UNIVERSITY OF LEICESTER
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UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

University of Leicester (UoL) Research Governance Office
SOP S-1038 UoL

Version 4.0, September 2021

End of Study Reporting Requirements for Research Studies Sponsored by the University of Leicester (UoL)

OFFICE BASE

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Effective Date: October 2021

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. In addition, there are regulatory requirements to submit final study reports to the Sponsor, REC, HRA and the MHRA as appropriate.

2. SCOPE

This SOP applies to all research studies that are sponsored by the University of Leicester (UoL).

3. DEFINITION

The reporting requirements are triggered from the date of the end of the study which should be defined in the protocol and the IRAS form.

4. END OF STUDY NOTIFICATION

The Sponsor will notify the Chief Investigator or their delegate of the requirement to and deadline for submitting the relevant End of Study Report. It is the responsibility of the CI to complete the appropriate forms and submit these to the Sponsor and the relevant regulatory authorities.

The HRA website should be consulted for full guidance on End of Study reporting: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/

4.1 Notification to the REC

There are separate forms for use in clinical trials of investigational medicinal products (CTIMPs) and all other research. The appropriate form should 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 should be used.

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

A 'Declaration of the end of a Clinical Trial' form should 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 trial study report will be accepted. After this stage it is not possible to submit any further amendments to the trial.

The Sponsor will issue an End of Study Declaration acknowledgement email which must be retained in the Trial Master File.

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) 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.

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

6. Final Report on the Research

A summary of the final research report should be sent to the REC, HRA and MHRA for CTIMPs, within 12 months of the end date as declared in the End of Study Declaration Form. Production of the report is the responsibility of the CI who should submit it on completion to the Sponsor and the relevant regulatory authorities. The Sponsor will issue a Final Report acknowledgement email which must be retained in the Trial Master File.

The HRA website should be consulted for full guidance on the final report requirements and submission of the final report form: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/

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 and REC /HRA.

The HRA website should be consulted for full guidance on the publication of research findings: https://www.hra.nhs.uk/planning-and-improving-research/best-practice/publication-and-dissemination-research-findings/

9. Responsibilities

	Responsibility	Undertaken by	Activity
1	CI	CI or delegate	Complete End of Study Notification form and submit to Research Governance Office (All studies)
2	CI	CI or delegate	Complete Declaration of the end of a Clinical Trial Form if applicable (CTIMPs) and submit to Research Governance Office.
3	CI	CI or delegate	Submit End of Study Notification forms and Declaration of the end of a Clinical Trial Forms to the REC and MHRA respectively within 90 days of the end of study.

	Responsibility	Undertaken by	Activity
4	CI	CI or delegate	Produce a final research report and submit to the Research Governance Office.
5	CI	CI or delegate	Submit the final research report to the REC (and MHRA if applicable) within 12 months of the end of the study.
6	CI	CI or delegate	Fulfil obligations made to participants regarding the end of the study.
7	CI	CI or delegate	Fulfil the requirements of the Health Research Authority (HRA) regarding transparency of research results.

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

Development and approval Record for this document

Author/Lead Officer:	Cat Taylor
Job Title:	Head of Research Assurance
Reviewed by:	Research Sponsorship Management and Operations Group
Approved by:	Professor Nigel Brunskill 
Date Approved:	13/10/2017

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
August 2015	2	Wendy Gamble	Reviewed and revised to include University of Loughborough on front page and minor administrative changes to version number and dates.
Oct 2016	3	Diane Delahooke	Change of logo and RGO address. Consistency checks with UHL and HRA updates.
Sept 2021	4.0	Cat Taylor	Updates throughout to process – CI or delegate responsibility for submitting end of study declarations to relevant authorities. Administrative changes. Referral to HRA website for final reporting requirements.

Distribution Record

Date	Name	Department	Received