1. Introduction

1.1 This Standard Operating Procedure (SOP) describes the procedure to ensure that all regulatory and Sponsor processes have been completed and therefore confirm the end of Sponsor Green Light. This process has been implemented for all studies that submit end of study declaration after 1st April 2020.

1.2 At the end of research activity there are a number of procedures that must be undertaken as part of the regulatory / statutory requirements. 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

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

3. Outcome

3.1 The outcome will be that UHL can be assured that all processes and regulatory / statutory requirements have been successfully completed prior to archiving.

4. Procedure

4.1 This process will commence when 'end of study' is declared. The definition of the End of Study used within study documentation will be used as the defined study end. When a definition is not provided, the date of the End of Study Declaration will be used. This date will be added to the EDGE database and will be considered as the start of 12 months' timeframe.

4.1.1
The Sponsor will send an acknowledgement, Appendix 4 SOP S-1030 detailing activities required to be completed within 12 months of the End date stated on the End of Study Declaration (EoS) to the CI or their delegate

4.1.2
The Sponsor will send a reminder notification (Appendix 2), at 6 months from EoS asking for progress update, with further emails if no response received

4.1.3
The Sponsor will send a reminder notification (Appendix 3), at 9 months from EoS asking for progress update, with further emails if no response received

4.1.4
The Sponsor will send a reminder notification (Appendix 4), at 10 months from EoS asking for progress update, with further emails if no response received

4.1.5
The Sponsor will send a reminder notification (Appendix 5), at 11 months from EoS asking for progress update, with further emails if no response received

4.2 In cases where there has been no response or updates, the research activity will be discussed at the R&I Governance meeting and a resolution sought in line with the Non-Compliance SOP S-1016 UHL.

5. End of Sponsor Green Light Process Checklist

5.1 Once the final report is received an acknowledgement and end of sponsor green light checklist/s with be sent to the CI for completion. The 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 confirmed, the CI can archive the TMF as per sponsor SOP-1029 Archiving.

6. Procedure

6.1 Single site

6.1.1 An email request Appendix 6 will be sent to the CI requesting completion of the End of Sponsor Green Light Checklist Appendix 1A

6.1.2 The Sponsor will send a reminder notification Appendix 8 at 1 months from original request asking for progress update, with further emails if no response received.

6.1.3 The Sponsor will send a reminder notification Appendix 10 at 2 months from original request asking for progress update and response within 30 days.

6.1.4 On receipt of End of Sponsor Green Light check list CI Site (Appendix 1A), the Sponsor will acknowledge receipt (Appendix 13), and complete EDGE Attribute lists and workflows. Where further information is required Appendix 12 will be sent outlining the information required.

6.1.5 On receipt of a completed End of Sponsor Green Light check list (Appendix 1A), the Sponsor will acknowledge receipt (Appendix 13), complete the EDGE Attribute lists and workflows. Where further information is required Appendix 12 will be sent outlining the information required.

6.2 Multi Site

6.2.1 An email request Appendix 7 will be sent to the CI requesting completion of End of Sponsor Green Light Checklists Appendix 1B for all collaborating sites. Once the collaborating site checklists are complete, the CI will complete the End of Sponsor green light checklist (Appendix 1A) and return the completed forms Appendix 1A and 1B to the sponsor

6.3 The Sponsor will send a reminder notification Appendix 7 at 1 month from original request asking for progress update, with further emails if no response received.

6.4 The Sponsor will send a reminder notification Appendix 9 at 2 months from original request asking for progress update and response within 30 days.

6.5 On receipt of End of Sponsor Green Light check list CI Site (Appendix 1A) and collaborating site end of Sponsor Green Light checklists (1B), the Sponsor will acknowledge receipt (Appendix 13), and complete EDGE Attribute lists and workflows. Where further information is required Appendix 12 will be sent outlining the information required.

7. Non Compliance

7.1 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.

7.2 Trial Steering Committees & Data Monitoring Committees

To maintain strict independence, independent members of the trial steering committee and /or independent monitoring committee members should not gain any academic credit by being a co-author on study publications.

8. Submission of Publication

8.1 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.

9. Responsibilities

	Responsibility	Undertaken by	Activity
1	Sponsor	Chief Investigator / Delegate	Complete End of Green Light Process Check List
2	Sponsor	Sponsor or their delegate	Remind CI of requirement
3	Chief Investigator	Chief Investigator / Delegate	Notify Sponsor of completion of tasks within 12 months of EoS

10. Who Guideline Applies To

10.1 This guideline applies to all staff within UHL and external to UHL who are delivering research at Leicester's Hospitals.

11. Guideline Standards and Procedures

11.1 The SOP is detailed so the process can be clearly followed. No supporting flowchart is required / provided.

12. Education and Training

12.1 None.

13. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Sponsor Audit	Randomly chosen for audit	Carolyn Maloney	As and when	A report will be produced

14. Supporting Documents and Key References

SOP S-1045 Appendices 1a, 1b, 2, 3, 4, 5 & 6

SOP S-1016

15. Key Words

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

16. Contact and Review Details

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	**Executive Lead** **Medical director**
Details of Changes made during review: **Review and update**	

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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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