



SOP Number: NCR II 001  
SOP Title: Protocol writing

	NAME	TITLE
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**1. PURPOSE**

This SOP provides brief guidance on how to write a research project protocol and aims at standardising practice. It is part of a series that were created by the National Cardiac Research Improvement Initiative (NCRII) based on the successful analogous National Thoracic Research Improvement Initiative (NTRII) led by Professor Eric Lim.

**2. INTRODUCTION**

The research protocol is an essential part of a research project. It is a full description of the research study and will act as a 'manual' for members of the research team to ensure everyone adheres to the methods outlined<sup>1</sup>.

Protocols have common elements and items that need to be addressed and templates are useful to guide researchers. Protocols should describe as much detail about the research project as possible, to enable the review bodies (if needed) to fully understand the research project.

**3. SCOPE**

This SOP covers the content of a research protocol to ensure efficient information delivery.

**4. SPECIFIC PROCEDURE**

The sections of the protocol (dependent on your project) should be the following:

**Title page**

Project title, short title and author(s).

**List of abbreviations**

Abbreviations used in the protocol and their meaning should be explained at the beginning of your protocol.

**Short summary**

The short summary can be presented in a table and provides a brief overview on your project. It should include the following information: title, short title/acronym, sponsor name, REC reference, overall aim, design, primary endpoint, inclusion criteria, exclusion criteria,

**Background**

Present the rationale behind your work (gaps in the literature, clinical practice limitations encountered and so on) and the reasons for the research project that you want to undertake.

**Aims and objectives**

Present in two sentences the question(s) that you are aiming to answer. You can also include secondary endpoints if you wish.

**Methods**

Explain how you are planning to undertake your research. Be sure to expose all stages of your research (how the data is going to be gathered, the permissions you are going to ask for, the analysis of the data that you are planning to undertake).

**Statistical analysis**

If necessary, provide the analytical methods that you will need to use to answer your main question. You do not need to be specific, but you need to plan ahead on what tools/programs you will be using for your research project.

**Data management**

Explain how the data will be treated. You should specify who will have access to the data and how the data will be stored.

**Outputs**

Expose how you are planning to disseminate your results.

**References**

In an organised and homogenous format. Use of a referencing tool is encouraged (Mendeley is a very good referencing manager and is available for free).

**5. REFERENCES**

<sup>1</sup> Protocol - Health Research Authority. <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/>

**6. CHANGE HISTORY**

SOP no.	Effective Date	Significant Changes	Previous SOP no.