1. Introduction

This Standard Operating Procedure (SOP) describes the process that the University Hospitals of Leicester NHS Trust (UHL) follows for reviewing and approving any UHL sponsored research. The sponsor is the individual, company, institution, or organisation that takes on legal responsibility for the initiation, management and/or financing of the research.

Arrangements and subsequent documentation for an UHL sponsored study must be reviewed by appropriate personnel within the Research & Innovation Directorate at UHL to ensure that:

- UHL can deliver the study with or without external support
- An appropriate Peer/Scientific review has been conducted
- The study has adequate funding, and all applicable contracting is in place

2. Scope

This SOP applies to all internal staff conducting UHL sponsored research.

3. Determining which organisation is the sponsor

The sponsor is usually the employer of the Chief Investigator (CI). If the CI is substantively employed by UHL then UHL will likely be the organisation that is the sponsor and the research application will be processed by the UHL R&I team via uhlsponsor@uhl-tr.nhs.uk. Alternatively if the CI is substantively employed by the University of Leicester (UoL) then UoL will likely be the organisation that is the sponsor and can be contacted via rgosponsor@leicester.ac.uk .

4. Requirements for sponsorship review and approval

4.1 Documentation required

It is expected that, as a minimum, study documentation will consist of the following:

a)	Completed Sponsor Request Form; https://forms.gle/21UZHpf5jnhNxM9eA
b)	Protocol; it is recommended that the HRA Protocol Templates are utilised as appropriate. You may of course use your own template, but we recommend that you check it against the HRA examples to ensure it captures all the relevant elements. Please see SOP S-1021 UHL for further information.
c)	Full Data Set from the Integrated Research Application System (IRAS). Please be aware that some questions ask for information about the study in language which can be understood by a 'lay' person. In addition, it is recommended that you do not simply copy and paste the protocol into the IRAS form. Guidance on specific questions can be found within the IRAS

	form and it is recommended that researchers take the time to read the FAQs and question specific advice available within IRAS.
d)	Participant documentation where applicable, such as Informed Consent Forms (ICF), Participant Information Sheets/Leaflets (PIS/L), Letters of Invitation, and Letters to GP – examples of ICF and PIS/L can be found here; hra-decisiontools.org.uk It is particularly important that participants give express permission for each aspect of the research. This may include storage of their data or tissues outside of the NHS organisation that provides their care. Permission must also be sought to allow the Sponsor to access their medical notes and research data as part of the monitoring and audit process. Wording for these aspects is suggested on the templates.
e)	Study recruitment aids, such as posters, advertisement text and example social media posts.
f)	Evidence of Peer Review as relevant to nature of study (Appendix 1). The Peer Review process ensures the methodology employed in a research study will produce robust and credible results. It is expected that the reviewer is independent from the research team and that they should not have had any input into the design, supervision, collaboration, recruitment, conduct and subsequent analysis of the research study. Please see section 4.2.
g)	Evidence of costing and confirmation of adequate funding available for the duration of the study. Please see section 4.3.
h)	Investigator Brochure or Summary of Product Characteristics (where relevant). Please see 4.4.
i)	Signed and dated copy of the Chief Investigator CV and copy of relevant training certificates.
j)	Completed Organisation information Document (OID) and Schedule of Events (SoE) or Cost Attribution Template (SoECAT). Please see section 4.5.

4.2 Peer Review

It is the responsibility of UHL to ensure that an appropriate peer review has been undertaken.

It may be necessary for UHL to arrange peer review when it has not already occurred as part of a competitive funding process.

NIHR Portfolio studies that have been peer reviewed as part of the funding application process will not usually require a further review.

Where the proposed research has not been subject to rigorous external review, or in the case of a student

project not being submitted to the NIHR for adoption, or review by an academic supervisor, the Chief Investigator may arrange for an appropriately qualified person to conduct the Peer Review on behalf of UHL. A copy of the Peer Review form is in Appendix 1. The form must be completed and submitted along with the other documents required for sponsor review.

If a researcher does not accept the comments within a Peer Review, it can be escalated to the Clinical Management Group Lead and the R&I Management Group for further discussion and appropriate action.

Peer review must be undertaken before confirmation of sponsorship is agreed and before submission to the main REC / HRA and MHRA, if required.

Details of the peer review must be documented in the Trial Master File and Investigator Site file.

4.3 Evidence of Costing & Funding

Every research study must provide evidence of adequate funding provision for the duration of the study. In cases where adequate funding is not forthcoming for future years, it will be expected that the UHL department where the Chief Investigator is employed will underwrite the study to ensure completion. R&I finance authorisation will be requested as part of the sponsor review process.

4.4 Investigator Brochure (IB) / Summary of Product Characteristics (SPC)

Trials of Investigational Medicinal Products, or medical device trials utilising non-CE marked devices, must be accompanied by either an IB or SPC as applicable. Copies of the IB / SPC will be forwarded to Pharmacy / Medical Physics for review as applicable.

4.5 OID and SOECAT

The Organisation Information Document (OID) should be used to provide information on participating NHS/HSC organisations in the UK for non-commercial studies. An outline Organisational Information Document for each site type should be completed as part of your submission. For non-commercial studies it should be accompanied by a completed Schedule of Events or a Schedule of Events Cost Attribution Template (SoECAT). The two documents allow the sponsor to make clear what activities will be undertaken locally and the cost type for each activity.

If a SoECAT has been completed as part of a funding application, then you should supply the SoECAT. You will need to provide one SoECAT per outline Organisation Information Document. If any of the details have changed during the funding process these should be reflected in the SoECAT submitted with the IRAS Form. The SoECAT will have to be reauthorised by an AcoRD specialist.

4.6. NIHR Portfolio adoption

The CI must make every endeavour to have their study adopted on to the NIHR portfolio. Eligibility is defined here;

https://www.nihr.ac.uk/documents/researchers/i-need-help-to-deliver-my-research/eligibility-criteria-for-nihr-clinical-research-network-support.pdf

Please contact UHLsponsor@uhl-tr.nhs.uk for guidance if required.

4.7 Publication and dissemination plans

Providing participants with a summary of the findings acknowledges and appropriately respects the contribution they have made. Information about the publication and dissemination arrangements should be included in the participant information sheet and also in the IRAS form and protocol.

Involving patients or other people with relevant experience at an early stage in your planning will help you to provide feedback and dissemination of the study results in a user-friendly way which is accessible to multiple audiences.

4.8 Patient and public involvement

Research should involve patients and the public where possible. Research teams which involve patients and the public in the design, conduct and dissemination of research perform more effectively because:

- they are more relevant to participants
- they are designed in a way which is acceptable to participants
- they have participant information which is understandable to participants
- they provide a better experience of research
- they have better communication of results to participants at the end of the study.

5. Sponsor Review Process

On receipt of a valid application, the R&I Head of QA and Compliance or their delegate will commence a review of all submitted documentation.

An application will be deemed as 'valid' only when all key documentation for the study has been received.

The Initial Sponsor Documentation Review may take up to 14 calendar days. Where appropriate, a meeting to discuss the initial documentation review will be arranged with the CI and relevant members of the study team.

Documentation must not be amended by the research team whilst the sponsor review is ongoing. Queries for the application will be returned to the CI/research team. A response to each question, revised documentation and any points of clarification will be required before a further review is conducted. Only when all queries, required amendments and points of clarification have been satisfied will the UHL confirm Sponsorship in principle, thereby giving authorisation to the CI to progress applications to Regulatory Agencies, such as the MHRA, HRA, and NHS Research Ethics for example. UHL will confirm sponsorship by signing off the IRAS form. This signature can only be by an authorised signatory, such as the R&I Manager, R&I Head of QA and Compliance, or the R&I Director of Operations.

For an overview of the process for setting up UHL sponsored research from start to finish, please see appendix 2.

6. Supporting Documents and Key References

SOP S-1003 - UHL Sponsor risk assessment and management

SOP S-1021 – UHL Protocol

SOP S-1023 – UHL IB SmPC

Key Performance Indicator	Method of Assessment	Frequency	Lead
N/A	R&I Routine Audit	As required	R&I Quality Assurance Manager

7. Key Words

Research, Innovation, Participants, Trials, HRA, Sponsor, Protocol, IRAS, SoECAT, Peer Review, NIHR, OID.

This line signifies the end of the document.

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

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney	**Job Title:** Director of Operations
Reviewed by:	R&I Governance Meeting	
Approved by:	Professor Nigel Brunskill	**Date Approved: PGC 21.6.24 (as a category B SOP)**

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
November 2013	2	R&D Management Group	Update & Clarification of sponsor review process.
March 2015	3	R&I Management Group	Changes to Logos and personnel titles. Additions to 3.7 Peer Review section. Added sections 3.8, 3.9 & 3.10.
November2016	4	CM, LW, JJ	Mandating use of Protocol Template, consistency checks, mandating use of HRA wording for Consent Forms & PIS. Amalgamation of application form.
March 2017	5	CM	Update to Logo.
January 2018	6	CM	Changes to reflect Sponsor review now happening in EDGE.
Sep 2018	7, 8	CCL	Version number out of sync, updated to reconcile version

			number per existing docs and Review Record. Added Leicester's Research logo to Appendix 1.
October 2020	9	CM LW	Update and review.
January 2021	10	CM, LW	Inclusion of MHRA Gateway information. Appendix 1 obsolete from 01.02.2021, Reformatting to new template.
April 2024	11	JB	Full document update due

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

University Hospitals of Leicester NHS Trust

SOP S-1002 Appendix 1: Sponsorship review and approval - Peer Review Form

Thank you for agreeing to undertake a peer review of this project. Please ensure ALL sections are completed.

Chief Investigator: Project Title:

1. Does the project have a clear hypothesis or study objective?

□ YES - satisfactory □ NO – requires improvement (please comment below)

2. Does the background information adequately justify the study?

□ YES - satisfactory □ NO – please comment below

3. Is the proposed sample size sufficient to answer the research question?

□ YES □ NO – please explain below

4. Is the methodology appropriate for the project?

□ YES □ NO – please suggest improvements below

5. Is the clinical/biological significance clearly explained?

□ YES □ NO – please comment below

6. Given the current proposal, is the study feasible and achievable (able to answer the research question)?

□ Very likely

□ Probably – please explain concerns below

□ Not likely - please offer advice below

7. Any other comments you wish to make about the study?

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8. Declaration

I declare that I have not been involved in the design of this study, am not part of the study team, have read and reviewed the study proposal/protocol and that I have no conflict of interest in acting as a referee.

Signature: …… Date: …….

Print Name: ……

Post held: ……

Contact Address: …….

Contact Details:

1. Telephone: …….. 3. Email: ……

* Please return this review to the uhlsponsor@uhl-tr.nhs.uk

SOP S-1002 Appendix 2 Sponsorship review and approval overview