics Committees require a written study protocol to be appended to your application.

**Please note:**

* If a proposed study (e.g. pharmaceutical or collaborative study*)* already has a protocol then that should be used – there is no need to write another protocol.

**COVER PAGE**

|  |  |
| --- | --- |
| DATE | VERSION NUMBER |
| **STUDY TITLE** |  |
| **Short title** |  |

**PRINCIPAL INVESTIGATOR**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name**  |  | **Title** |  |
| **Institution** |  | **Department** |  |
| **Phone**  |  | **Email** |  |

**OTHER INVESTIGATOR(S)***: Have you included appropriate inter-disciplinary collaborators? Eg if you are involving another area in your project/audit/research, you should consider having a collaborator who is familiar with that area.*

|  |  |  |  |
| --- | --- | --- | --- |
| **(1) Name**  |  | **Title** |  |
| **Institution** |  | **Department** |  |
| **Phone**  |  | **Email** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **(2) Name**  |  | **Title** |   |
| **Institution** |  | **Department** |  |
| **Phone**  |  | **Email** |  |

**Do any investigators have a conflict of interest? Eg financial or commercial associations**

**SUGGESTED PROTOCOL FORMAT**

1. ***Research question or audit statement***
2. ***Background / Rationale***

*This section provides justification for the project - why is the topic important, why does the study need to be done?*

*What is known in the literature about this topic, where are the knowledge gaps, and how does your research question fit within this?*

*Have you undertaken a literature review of the topic you wish to study? (Useful resources include The Cochrane library , Pubmed).*

*How will answering this question contribute benefit to individuals / the community or the way we provide care?*

***C1) Aims and Objectives***

*(General)*

*What does the study intend to accomplish? There may be more than one aim or objective.*

*Example*

*The objective of this study is to determine if maternal morbid obesity is associated with increased rates of failed induction of labour.*

***C2) Hypotheses (Or audit standard if audit is to be undertaken)***

*(Specific)*

*A Hypothesis is a simply worded “testable” statement. The results of the study will prove or / disprove the hypothesis*

*Example*

*Following induction of labour with a Cook’s balloon, the rates of successfully establishing labour will be no different among women with obesity, and women with a BMI in the normal range.*

***D) Methodology***

*In this section you will need to describe exactly what happens in the study. The content will vary with study design, but may include how cases or potential participants are identified, how randomisation occurs, what measurements are taken and when, precise details of treatments/ interventions used, how compliance will be measured, under what circumstances treatment may be withdrawn. Guidance for what should be included in this section are listed below*

* 1. *Study type*

 *E.g. prospective or retrospective, observational study, randomised controlled study, cross- sectionational survey*

* 1. *Population: ADHB, Other DHB, inpatient, outpatient etc*

 *How will you identify and recruit participants*

 *If randomisation is being used, how will this be performed?*

* 1. *Inclusion/exclusion criteria*

*Who will be eligible for the study - consider age, type and stage of disease (and how this defined/diagnosed), co-morbidities*

*Who will be ineligible to enter? – consider those criteria that may limit someone’s ability to give informed consent (e.g. non-English speaking and no interpreter, <16 years), contraindications to study treatment, inability to comply with treatment or procedures*

***For non-audit / research only:***

* 1. *Is there an intervention? Describe (how is it administered / when)*
	2. *Are any questionnaires involved? Who will administer the questionnaire? When will it be undertaken? Is it a valid instrument for answering the study question?*
	3. *What is the primary outcome?*

*What is the most important and clinically relevant outcome of the study? This is the measurement which will be used to answer the aim of the study. There is usually one primary outcome.*

*How will this be measured? When will it be measured? Who will measure them?*

 *Examples*

*Birth prior to 34 weeks gestation*

 *Total estimated blood loss within 24 hours of birth (mL)*

* 1. *What are the secondary outcomes?*

*What are the other measurements of interest in the study?*

 *How will these be measured? When will they be measured? Who will measure them?*

*h. What other data will be collected?*

*Do you need to collect data on other variables e.g. to account for potential confounding variables or to explain or describe your study population and findings?*

*i. Sample size (and justification);*

*j. Equity consideration*

*Consider whether equity, especially for Māori, should be addressed in your study? If so, how will you do this? Or why will you not do this?*

*Is Maori approval required? Have you consulted with any involved groups? Eg Māori, other ethnic groupings, patients and public? Consider discussing with the DHB Maori Health Advisor.*

*k. Statistical plan:*

*We recommend consulting a biostatistician to complete this section.*

*l. Prepare dummy tables for your analyses*

***E) Ethics and safety***

*Is ethics approval required? If you believe not, provide an appropriate statement for a journal explaining this*

*What are the risks of participating in the study? What are the benefits?*

*Is informed consent required? How will this be obtained?*

*Does your research involve potentially vulnerable populations?*

*Describe how you will care for data safely. How will you ensure privacy and confidentiality during your data collection. Consider whether any data will be shared and if so, how data safety will be addressed. What will you do with your data at the end of the study? How long will it be stored and where?*

***F) Project Management***

*How long will the study take to complete? Is the study feasible?*

*Who will do what in the study e.g. who will prepare the ethics application, who will extract data, who will do analysis, who will prepare manuscript? Is funding required?*

***G) Timetable/line***

*Include time for necessary approvals, conduct of the study, analysis and reporting/dissemination/publication*

***H) Resources***

*Do you need data extraction services? Who will do/pay for this?*

*Do you need statistical support? What statistical software will you use?*

*Does the research project involve the use of clinical staff during their rostered clinical hours? If so, has there been consultation and approval from the appropriate line managers?*

***I) Research Output***

*How do you plan to disseminate your findings?*

*Do you plan to feedback if participants are involved?*