University of Leicester and University Hospitals of Leicester NHS Trust Joint Research Support Office Standard Operating Procedures

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

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

Version 4.0, September 2023

Office Base

Research Governance Office
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Effective Date: October 2023

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

1.0 Introduction & Scope

The aim of this Standard Operating Procedure (SOP) is to define requirements for the development and review of study protocols (protocol) for research sponsored by the University of Leicester (UoL).

A protocol is a key document that acts as the 'manual' for the whole study. A protocol must be produced for each individual study, and will form the basis of every application to regulatory authorities and the development of other study documents such as the Informed Consent Form(s) and Participant Information Sheet(s). A comprehensively written protocol will ensure a smooth approvals process and facilitate the management of the study.

2.0 Procedure

A protocol must clearly detail all aspects of the study design, methodology and analysis It must be compliant with all relevant regulatory, ethical and legal requirements. These requirements will vary depending on the nature of the study and researchers must take these into consideration during the development and drafting of their protocol.

3.0 Research study protocol development

Templates are available from the HRA and/or the Research Governance webpages and must be used by all investigators when developing a new study protocol.
Authors developing a 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.

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

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

Iterations and drafts must be maintained by the researcher. The Sponsor will retain drafts reviewed as part of the Sponsor Review processes. Comments and revisions, including those requested via the peer review process, must be clearly documented.

Following the regulatory approvals process (initial and/or for an amendment affecting the protocol), the research team are responsible for obtaining a signed signature page for every approved version of the protocol for each site. This must be signed by a representative of the Sponsor, Chief Investigator and Principal Investigator. A copy must

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be maintained in the Trial Master File (TMF)/Investigator Site File (ISF), as appropriate. For Clinical Trials of Investigational Medicinal Products (CTIMPs), a fully signed protocol signature page must be provided as part of the request for site Sponsor Green Light.

Electronic signatures are accepted.

4.0 Protocol Amendments

There is a formal process for making amendments to the approved version of the protocol (refer to SOP 1018 'Process for Sponsor approval of amendments'). Protocols must not be altered or amended without prior discussion with the Chief Investigator. Other research team members must also be consulted as appropriate and in accordance with the nature of changes being made (i.e., Statisticians, Pharmacists, Principal Investigators, funders etc.).

Once agreed by the Chief Investigator (and other relevant individuals, as applicable), protocol amendments must be submitted to the Research Governance Office (RGO) for formal review and approval by the Sponsor in accordance with SOP 1018 'Process for Sponsor approval of amendments'.

5.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator	Chief Investigator	Ensure Protocol uses or includes all necessary sections as detailed in relevant protocol template
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.
Chief Investigator /UoL as Sponsor	Chief Investigator (or delegate) /RGO	Ensure that Final Protocol is signed by appropriate individuals
Chief Investigator /UoL as Sponsor	Chief Investigator (or delegate) /RGO	Ensure that any amendments or revisions to the Protocol are managed in accordance with SOP S-1018 UoL.

6.0 Development and approval Record for this document
This table is used to track the development and approval of the document

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Management and Operations Group (RSMOG)	Professor Nigel Brunskill	28/09/2023

7.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

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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.
September 2023	4.0	Cat Taylor	Administrative Updates Updates to wording to clarify the process Updates to responsibilities table Removal of distribution record and monitoring and audit criteria

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