1. Introduction

This Standard Operating Procedure (SOP) describes the processes required at the end of a research study. There are reporting obligations in addition to ensuring transparency of research study data.

There is an expectation that clinical study data be published including a summary of results on a publically accessible register.

2. Scope

This SOP applies to all research studies that are hosted by the University Hospitals of Leicester NHS Trust (UHL).

3. Definition

The reporting requirements are triggered from the date of the end of the study which should be provided in the protocol, original application or and subsequent amendments where appropriate. In most cases it will be the date of the last visit of the last subject undergoing the study. The end of the recruitment period does not automatically signify the end of the study.

4. End of Study Notification

It is the responsibility of the Chief Investigator to complete the appropriate forms and submit these to the Sponsor at the end of the study. The Sponsor should then forward the information to the HRA/REC/MHRA as appropriate. In addition it is expected that the Sponsor will notify the UHL R&I Office that the study activity has ceased.

5. Early Termination or Abandoned Studies

If a study is terminated early for any reason, including lack of recruitment or lack of funding, the Sponsor must notify the REC / HRA and the MHRA (as appropriate). In addition, in these cases, it is expected that the Sponsor and / or PI will include the UHL R&I Office in conversations / communication about the intention to close a study early.

If a study is abandoned prior to commencement the PI or Sponsor must notify the R&I Office in writing, outlining the reasons for abandoning the study. This information must be added to the EDGE database.

6. Final Report of the Research

A summary of the final research report must be sent to the HRA / REC, and MHRA as appropriate. There is no standard format for final reports but it is expected that the UHL R&I Office will receive notification of any publications that come from the research. It is not necessary for final reports to be copied to UHL R&I, but notification that the site has closed must be received by R&I Office.

7. Participants at the End of Study

At the end of the research study it is expected that all commitments made to the participants as described in the IRAS application, the protocol and the Patient Information Leaflet will be fulfilled. This may include care after research and/or providing information about the outcome of a study.

8. Publication and Dissemination

Researchers and Sponsors are expected to ensure, as a minimum that research is registered and summary results are published on a suitable publicly-accessible register. Reference to the IRAS

ID number should be made in publications and reports to allow tracking of transparency commitments made to the funder, HRA & REC.

The requirements of the Health Research Authority (HRA) to ensure transparency are available on the HRA Website.

9. Responsibilities

	Responsibility	Undertaken by	Activity
1	Sponsor	CI or delegate	Complete End of Study Notification form and submit to Research Office (All studies)
2	Sponsor	CI or delegate	Complete Declaration of the end of a Clinical Trial Form if applicable (CTIMPs) and submit to Research Office.
3	Sponsor	CI or delegate	Fulfil obligations made to participants regarding the end of the study.
7	Sponsor	CI or delegate	Fulfil the requirements of the Health Research Authority (HRA) regarding transparency of research results.

10. Who Guideline Applies To

All staff within UHL and external to UHL who are delivering research.

11. Education and Training

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

12. Education and Training

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

None

15. Key Words

Research, Innovation, EDGE, REC, MHRA, HRA, Final Report, EOS, End of Study, Termination

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**	

17.

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This table is used to track the development and approval 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:	UHL R&I Governance Meeting	
Approved by:	**Professor Nigel Brunskill**	**Date Approved:** 09/07/2021.

REVIEW RECORD			
Date	**Issue No.**	**Reviewed By**	**Description Of Changes (If Any)**
February 2017	1	CM	Update to logos.
February 2019	3	CM, LW	Consistency check, update to logos
July 2021	4	LW JJ	Update and review, Update to new trust template

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