




SOP Number 002
SOP Title Protocol Development

	Name	Title	Signature	Date
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1. PURPOSE

The purpose of this SOP is to provide instructions for the development and review of a clinical research protocol.

2. INTRODUCTION

The protocol is a key document in clinical research which needs to be developed in a timely manner in conjunction with expertise that covers all areas such as statistics, drug safety, trial management, monitoring, sponsorship requirements and quality review.

3. SCOPE

The scope of this procedure is for all clinical trials sponsored by the University of Oxford, but may also be used for other research studies at the discretion of the unit.

4. DEFINITIONS

Protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial.

Submission Package

Protocol and relevant supporting documents needed for submission to the Sponsor, Research Ethics Committee, and the Competent Authority.

5. RESPONSIBILITIES

Chief Investigator (CI) or delegate

The CI or delegate is responsible for appointing an editor and developing the protocol.

Statistician

The statistician is responsible for providing statistical input into the protocol.

Editor

The editor is the person identified to coordinate the authorship and review of the different sections of the document.

Reviewers

Reviewers contribute to the development and content of the protocol. They may include, but are not limited to, representatives from the Trial Management Group (TMG), statisticians, Sponsor, pharmacists, and pharmaceutical companies.

Key Parties

A subset of the Reviewers who provide written confirmation that they are satisfied that the final version of the protocol is ready for submission. This must include a representative from the Sponsor office and the Chief Investigator (CI), and should include a statistician and a quality reviewer.

Sponsor

Responsible for review and approval of submitted documentation, together with continued oversight of progress.

Quality Assurance Manager or equivalent

Responsible for review of protocols and supporting documentation for consistency and regulatory compliance.

6. SPECIFIC PROCEDURE

6.1 Initial Planning of the Protocol Development Phase

CI or delegate from the unit appoints the editor to co-ordinate the development of the protocol.

Initial protocol development discussions with the CI should include agreement on who needs to be involved in the writing and review of the protocol. The group should be kept as small as possible whilst remaining representative of the stakeholders and ensuring that it provides the necessary relevant expertise. Discussion should also include agreement on milestones and timeframes.

6.2 Protocol Development and Review

The editor works with the CI and statistician to develop the protocol using an appropriate template.

The editor ensures a draft protocol is sent to all relevant reviewers (except Sponsor at this stage) stating clearly the deadline for review and instructions to track comments in such a way that the current content is not deleted.

The editor considers all comments, and produces the next draft of the protocol. It may be necessary for this review process to be repeated.

A Risk Assessment (RA) based on the MHRA RA model, should also be considered at this stage. The editor produces Final Draft taking into account any additional information arising from the Risk Assessment.

A QC check for consistency and coherence should take place before submission to the Sponsor.

6.3 Sponsor Protocol Review

Once the editor is satisfied that adequate review has been done, the draft protocol **must** be sent for review to the Sponsor, and timelines will be agreed.

Where appropriate, contact should also be made with the contracts team in the Joint Research Office (JRO, Oxford), who will identify the need for setting up appropriate contracts and agreements.

The editor must act upon comments received from the Sponsor and should discuss significant comments with appropriate personnel, before responding to the Sponsor. All comments raised by the Sponsor should be addressed within the timeline agreed.

The editor should keep the Sponsor updated on progress of development to the next stage and, in the event that the project has been put on hold, the Sponsor should be informed in a timely manner.

6.4 Preparation of Submission Package

The editor prepares all other documents required for submission ensuring that information is consistent throughout.

Where possible, the editor should ensure that the Quality Assurance Manager (or equivalent) is also involved in the review of the supporting documents before package is sent to Sponsor for review.

6.5 Review of Submission Package by Sponsor

The editor highlights any changes made to the protocol since the last Sponsor review.

The Sponsor reviews the Submission Package and advises on required changes. The final Submission Package must be provided to the Sponsor.

6.6 Reviewers Approval of Final Version

Editor should ensure that there is documentation of evidence that the Key Reviewers have approved the protocol marked as final version.

7. RELATED DOCUMENTS

CTRG Protocol Template or relevant departmental protocol template.
Any associated instructions.

8. REFERENCES

MHRA Good Clinical Practice Guide, (2012)

MRC/DH/MHRA Joint Project Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products 10th October 2011

9. CHANGE HISTORY

Version No.	Effective Date	Significant Changes	Previous Version No.
1.1	01 Jan 2014	Updated into new Core SOP template Clarification Section 7	1.0
2.0	24 Jun 2014	SOP text unchanged. Version number updated only.	1.1
3.0	See page 1	Updated scope and first page in line with SOP template. Included the responsibilities of the CI, Statistician, Sponsor and Quality Assurance Manager within Section 5.	2.0