1. Introduction

1.1 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.

1.2 There is an expectation that clinical study data be published including a summary of results on a publicly accessible register. In addition, there are regulatory requirements to submit final study reports to the Sponsor, the REC, HRA and MHRA as appropriate.

2. Scope

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

3. Definition

3.1 The reporting requirements are triggered from the defined date of the end of the study which should be provided in the protocol. 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 (EoS)

4.0.1 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.

4.0.2 The Sponsor will then forward the information to the REC which gave a favourable opinion of the research, the HRA and the MHRA as appropriate.

4.1 Notification to the REC

4.1.1 There are separate forms for use in clinical trials of investigational medicinal products (CTIMPs) and all other research. The appropriate form must be sent within 90 days of the end of the study. The Sponsor does not have a separate form to complete. The forms published on the HRA website must be used.

4.2 Declaration of the End of a Clinical Trial of an Investigational Medicinal Product to MHRA

4.2.1 A 'Declaration of the end of a Clinical Trial' form must be sent to the MHRA within 90 days of the end of the study. Once the declaration of the end of a clinical trial form has been received by the MHRA, only the end of study report will be accepted. After this stage it is not possible to submit any further amendments to the study.

4.3 The Sponsor will send an acknowledgement, Appendix 4 and the End of Sponsor Green Light process will commence as per Sponsor SOP S-1045.

4.3.1 The Sponsor will send a reminder notification (Appendix 1), one month prior to the expected EoS date asking for progress update, with further emails if no response received

4.3.2 The Sponsor will send a reminder notification (Appendix 2), at the expected EoS date

asking for progress update, with further emails if no response received

4.3.3 The Sponsor will send a further reminder (Appendix 3) at 1 month following expected E0S date

4.4 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. Early Termination or Abandoned Studies

5.1 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) within 15 days of the date of termination with an explanation of the reasons for the early termination. Where it is necessary to seek ethical review of related actions such as informing subjects and arranging continuing care and follow up outside the study, a notice of substantial amendment could be submitted alongside the declaration of early termination.

5.2 If a study is abandoned prior to commencement the CI or Sponsor must notify the main REC, HRA and MHRA (as appropriate) in writing, outlining the reasons for abandoning the study.

6.0 Closure of sites must be documented and retained in the Investigator Site Files as well as within the site section of the Trial Master File (TMF). Undertaking relevant procedures as per SOP-S-1024 Site Closedown.

7. Final Report on the Research

7.1 A summary of the final research report must be sent to the HRA and MHRA (as appropriate), within 12 months of the end of the study as per sponsor SOP S- 1045 End of Sponsor Green Light.

7.2 Production of the report is the responsibility of the CI who must submit it via the HRA website https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/

7.3 On completion the CI will receive an acknowledgement email from the HRA including a summary of final report. A copy of this this email should be forwarded to the Sponsor

8. Participants at the End of Study

8.1 At the end of the research study it is expected that all participants are thanked for their contribution and all commitments 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.

9. Publication and Dissemination

9.1 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 and REC / HRA.

9.2 https://www.hra.nhs.uk/planning-and-improving-research/best-practice/publication-and-dissemination-research-findings/

10. Responsibilities

	Responsibility	Undertaken by	Activity
1	CI	CI or delegate	Complete End of Study Notification form and submit to Sponsor (All studies)
2	CI	CI or delegate	Complete Declaration of the end of a Clinical Trial Form if applicable (CTIMPs) and submit to Sponsor.
3	Sponsor	R&I Deputy Chief Operating Officer or delegate	Submit End of Study Notification forms and Declaration of the end of a Clinical Trial Forms to the HRA/MHRA respectively within 90 days of the end of study.
4	CI	CI or delegate	Produce a final research report and submit via HRA website and provide a copy of acknowledgement email and summary to the Sponsor
5	CI	CI or delegate	Fulfil obligations made to participants regarding the end of the study.
6	CI	CI or delegate	Fulfil the requirements of the Health Research Authority (HRA) regarding transparency of research results.

11. Who Guideline Applies To

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

12. Guideline Standards and Procedures

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

13. Education and Training

13.1 None.

14. Monitoring and Audit Criteria

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

15. Supporting Documents and Key References

SOP S-1030, SOP S-1045, SOP1024

16. Key Words

Research, Innovation, Volunteers, Participants, CTIMPS, Trials, EOS, End of Study, MHRA, Final Report, Publication, End of Sponsor Green Light, Site closure

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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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REVIEW RECORD

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
May 2015	2	Carolyn Maloney	Changes to Logo and corporate identity
July 2016	3	CM, LW, JJ	Consistency checking. HRA updates.
February 2017	4	Carolyn Maloney	Update to logo.
Sept 2018	5	JJ, LW, CCL	Update to R&I logo Reference to S-1024 Study Closedown
Nov 2019	6	CM,JJ,AM,LW	Addition of requirement to thank all participants
February 2021	7	CM LW JJ	Update and review, Reformatting to new template
February 2022	8	CM LW	Update and addition of EoS reminder emails.

DISTRIBUTION RECORD:

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