

# Tips when preparing your research protocol

**A well-written, comprehensive study protocol is essential for high-quality research. All research studies, including low risk studies, require a research protocol that contains sufficient detail for ethical, governance, and methodological appraisal.**

In preparing a research protocol, you must first decide **what you want to know more about**. The question that you want to research must be viable as a research project and lead to new knowledge.

A **research protocol** is a detailed set of activities for the project you propose that are supported by evidence from other research and from preliminary investigations. The protocol will guide you through your activities / experiments and shows some foresight into your aims. It shows evidence of planning, including how you anticipate potential problems and how you will deal with them.

**Please consider the following questions when producing a research protocol:**

## **Is it a good research idea?**

- Does the protocol make a convincing and coherent case for the importance of issues to be researched?
- Does the proposal make a convincing and coherent argument for the need of your research to fill gaps in current knowledge?
- Does the research protocol frame issues in a way that makes them amenable to research using the methodologies and design proposed?
- Are the research aims and objectives clearly described and explained?

## **Are the methods sound and appropriate?**

- Are the design and methods for the proposed study fully described, explained, and justified?
- Will the research design and methods deliver the aims and objectives?
- Are the design and methods the most efficient way to deliver the aims and objectives?
- Will the research results be generalisable or transferrable beyond the immediate research setting?
- Does the protocol describe and explain the steps the research will take to avoid potential sources of bias?
- Can the proposed research meet the relevant legislative and regulatory requirements?

## **Is the study practical and feasible?**

- Is the research process described in sufficient detail to assess feasibility?
- Can you complete the research within the time described in the protocol?
- Can you conduct the study with the resources described in the protocol?
- Does the investigators' team incorporate the range and experience needed to conduct the study?
- Does the protocol describe the research setting's benefits and limitations?

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## The research protocol's structure

### Title

This should be concise and descriptive, identifying the **main objective** and **study population**.

### Investigator's details

- You should provide names and contacts for all investigators.

### Introduction / Background

- Explain the background and context of your proposed research.
- Summarise the published literature that supports your research idea.
- Identify the gaps in existing literature.
- Justify why your research would create valuable and useful knowledge; and the potential impact of your research findings.

### Research questions

- Formulate your research questions clearly. You should have an answerable question that is clear and well-defined / focused to conduct your research within an appropriate time frame.

### Aims and Objectives

- Outline concise and precise main objective/s and secondary objectives (if applicable).

### Study Design and Methods

#### • Study Design:

What study design is most appropriate to answer your research question?

#### • Setting:

Where will the research take place? Your study may take place in multiple sites.

#### • Subjects / Patients / Participants:

- You should provide detailed information about your subjects. For example, describe the study population, including a rationale of why they were chosen.

- Describe the methods in which subjects will be identified and recruited, and what inclusion and exclusion criteria will be used.
- You must justify your sample size and state whether you have used sample size calculations.
- You may also need to describe the research participation criteria, participant retention strategies, and withdrawal criteria.

#### • Randomisation methods:

- Some research strategies require randomly allocating patients to the different experimental groups or interventions. You must explain what randomisation methods you will use.

#### • Assessment or measurement methods:

- What data will be collected and why? For example, how will you measure your participant's quality of life, what instruments will you use and are they the most appropriate? You should clearly describe any research equipment you are using.

#### • Outcome measure / objectives:

The measurement outcomes you use to support or reject the hypothesis can be stated or separated into primary and secondary outcomes.

#### • Interventions (if applicable):

- You should describe the research intervention. If you are giving a treatment or investigation, the dose, timing, method of providing, administering, and receiving the treatment should be detailed.
- All necessary risks should be made clear, including the methods where intervention will be monitored.

### Ethical considerations

- You should read any appropriate ethical guidelines and ask yourself how / whether your project follows these.

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- Outline the methods by which the patient/subject's interests will be safeguarded. For example, within the risk limitation process, outline how you will maintain confidentiality or anonymity and how you will monitor any adverse side effects.

### Timescales

- You should map out a reasonable work schedule to monitor your progress and manage your project effectively.

### Dissemination

- You might like to give some consideration as to what findings might be publishable and where you would like them to appear.
- You should also consider how your research findings could be adopted. Discuss any barriers you foresee to how your research findings are adopted either in a healthcare setting or to the next stage of research.
- What can you do to overcome these barriers and ensure your research findings have the maximum impact?

### Contact

For more information and advice, contact the Research Development Officer on (07) 5687 8310 or e-mail

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