# UNIVERSITY OF LEICESTER
# &
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## JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE

## STANDARD OPERATING PROCEDURES

## University of Leicester (UoL) Research Governance Office
## SOP S-1027 UoL

Version 3.0, September 2021

# Process for Writing Study Protocols for Research Sponsored by University of Leicester


OFFICE BASE

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Effective Date: October 2021

## 1 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 University of Leicester (UoL).

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 Scope

This SOP applies to all undertaking research sponsored by UoL.

## 3 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.

Protocol templates available on the HRA and/or the Research Governance website must be used as a starting point when developing a new protocol.

Whilst it is not a mandatory requirement of the HRA to use these templates, UoL as Sponsor is mandating their use.

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

## 4 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 Trial Clinical Study Report.

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

4.4 During development, a protocol must be clearly marked as 'draft' and must be version controlled, dated and appropriately filed. The Sponsor recommends using the following version control and file naming format:

Sponsor Ref (IRAS Number)_Protocol_vX.X_DD-MM-YYYY (you can also add 'DRAFT', 'TRACKED CHANGED' (or 'TC') or 'CLEAN' to the end of the filename to make it easier to identify documents)

Whilst documents are in draft, the Sponsor recommends versions to be listed as v0.1, v0.2, v0.3 etc.

Pages should also be numbered with the 'Page X of Y' format.

4.5 These early iterations must be maintained in a Sponsor Review file with comments and revisions clearly documented. It is expected that this file be maintained along with all other study documentation.

4.6 Once the Protocol has been finalised, the final document should be changed to v1.0.

4.7 Prior to Sponsor Green Light being issued the Protocol Signature Page should be completed by obtaining signatures 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

4.8 The original signed copy of the final version of the Protocol should not be removed from the Trial Master 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). A copy of the Protocol should be stored electronically and adequately backed up.

## 5 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 S-1026 UoL Sponsor Green Light Process for Amendments.

## 6 Responsibilities

| | Responsibility | Undertaken by | Activity |
|---|---|---|---|
| 1 | Chief Investigator | Chief Investigator | Ensure Protocol uses or includes all necessary sections as detailed in relevant protocol template |

| | Responsibility | Undertaken by | Activity |
|---|---|---|---|
| 2 | Chief Investigator | Chief Investigator | Maintain the original and subsequent protocol versions in the Trial Master File with evidence of all applicable regulatory and Sponsor approvals and supporting documentation. |
| 3 | Chief Investigator /UoL as Sponsor | Chief Investigator /UoL as Sponsor | Ensure that Final Protocol is signed by appropriate individuals |
| 4 | Chief Investigator /UoL as Sponsor | Chief Investigator /UoL as Sponsor | Ensure that any amendments or revisions to the Protocol are managed in accordance with SOP S-1026 UoL. |

## 7 Monitoring and Audit Criteria

| Key Performance Indicators | Method of Assessment | Frequency | Lead |
|---|---|---|---|
| All research sponsored by UoL has appropriate Risk Assessment | Included in the monitoring / audit programme. | Random audits / monitoring conducted on 10% of research activity. | Research Governance Manager 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:** | Cat Taylor |
| **Job Title:** | Head of Research Assurance |
| **Reviewed by:** | Research Sponsorship Management and Operations Group |
| **Approved by:** | Professor Nigel Brunskill  |
| **Date Approved:** | 13/10/2021 |

## Review Record

| Date | Issue Number | Reviewed By | Description Of Changes (If Any) |
|---|---|---|---|
| Nov 2016 | 2 | Diane Delahooke | Logo changed and reference to HRA templates added. |
| Sept 2021 | 3.0 | Cat Taylor | Updates throughout to reflect current Sponsor recommendations and processes and to make administrative changes. |

## Distribution Record

| Date | Name | Department | Received |
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