Protocol Template for QA Projects

ERM # <insert no>

The protocol is defined as a document that provides sufficient detail to enable:

* understanding of the background, rationale, objectives, study population, interventions, methods, statistical analyses, ethical considerations, dissemination plans, and administration of the project; replication of key aspects of project methods and conduct;
* appraisal of the project’s scientific and ethical rigor from ethics approval to dissemination of results.

The protocol is more than a list of items. It should be a cohesive document that provides appropriate context and narrative to fully understand the elements of the project. For example, the description of a complex intervention may need to include training materials and figures to enable replication by persons with appropriate expertise.

A full protocol must be submitted in ERM together with relevant associated documents for review by the Women’s Research Advisory Committee.

If the details for certain items have not yet been finalised, this should be stated in the protocol and the items updated as they evolve.

Project leads are expected to adhere to the protocol as approved by the Research Governance Committee. Once approved amendments can’t be made to the QA protocol.

Notes:

* QA projects must be completed in 2 years
* No amendment can be made to the QA project once approved.
* QA is for Women’s site projects only, and data must remain at the Women’s.
* If this is a multisite QA, an ethics application is required
* Check what approval is require for publication? QA approval is at the institutional level, if you require ethical approval for publication, an ethics application is required.

# QA Project Protocol

|  |  |
| --- | --- |
| 1. Project Title: |  |
| 1. ERM Project ID: |  |
| 1. RWH Local ID: | *Research Office to complete* |
| 1. Protocol Version No: |  |
| 1. Protocol Date: |  |
| 1. RWH Principal Investigator: |  |
| 1. PI contact information: |  |
| 1. Other Key Personnel: |  |
| 1. Contact Information: |  |
| 1. **Background:**   a) What activity has been undertaken in this subject area before? | |
| b) What are the limitations of this previous activity? | |
| c) Why is this project important and what will it add to the literature or how will it improve patient care? | |
| 1. **Project Aim and Objective/s:**   Please describe the specific study aim/s, and/or question/s being investigated. | |
| 1. **Project Design and Methods:**    1. Participant recruitment:   Where, by whom and who will be asked to participate in recruitment. (Inclusion/Exclusion criteria)? | |
| * 1. Project Procedures:   a) How will the specific project be carried out? | |
| b) If there are participants, what will they have to do during the study, when and how often? | |
| c) What will the project lead do, where and when? | |
| * 1. Data Collection and Storage:   a) What data will be collected and how (from medical records, questionnaires, survey)? | |
| b) How will data be stored (electronically, paper, etc)? | |
| c) How long will data be stored and how will it be destroyed? | |
| * 1. Sample Collection and Storage:   a) What samples will be extracted /used)? | |
| b) How will the samples be accessed and how will they be stored? | |
| c) How long will the samples be used, and how will they be destroyed? | |
| 1. **Data Analysis**    1. Justification of sample size:   Describe how the sample size was determined; based on a power calculation, a convenience sample of all people attending a clinic or program, etc. | |
| * 1. Proposed means for analysing the data citing specific statistical techniques:   What statistical techniques will be used to analyse the data? Descriptive statistics such as percentages and means or medians may be sufficient dependent on the project. | |
| * 1. Proposed means for analysing the samples citing the specific techniques: | |
| * 1. Dissemination of Results   Describe how you are intending to inform others of the results e.g., publishing, conference presentations. | |
| 1. **References:**   Note any literature or web references that may have been cited. | |

Research Office 9/10/24