

**PROTOCOL DEVELOPMENT**

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| **Version** | **Date** | **Reason for Change** |
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1. **Background**

A research protocol is the document that outlines the study plan for a clinical research project. The plan must be carefully designed to safeguard the health and safety of the participants, as well as answer specific research questions. A protocol describes who the participants are in the study, the schedule of study procedures, and the length of the study.

1. **Purpose**

This SOP describes writing a research protocol to SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) and HRA guidelines. These guidelines should be follow for all interventional studies and all projects which come require NHS or Social Care Ethical approval.

1. **Procedure**

The [Protocol Template](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/Protocol-Template.docx) should be used to generate a study protocol if required, omitting any sections that are not relevant to the study. The document should be named and versioned according to the guidance in [SOP2 Document control](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP2-Document-Control.docx).

Any amendment to an NHS REC approved protocol must receive REC and NHS R&D approval **before** the changes are implemented. The RKE Office must also be informed to ensure that the changes do not affect the terms of sponsorship and insurance cover.

The contents of the study protocol should include the following topics (where applicable):

1 INTRODUCTION

1.1 Background

1.2 Rationale

2 STUDY OBJECTIVES

2.1 Primary Objective

2.2 Secondary Objective

2.3 Primary endpoint/outcome

2.4 Secondary endpoint/outcome

3 STUDY DESIGN

4 STUDY SETTING

5 ELIGIBILITY CRITERIA

5.1 Inclusion Criteria

5.2 Exclusion Criteria

5.3 Withdrawal Criteria

6 STUDY PROCEDURES

6.1 Recruitment

6.1.1 Patient Identification

6.2 Consent

6.3 Randomisation

6.3.1 Method of implementing the allocation sequence

6.4 Blinding

6.5 Unblinding

6.6 Baseline Data

6.7 Study Assessments

6.8 Long term follow-up assessments

6.9 Qualitative assessments – nested studies

6.10 Withdrawal Criteria

6.11 Storage and analysis of samples

7 ADVERSE EVENTS

7.1 Definitions

7.2 Reporting procedures

7.2.1 Non serious AEs

7.2.2 Serious AEs

8 STATISTICS AND DATA ANALYSIS

8.1 Sample size calculation

8.2 Planned recruitment rate

8.3 Statistical analysis plan

8.3.1 Summary of baseline data and flow of patients

8.3.2 Primary outcome analysis

8.3.3 Secondary outcome analysis

8.4 Subgroup analyses

8.5 Adjusted analysis

8.6 Interim analysis and criteria for the premature termination of the study

8.7 Subject population

8.8 Procedure(s) to account for missing or spurious data

8.9 Other statistical considerations

8.10 Economic evaluation

9 DATA HANDLING

9.1 Data collection tools and source document identification

9.2 Data handling and record keeping

9.3 Access to Data

9.4 Archiving

10 MONITORING, AUDIT & INSPECTION

11 REGULATORY ISSUES

11.1 Ethics Approval

11.2 Peer review

11.3 Public and Patient involvement

11.4 Regulatory Compliance

11.5 Protocol compliance

11.5.1 Notification of Serious Breaches to GCP and/or the protocol

11.6 Data protection and patient confidentiality

11.7 Conflicts of Interest

11.8 Indemnity

11.9 Amendments

11.10 Access to the final study dataset

12 DISSEMINATION POLICY

12.1 Authorship eligibility guidelines and any intended use of professional writers

13 REFERENCES

14 APPENDICES

Appendix 1 - Summary of investigations, treatment and assessments

Appendix 2 - Amendment History

1. **Related Documents**

[Protocol Template](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/Protocol-Template.docx)

[SOP2 Document Control](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP2-Document-Control.docx)

1. **References**

Spirit Guidelines

<http://www.spirit-statement.org/>

HRA

<http://www.hra.nhs.uk/>