Writing a study protocol

Study protocol and study handbook

A study protocol is a document describing how a research project is structured and implemented. It summarizes the background, aims and objectives, study design, methods and operationalization of the research project. The study protocol should contain sufficient details to make it possible to the reader (usually a collaborator, donor or ethics agency) to decide whether or not the study is sound and justified. However, the study protocol does not need to address practical details of how the study will be conducted. These practical details will be described in another document called *study handbook* which is aimed for people who are involved in day-to-day running the research and provides precise details on how different stages of the research are to be conducted. A study handbook is essential especially when the research team is big and the study is undertaken in more than one area to make sure that standard procedures are followed by all team members.

Outline of a study protocol

There is no single standard outline for a study protocol and the items included depends on the study design and the amount of details required by the intended reader. However, there are certain sections which are needed to be present in every study protocol. A typical outline could be as below.

- Study title And main researchers and collaborators
- Summery of the study
  1. Background (introduction)
  2. Aims and objectives
  3. methods
     - 3.1 study description
       - 3.1.1 Study design
       - 3.1.2 Study site
       - 3.1.3 Study population
       - 3.1.4 Proposed intervention (if interventional)
       - 3.1.5 Main exposures and outcomes
     - 3.2 Selection of the study population
       - 3.2.1 Inclusion criteria
       - 3.2.2 Exclusion criteria
       - 3.2.3 Sampling
       - 3.2.4 Randomization (in RCT)
     - 3.3 Study procedures
       - 3.3.1 Procedures at enrolment
       - 3.3.2 Follow-up (if cohort)
       - 3.3.3 Measurement of exposures and confounders
       - 3.3.4 Measurement of outcomes
       - 3.3.5 Laboratory and other methods (if applicable)

3.4 Sample size
3.5 Data processing
3.6 Planned analysis

4. Ethical considerations
   4.1 Confidentiality
   4.2 Informed consent
   4.3 Ethical approval
5. Logistics
   5.1 Distribution of responsibilities
   5.2 Timetable
   5.3 Budget
6. References

- Appendices

More details on contents of a study protocol

The title and collaborators

A short and specific title should be chosen which provides some information about the main objective of the study and if possible the design. Collaborators are people who are essential parts of the study and are actively involved such as fellow researchers, lab scientists, statisticians etc.

1. Background

This major section of the protocols is written with the main objective of justifying why the research should be undertaken. It tells the story behind the study. The background reviews the relevant literature in order to address the following issues:

- What study question the study aims to answer?
- Why is this question important?
- What previous work has is relevant and led up to this study?
- Is the proposed study population appropriate to answer this question?
- What are the relevance of the results of the study to advancement of knowledge and improvement of public health>?

2. Aims and objectives

Aim is a general description of the goal of the study. For example the aim of an observational study on burns could be to describe the epidemiology of burns in a particular area and among a particular population. Objectives are more specific than aims and they describe in more detail and more specifically what the study aims to achieve. An objective should have a measurable outcome. For example and objective of the previous example could be to calculate the incidence of burn injuries in the population.

3. Methods

The methods section is usually the longest section of the study protocol. It

describes how the study will be implemented from identifying the study population down to the planned statistical analysis. The structure of the methods section depends on the study design for example the subheadings of a case-control study will be different than subheadings of a cross-sectional survey.

Study design:
The specific study design(s) intend to be used in the study should be mentioned. For example this could be:

- A case-control study
- A descriptive cross-sectional study
- A randomized double-blind interventional study
- A prospective cohort study

Study site
A brief description of places where the study will be undertaken is written here. This could be a hospital or a number of health centres in a particular area, a particular community, a laboratory etc.

Reference (target) population and study population
Before describing the study population, the reference population has to be described. The reference population is the population to which the study results could be generalized. It is the population from which the study population has been selected.

- All pregnant women in the study area
- All children aged 0-5 years in the catchment area of the children's hospital

Then the study population has to be described. This could be:

- Pregnant women attending an antenatal clinic for the first time in the study area.
- Children aged 0-5 years admitted to the children's hospital.

Interventions
If there are any interventions in the study they should be described here. For example:

- 50 mg atenolol taken once a day unsupervised for 3 months or an identical placebo taken in the same way.
- A one-to none 10-minute educational session given at home by a trained personnel on prevention of diarrhea, repeated weekly for 4 weeks.

Exposures and confounders
Mention main exposures you intend to collect information on. Also mention potential confounders that you want to study. Selection of what exposures and confounders to include are related to the outcome under investigation. A proper literature review is required before deciding which ones to include.

Outcome
Mention the main outcome of the study and other outcomes that you intend to study. Keep in mind the objectives of the study while citing the outcomes.

Selection of the study population
A case definition has to be provided It. Describe how the participants are selected for the study. If the study involves randomization or any random selection procedure, this should be described. It is important that the same selection procedure is followed for all participants. For example every second pregnant woman who attends the health centre for the first antenatal visit will be selected.

The precise description of the condition/event under study is given in the case definition. A case definition tells specifically what do we mean by a case in such a way that it can differentiate clearly a case from a non-case. For example

- Any child aged 0-5 years who is admitted to the children's hospital for diarrhea during the period from 1 Jan 2010 till 31st December 2010.

Inclusion and exclusion criteria
It is essential to specify exactly which subjects are included in the study and which ones are excluded. Inclusion criteria are usually apparent from the case definition but exclusion criteria are not. It is better to specify these criteria separately to avoid mistakes in selection of participants.

Sampling
We usually study a sample of the reference population. We have to make sure that this sample is representative to the population. This is done by following a uniform and random procedure for recruitment of participants. For example eligible children of a hospital could be selected by simple random selection from a daily list of all admissions of that day.

Randomization
If an RCT is undertaken, it must be clarified how the intervention and control groups are selected, i.e. how the subjects are randomized to be either part of the intervention arm or the control arm.

Study procedures (Data collection)
This part describes procedures and tools used for data collection and follow-up and how these tools were developed and administered.

Measurement of exposures, confounders and outcomes
Some details to be provided on how exposures and outcomes are measured. Data collection tools could be a face-to-face or a self-administered questionnaire, a form to record hospital data, physical measurements, lab tests etc. Enough information has to be provided on each method to enable the reader decide whether or not they are appropriate.

Follow-up
In a cohort or intervention study it is important to specify how the participants are followed over time and outcomes/ change in exposure status are ascertained.

Sample size
The sample size should be calculated according to appropriate sampling procedures and this should be made clear in this section.

Data processing
Describe how the data was handled after it was collected from participants. This includes procedures to ensure high quality data and minimizing error. These could include checking questionnaires, data entry, double entry, consistency checks, use of intelligent software and preparation of data for analysis.

Plan of analysis
Describe briefly how the data will be analyzed and what procedures will be used to investigate associations between exposures and outcomes and control of confounding.

4. Ethical considerations
Describe how the ethical aspects of the study are addressed. What potential risks the participants are subjected to and how are these justified. Specifically describe how confidentiality is maintained and informed consent is obtained from the participants. Also mention what authority has given ethical approval to the project.

5. Logistics
If the study involves a team and multiple centre, it is useful how staff and resources are managed and what administrative procedures are in place to ensure smooth running of the project throughout its different phases.

It is useful to have a diagram showing the timetable of different phases and tasks of the project. This will be a good planning and monitoring tool.

Having an accurate estimate of the costs is an essential part of the planning of a research project. A budget plan is an essential part of any grant application.

6. References
List references cited in the protocol in a uniform way.

Appendices
May include sample size calculation, questionnaires, data collection forms, patient information sheet, consent form etc.