LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1027 LU

Process for Writing Study Protocols for NHS Research Sponsored by Loughborough University

Effective Date: October 2015

1.0 Introduction

The aim of this Standard Operating Procedure (SOP) is to define requirements for the format and content of study protocols for research sponsored by Loughborough University (LU).

A research protocol is an extremely important document that essentially acts as the 'manual' for the whole research study. It is expected that a Protocol be produced for each individual research study, and forms the basis of every application to regulatory authorities. A comprehensively written Protocol will enable a smooth and less arduous approvals process.

2.0 Scope

This SOP applies to all undertaking research sponsored by LU.

3.0 Procedure

A research protocol must detail clearly all aspects of the study design and methodology. It must detail procedures associated with the entire study and be compliant with all relevant regulatory, ethical and legal requirements. These requirements will vary depending on the nature of the research activity and must be discussed in detail during the development of a research protocol. It is recommended that the Sponsor templates are used as a starting point when developing a new protocol.

The template, Research Protocol (Non-CTIMP), is available on the Ethics Approvals (Human Participants) Sub-Committee website.

While it is not a mandatory requirement of the Sponsor to use these templates, if during the Sponsor risk assessment and Approval Process it is considered that the document titled 'protocol' is not adequate, the Chief Investigator will be asked to re-submit using the provided template.

Guidance on the completion of Protocol template sections can be found within the template document.

4.0 Research study protocol management

4.1 Authors developing a study protocol must collect adequate background information from all available sources (pre-clinical data, published information, information from potential collaborators, etc) to enable appropriate design and methodology to be defined.

4.2 Appropriate statistical advice must be sought at an early stage, and consideration must be given to the data processing aspects of the proposed study and the format of the Study Report.

4.3 Regular communication with the LU Research Governance Officer is essential during the development of a protocol in order to facilitate smooth progression through the regulatory framework, and faster Sponsor authorisation.

4.4 During development, a protocol must be clearly marked as 'draft' and must be version numbered, dated and appropriately filed. These early iterations must be maintained in a 'pre-approval' file with comments and revisions clearly documented. It is expected that this file be maintained along with all other study documentation.

4.5 Once the Protocol has been finalised, the final document should be clearly marked "Final Protocol" and appropriately dated. Each page of the document should be marked in the header with the protocol number, date of the document and numbered page x of y. All Appendices must be similarly dated and paginated.

4.6 Following production of the Final Protocol approval signatures must be collected and dated (Appendix A), from:

- The Author (if different to the Chief Investigator (CI))
- A representative of the Sponsor
- The Principal Investigator (if different from the CI) at each participating site

4.7 The original signed copy of the Final Protocol should not be removed from the Study File. Working copies can be printed as required. Additional copies should be prepared for retention by individual Investigator(s) and other collaborators (e.g. Pharmacy, R&D). An electronic copy of the Final Protocol should be stored electronically and adequately backed up.

5.0 Protocol Amendments

Once the final Protocol has been approved it must not be informally altered. It must be made clear to all collaborators that they must not change the Protocol without prior discussion with the Chief Investigator and the approval of the Sponsor.

Once agreed by the Chief Investigator, Collaborators and Sponsor, protocol amendments may be submitted for formal approval in accordance with the SOP-1026 LU Sponsor Approval Process for Amendments.

6.0 Responsibilities

	Responsibility	Undertaken by	Activity
1	Chief Investigator	Chief Investigator	Ensure Protocol uses or includes all necessary sections as detailed in relevant protocol template
2	Chief Investigator	Chief Investigator	Maintain the original and subsequent protocol versions in the Trial Master File with appropriate evidence of approval / favourable opinion and supporting documentation.
3	Chief Investigator /LU as Sponsor	Chief Investigator /LU as Sponsor	Ensure that Final Protocol is signed by appropriate individuals prior to submission, and at each site
4	Chief Investigator /LU as Sponsor	Chief Investigator /LU as Sponsor	Ensure that any amendments / revisions to the Final Protocol are managed in accordance with SOP-1026 LU.

7 Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored by LU has appropriate contracts in place.	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity.	Research Governance Officer or their delegate

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Jackie Green	**Job Title:** Research Governance Officer
Approved by:	Ethics Committee	**Date Approved: 23/10/15**

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**

APPENDIX A

Signature Page

Chief Investigator Name: _____

Chief Investigator signature: _____

Date: _____

Sponsor Representative Name: _____

Sponsor Representative signature: _____

Date: _____

Principal Investigator Name: _____

Principal Investigator signature: _____

Date: _____

(in cases of Multi-centre studies, this must be replicated for each site)