1. Introduction

This Standard Operating Procedure (SOP) describes the procedure for ensuring that all regulatory and Sponsor processes have been completed at the end of a research study, to allow confirmation of completion, issuing the 'End of Sponsor Green Light'.

At the end of research activity there are a number of procedures that must be undertaken as part of the regulatory / statutory requirements prior to archiving. UHL as Sponsor is required to ensure that Chief Investigators (CI) carry out all tasks within 12 months of the declared end of study date.

2. Scope

This SOP applies to all research sponsored by University Hospitals of Leicester (UHL) NHS Trust.

3. Procedure

This process will commence following submission of the 'end of study declaration' and this is considered the start of the 12 month end of study time frame (this date is added to EDGE). The end of study declaration is submitted following the end of study defined in the protocol and IRAS.

The Sponsor will send an end of study report email reminder (T1019), at 6, 9 and 11 months from end of study requesting a progress update, if no response received in the meantime.

In cases where there has been no response or updates, this will be escalated to the R&I Head of QA and Compliance.

3.1 End of Sponsor Checklist

Once the end of study report is received an end of sponsor green light checklist (T1018) will be sent to the CI or delegate for completion, within 12 months of the end date stated on the End of Study Declaration (EoS). This checklist confirms that all sponsor processes have been completed and the sponsor can confirm end of green light. Once end of sponsor green light process is complete, the CI can archive the TMF as per sponsor SOP S-1029 Archiving.

The Sponsor will send a reminder notification (T1020) at 1 and 3 months from original request asking for progress update, if no response received.

On receipt of end of sponsor green light checklist (T1018), the Sponsor will complete EDGE Attribute lists and workflows.

4. Non Compliance

Failure to demonstrate compliance to this SOP will result in implementation of the SOP S-1016 UHL Non Compliance SOP, and may affect the decision to sponsor future trials.

5. Submission of Publication

The CI or delegate (Lead Author) must on acceptance of publication to a journal, provide a copy of all publications to the Sponsor and file a copy in the Trial Masterfile/Investigator site file.

6. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency
Sponsor Audit	Randomly chosen for audit	Joana Louro	As and when

7. Supporting Documents and Key References

T1018 - End of Sponsor Checklist

T1019 - End of Study Report Email Reminder

T1020 - Request for Completion of Sponsor Green Light Checklist reminder

SOP S-1016 UHL Non- Compliance

8. Key Words

Research, Innovation, EDGE, REC, MHRA, HRA, Sponsor, Green Light

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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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