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; and 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.

The full protocol must be submitted together with associated documents for approval by the Human Research Ethics Committee (HREC).

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.

The protocol is a “living” document that may require to be modified during the project. A transparent audit trail with dates of important changes in project design and conduct is an essential part of the scientific record.

Project leads are expected to adhere to the protocol as approved by the HREC and to document amendments made in the most recent protocol version.

Important protocol amendments should be reported to the Office for Research as they occur.

|  |  |
| --- | --- |
| 1. Project Title: |  |
| 1. Protocol Version No: |  |
| 1. Protocol Date: |  |
| 1. Project Lead Institution: |  |
| 1. Project Lead Person (repeat if more than lead, ie at multiple institutions: |  |
| 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 (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 analyzing the data citing specific statistical techniques:   What statistical techniques will be used to analyze the data? Descriptive statistics such as percentages and means or medians may be sufficient dependent on the project. | |
| * 1. Proposed means for analyzing 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. | |