1. Introduction

This Standard Operating Procedure (SOP) describes the process that the University Hospitals of Leicester NHS Trust (UHL) will follow when conducting initial research documentation reviews prior to confirmation that the organisation will act as the Sponsor.

The review will be conducted by appropriate personnel within the Research & Innovation Directorate at UHL, and will ensure that:

- Documentation has been reviewed to ensure that UHL is able to deliver the study with or without external support.
- An appropriate Peer /Scientific Review has been conducted
- A study has adequate funding

The outcome is that UHL as a Sponsor has confirmed that there is robust study documentation & management process in place.

2. Scope

This SOP applies to all staff, and any external individual who approaches UHL to request that the organisation act as Sponsor for research activity.

3. Document Management

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

a)	Completed Sponsor Request Form – with effect from 1st February 2021 Appendix 1 will be replaced by a Google form (appendix 1 will then become obsolete) https://forms.gle/21UZHpf5jnhNxM9eA
b)	Protocol – It is recommended that the HRA Protocol Templates are utilised as appropriate in the study. 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)
d)	Participant documentation, 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 http://www.hra-decisiontools.org.uk/consent/examples.html
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 2)
g)	Evidence of costing and confirmation of adequate funding available for the duration of the study
h)	Investigator Brochure or Summary of Product Characteristics (where relevant)

i)	Signed and dated copy of the Chief Investigator CV and copy of relevant training certificate
j)	Completed Organisation information Document (OID) and Schedule of Events Cost Attribution Template (SoECAT)
NB:	With effect from **1st January 2021** the application process for Clinical Trials of Medicinal Products and Clinical Trials of Medical devices must be done through the MHRA Gateway. A list of documentation required for a submission is available https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk#clinicaltrialapplication

3.1 Completed Sponsor Request Form

The Sponsor Request Google Form - https://forms.gle/21UZHpf5jnhNxM9eA must be completed and submitted as part of the required documents when requesting that UHL act as Sponsor for a research study. The form asks for information that will be used by UHL to inform the Sponsor Review and Risk Assessment where appropriate.

3.2 UHL Protocol

UHL expects that the Protocol includes every aspect of the proposed study. It should be regarded as the 'manual'. A Protocol template is available from the HRA web pages

- Clinical Trials of Medicinal Products Protocol Template
- Qualitative Protocol Template

You may of course use your own template but it is essential that you check it against these examples to ensure that the relevant elements are captured.

3.3 Full Data Set IRAS

The Integrated Research Application System (IRAS) requires information about the study and should be completed once a final protocol has been agreed by the Chief Investigator (CI) and study collaborators (as appropriate). The information in the IRAS forms must be consistent with the Protocol and all other study documentation. The Full Data Set must be submitted for the Sponsor review, as this includes all parts of the form. Please note that every question must be answered as appropriate to the study, and references such as 'see above' must be avoided because some information may be lost when the form splits for submission to the various regulatory agencies.

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.

UHL as Sponsor requires set answers to some questions. The information about these can be found on the Sponsor Guidance document (Appendix 3).

3.4 Participant Information Documentation

It is imperative that participants are fully informed about their involvement within the study. Revisions to participant documentation are the most frequent requests of Ethics Committees. A https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/ is available on the Health Research Authority (HRA) web pages. Both UHL & the HRA strongly recommend that researchers use these examples.

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. It is expected that this wording is incorporated on all consent forms to be used in research sponsored by UHL this is within the guidance document (appendix 3).

All participant documentation must be reviewed by the Sponsor as part of the Sponsor Risk Assessment and Green Light Process. (SOP S-1003 UHL & SOP S-1014 UHL)

3.5 Study Recruitment Aids

Any literature or scripts that are proposed to increase awareness of a research study must be reviewed as part of the Sponsor review process. This will also be required for submission to the Ethics Committee. General awareness raising, such as posters informing that specific departments conduct research, do not necessarily require individual approval, but when referring to a specific study or a number of studies, formal approval is required. This includes when adding information on websites and utilising social media as a method of recruitment.

It is recommended that advice is sought from the R&I Head of Research Communications at UHL. They may be able to assist you with design, wording or signpost you appropriately, as well as providing advice on the appropriate use of social media to raise awareness of your study.

3.6 Peer Review

All research protocols require appropriate Peer Review (also referred to as "scientific quality review", "independent scientific review" or "independent review").

It is one of the responsibilities of a "research Sponsor" to ensure that:

'An appropriate process of independent expert review has demonstrated the research proposal to be worthwhile, of high scientific quality and good value for money'

Peer Review is the assessment of a research protocol by "reviewers" who are experts in the relevant field of study or discipline. Reviewers are able to offer independent advice on the scientific validity of the study.

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.

It is the responsibility of UHL to ensure that an appropriate Peer Review has been undertaken.

In certain instances 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 require a further review. However, it is important to recognise that this only applies where individual funding applications are similar to the final individual study protocol. Where multiple studies are being generated from a programme award, or where student research is being submitted to the NIHR for adoption, the NIHR Peer Review guidelines must be followed.

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 attached (Appendix 2). The form must be completed and submitted along with the other documents required for sponsor review.

The aim is to conduct the internal peer review process as quickly as possible after the identification of the need for such review to ensure that all studies reach the ethics and regulatory system without undue delay.

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 for the Trial Master File and Sponsor file.

3.7 Evidence of Costing & Funding

Every research study must provide evidence of adequate funding provision for the duration of the study. Where a study is long term, an undertaking to ensure adequate funds will be identified during the course of the research is expected. 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. In these cases a discussion to agree provision of funding in subsequent years will form part of the Sponsor Risk Assessment and Green Light Process. (SOP S-1003 UHL & SOP S-1014 UHL) Discussions about finances must be held with the UHL R&I finance team.

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

All protocols of research using Investigational Medicinal Products and / or Non CE Marked Devices must be accompanied by either an IB or SPC. Details of when these are required and an IB template can be found in S-1023 UHL. Copies of the IB / SPC will be forwarded to Pharmacy / Medical Physics for review.

3.9 Chief Investigator CV and appropriate training certificate

A signed and dated copy of an up-to-date summary CV (see IRAS template) from the Chief Investigator and relevant valid evidence of training must be provided. See SOP S-1008 UHL.

3.10 Copy of the OID and SOECAT

The Organisation Information Document should be used to provide information on participating NHS/HSC organisations in the UK. There are commercial and non-commercial versions available. 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. The two documents allow the sponsor to make clear what activities will be undertaken locally and the cost type for each activity.
Both the SOECAT and OID are available at this link: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/

4. Initial Sponsor Documentation Review

On receipt of a valid application, the Head of Research Operations or their delegate will commence a documentation review. With effect from October 2017 using the Sponsor Risk Assessment and / or relevant sponsor review and Sponsor Green Light Process as documented in SOP S-1003 UHL and SOP S-1014 UHL are recorded in the EDGE database.

An application will be deemed as 'valid' only when all key documentation for the study has been received. An email will be sent to the CI or point of contact for the study to confirm that the application is valid.

The Initial Sponsor Documentation Review may take up to 14 calendar days. Where appropriate and in accordance with SOP S-1003 UHL, a meeting to discuss the initial documentation review will be arranged with the CI and relevant members of the study team.

Comments on the documentation and any additional questions generated by the Sponsor Risk Assessment and / or sponsor review will be sent to the CI and where relevant the study team for comment and document revision as appropriate.
A system generated report will be sent to the CI and team.

A response to each question, revised documentation and any points of clarification will be required before a further review is conducted. Each point will be updated in EDGE. 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. MHRA, HRA, REC and NHS Trusts.

Sponsorship will remain 'in principle' only until all relevant external permissions have been received. The Sponsorship will be confirmed when the study team receive confirmation of the Sponsor Green Light in accordance with SOP S-1014 UHL.

It should be noted that only the R&I Manager Head of Research Operations, Associate Director and Director of Research at UHL have the authority to sign the IRAS form on behalf of the Sponsor.

5. Responsibilities

	Responsibility	Undertaken by	Activity
1	UHL R&I Office	Head of Research Operations or delegate	Confirm study documentation is valid and commence initial documentation review in accordance with SOP S-1003 UHL & SOP S-1014 UHL
2	UHL R&I Office	Head of Research Operations or delegate	Communicate findings of the initial documentation review with the CI
3	Chief Investigator	Chief Investigator or delegate	Respond to communication of findings from the initial documentation review. Amend documentation as required and return to Head of Research Operations or their delegate
4	UHL R&I Office	Head of Research Operations or delegate	Conduct re-reviews of documentation and points of clarification. Confirm in principle sponsor decision when appropriate

6. Monitoring & Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored by UHL has appropriate Peer Review	Included in the monitoring / audit programme	Random audits / monitoring conducted according to risk profile of research activity.	Head of Research Operations with the support of a UHL Clinical Trials Monitor and Trainer

7. Legal Liability Statement

Guidelines or procedures issued and approved by the Trust are considered to represent best practice. Staff may only depart from any relevant Trust guidelines or procedures in exceptional circumstances, and always only providing that such a departure is confined to the specific needs of an individual case. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional, it is fully appropriate and justifiable – such a decision is to be fully recorded in the patient's notes and in the research Site File. This table is used to track the development and approval of the document and any changes made on revised / reviewed versions.

8. Supporting Documents and Key References

SOP S-1002 Appendices 1, 2 & 3

SOP S-1003

SOP S-1014

SOP S-1021

SOP S-1023

9. Key Words

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

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

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Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	R&I Governance Meeting	
Approved by:	Professor Nigel Brunskill	**Date Approved:** 16/2/21

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

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