Protocol example for an observational study (cohort, case-control, cross-sectional, or descriptive)

Note the information provided here is for a research protocol and not a research proposal.

- A research proposal is usually written to persuade a grant committee or department, while a protocol is written to detail a clinical study's plan to meet ethical norms for participants.

Title page

- Title:
  - The title should be concise and yet descriptive.
  - Protocol ID/ acronym: Often a project has a "nick name" – that is used by the research team, this can be included.
  - Spend time to formulate the title well.

- Research team:
  - Names and contact details of research team (include all investigators).
  - Responsibilities of each team member.
  - Student number and degree if relevant.

- Funder (if applicable).

- Names of departments and/or laboratories and/or services involved in the research.

- Date.

- Version number.

Table of Contents

Remember to use page numbers.

Abbreviations

Include all abbreviations, which will not be understood by a lay person.

Definitions

This section should focus on describing the exposure and outcomes in the case of an observational analytical study, and safety and efficacy variables in the case of an interventional study. Other relevant definitions as required.

Plain language summary

Plain language summary should describe the project title in lay terms, the aim of the study, the study design, study setting, study population, sampling if appropriate, sample size, in the case of an interventional study whether a control will be used, what treatment will be administered. Potential risk for participants, including ethical risks. Describe whether participants will be remunerated. Will the outcome be made known to participants. Describe how the researcher will manage personal information.

Approx 750 words at a grade 8 reading level. Thus, short sentences and no medical jargon.

Introduction

- Should include information about the topic in general (with key terminology and definitions) as well as similar studies and methodologies.
- Literature: relevant, recent (preferably in the past 5 years) references (at least 5-10) from reputable sources indicated correctly.
- Current knowledge, controversies, motivation for planned study.
- Place information in a logical order (use subheadings), group similar information together and contrast with different information.
- Use paragraphs. A paragraph begins with the concept, the middle provides details, comparisons, examples, or evidence for that specific concept/idea, and the end concludes the paragraph with a final thought.
- Avoid plagiarism and do not use generative artificial intelligence to write your protocol.
- End your Introduction with a problem statement. This is the concept and problem that you identified. Your background discussion and literature review flows toward this statement.

Question

- Flowing from your Introduction, state the research question in a clear, concise and focused manner.

Aim and objectives

Aim

- An aim is the overall goal of your project. It is derived from your question and provides a broad perspective on what you hope to achieve. All your objectives and subsequent methods should combine to reach your aim and answer your question.

Objectives

- From your aim, state specific measurable objectives and any prespecified hypotheses if appropriate. Break down your aim into smaller and manageable measurable objectives. They must be short one-sentence, describing each objective that must be reached to reach your aim and answer your question.
    - Objective 1:
    - Objective 2:
    - Objective 3:

Methodology

Study design

- Indicate the appropriate study design.
- This must include whether this study is prospective or retrospective.

Setting

- Single site or multisite study.
- National or international.
- Describe the study setting, locations and relevant dates, including periods of recruitment, exposure, follow-up and data collection.

Participants

- Give the eligibility criteria, sources of participants, methods that will be used to recruit and select participants (and controls if appropriate, including a rationale for the selection of the cases and controls as well as matching criteria).
- List inclusion and exclusion criteria.
    - This must include clear timelines which describes participants eligible for participation (e.g. all patients registered at XYZ clinic between 01 January 2024 and 31 December 2025)
- Sampling strategy.
- If appropriate – describe follow-up of participants.
- For prevalence and incidence studies, mention the denominators.

Sample size

- Sample size and how it was calculated or estimated.

Measurement

- Briefly describe who does what, when, where, and how, during the measurement process and data collection.

Variables

- Ensure that the information you collect is what is needed to answer the research question/achieve the objectives.
- Describe all information/data that will be collected:
- Define demographic variables.
- Define the outcome variables, exposure variables.

- Define predictors, potential confounders, and effect modifiers.
- Provide diagnostic criteria, if applicable.
- Describe how quantitative variables will be managed in the analysis.
- Describe which variables will be collected as categorical (binary, nominal and ordinal), numerical variables (discrete and continuous).
- Metadata if relevant.

Data sources

- For each variable of interest, give sources of data and details of methods of assessment (measurement).
- Describe who will collect the data, and if data is collected from various sources, mention who will be responsible for which sections.
- Describe comparability of assessment methods if there is more than one group.
- In the case of a survey mention which languages will be used.

Bias

- Describe methods to address bias.

Statistical analysis

- Who will perform statistical analysis.
- Describe all statistical methods that will be performed, including those used to control for confounding.
- Describe any methods used to examine subgroups and interactions.
- Explain how missing data will be addressed.
- If applicable:
  - Explain how loss to follow-up will be addressed.
  - Explain how matching of cases and controls will be addressed.
  - Describe analytical methods to account for sampling strategy.
  - Describe any sensitivity analyses.

Pilot study

- Will a pilot study be performed?
- Who will perform the pilot study
- Who will be the population of the pilot study?
- How many participants are required for the pilot study?
- Will pilot study data be included in the study data set?

Ethics and integrity

- Will participants be remunerated? How is remuneration calculated?
- Describe all risks to participants
- Is a waiver of consent or waiver of ethics review requested – if so, motivate
- Will a published or copy-protected tool or instrument be used? Is permission required to use the tool, or is it open access?
- Will results be made known to participants?
- How will the general public be informed of the results?

- Gatekeepers: Define which gatekeepers need to be approached for approval. For example, Head of Department, University of the Free State, Free State Department of Health.
- Indicate that the study, including the pilot study, will only commence when final approval has been obtained from the HSREC.
- Indicate whether any feasibility study has been done.
- Describe whether data will be collected anonymously, confidentially or whether data will be deidentified. Will data be pseudo-anonymised?
- Describe whether personal information, special personal information or identifiable personal information will be processed.
- Describe the informed consent process and if recruiting any patients or students where a power relationship exists, how therapeutic misconception and duality in roles will be addressed.

Relevance and implementation of findings

- Indicate what may be done with the findings of the study.

Publication policy

- This section should clearly indicate which collaborators will be mentioned as contributors, who will be considered authors and who will be acknowledged.

Time schedule

- Provide a Gantt chart or table showing the timelines clearly.
- Duration of data collection and expected end date of data collection.

Budget and funding sources

- Limit the budget for direct study-related expenses.
- Provide line items and a total cost.

References

- List all relevant references.
- While no specific referencing style is mandatory, you must select one and adhere to it. Ensure that your chosen style includes in-text citations. Consider Vancouver, Harvard or APA.