



University of Leicester Research Governance Office Standard Operating Procedures

SOP S-1024 UoL

End of Study Activity (Declaration, Notification and Reporting Close out Activities) for Research Sponsored by the University of Leicester

Version 4.0 May 2024

Effective Date: July 2024

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

1.0 Introduction and Scope

This Standard Operating Procedure (SOP) applies to all research studies that are sponsored by the University of Leicester (UoL). The document describes the processes required at the end of a research study and covers closure relating to the 'End of Study' definition contained within the protocol, along with 'Early Termination' for safety, ethical or logistical reasons or closure of individual sites in multi-site studies.

Once a study/trial is confirmed as 'ended', there are a number of tasks that must be undertaken as part of regulatory and statutory requirements. The UoL, as Sponsor, is required to ensure that the Chief Investigator (CI) carries out all tasks within 12 months of the declared end of study date.

2.0 Procedure

The end of study reporting requirements are triggered as soon as the end of study definition (as written in the approved protocol) is met, or following the decision to terminate a study early. Study closure should be performed in accordance with regulatory requirements and Good Clinical Practice (GCP) guidelines, as appropriate.

Any changes to the end of study definition/end date should be submitted as an amendment (refer to SOP S-1018 (Amendments SOP)).

3.0 End of Study Notification

The Sponsor will notify the Chief Investigator (CI) or their delegate of the requirement to, and deadline for, submitting the relevant End of Study Notification. It is the responsibility of the CI to complete the appropriate forms and submit these to the Sponsor and the relevant regulatory authorities. When and how this notification occurs depends on the regulatory body (detailed below). Evidence of submission and any acknowledgements must be retained in the Trial Master File (TMF).

Before the end of study declaration form is completed, we recommend that you review the end of study definition in your study protocol and the guidance on the [HRA webpage](#) as well as the plans that were approved by the REC for;

- the use of any tissue and data that was collected during the course of the study
- the information that will be provided to participants
- how the results will be disseminated.

If you need to make any changes to the agreed arrangements, you should consider whether an amendment is required **before** submitting your end of study notification.

4.0 Notifying the Sponsor

For studies with an Infonetica record: Reminders will be issued to applicants ahead of the currently approved end of study date. The applicant should create an 'End of Study Declaration' sub-form, complete the relevant information and upload a copy of the end of study declaration form (please see Section 6 below) before submitting the sub-form. The system will generate a notification of receipt.

For studies without an Infonetica record: The RGO will contact researchers by email ahead of the currently approved end of study date with instructions on the relevant documentation to be submitted.

5.0 Notifying NHS REC and Regulatory Authorities

You must declare the end of a study to the NHS Research Ethics Committee (REC) that gave favourable opinion to the study within 90 days of the study ending using the appropriate form.

The [HRA website](#) should be consulted on the end of study declaration process (and obtaining the relevant form) for notifying:

- NHS Research Ethics Committee (REC)
- Competent Authority (MHRA) for CTIMPs and Medical Device trials
- Confidentiality Advisory Group (CAG)
- HRA and HCRW.

6.0 Notifying University Ethics

For studies with an Infonetica record: the process outlined in Section 5 above applies.

For projects without an Infonetica record: Complete the end of project monitoring report as per the guidance on the [University website](#) and then notify the HRA and HCRW.

7.0 Early Termination or Abandoned Studies

If a study is terminated early the Sponsor (or their delegate) must notify the REC, HRA and the MHRA (as appropriate) within 15 days of the date of termination with an explanation of the reason(s) 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 should be submitted alongside the declaration of early termination.

If a study is abandoned prior to commencement, the CI should inform the Sponsor. When authorised, the CI should then notify the relevant REC and all applicable regulatory authorities, outlining the reasons for abandoning the study.

Where a study is terminated early, consider whether it may also be necessary to notify;

- Trial Management Group/Data Safety Monitoring Committee (where they have not been involved in the decision)
- Funding body/study finance staff
- All site investigators for multi-centre studies
- Medicinal product supplier
- Participants.

8.0 Final Report Production and Submission

In order to aid research transparency, the results of a study/trial should be published within 12 months of the end of study on a publicly accessible register, and a final report should be submitted to the relevant authorities.

The [HRA website](#) should be consulted for instructions on how to submit final reports.

For studies with an Infonetica record: Reminders will be issued to applicants ahead of the deadline for submitting a final report. The applicant should create an 'End of project final report' sub-form, complete the relevant information and upload a copy of the final report before submitting the sub-form. The system will generate a notification of receipt.

For studies without an Infonetica record: The RGO will contact researchers by email ahead of the deadline for submitting a final report with instructions on the relevant documentation to be submitted.

9.0 Informing Participants

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/Sheet etc will be fulfilled.

The [HRA website](#) should be consulted for instructions on how to provide participants with a summary of the research findings.

10.0 Publication and Dissemination

The IRAS ID number should be referenced in publications and reports to enhance transparency and tracking to allow tracking of transparency commitments made to the funder and REC /HRA.

Further information is available on the [HRA website](#).

11.0 Site Close Down

Confirmation of closure must be provided to each participating site. Where relevant, a justification of the closure, the number of participants still receiving treatment and the proposed management of those participants should be included (i.e., early termination of a study/close down of a site). Early termination of a site should also be formerly documented via an amendment.

The Sponsor (or their delegate) will conduct a Site Close out Visit for all CTIMPs (Appendix 1).

For non-CTIMP research, the research team are encouraged to conduct a Site Close out Visit themselves (Appendix 3).

a copy of the completed and signed Report (Appendix 1 or 3), and a record of personnel in attendance (Appendix 2) must be retained in the TMF/Investigator Site File (ISF) as appropriate.

12.0 Archiving

Essential Documents must be archived in accordance with the Archiving SOP S-1032. Details of what documents are regarded as 'essential' are detailed in the SOP S-1015.

13.0 Non-Compliance

Where it is identified that the processes detailed above have not been followed, this will initially be raised with the CI (or their delegate). If required this may trigger the need for


a Corrective Action/Preventative Action (CAPA) document to be instigated (refer to SOP S-1012 for further details). Where non-compliance persists, SOP S-1016 UoL 'Non-Compliance' will be implemented at a minimum of a Major finding.

14.0 Responsibilities

Responsibility	Undertaken by	Activity
CI in collaboration with Sponsor	CI & Sponsor	Determine whether the Study: <ul style="list-style-type: none"> Is due to conclude as described in the study protocol; OR Requires an extension to the end date; OR Is to terminate early, and why.
CI	CI / PI	Discuss with Sponsor regarding study conclusion or extension requirement. Complete required documentation.
Sponsor	Research Governance Manager or their delegate	Maintain the relevant database/s with the end date and study status and notify the CI or their delegate of the requirement to, and deadline for, submitting the end of study declaration.
CI	CI or delegate	Complete the relevant 'End of study declaration' form and ensure that all relevant parties are informed within the required timelines
CI	CI or delegate	Produce a final research report and submit to all relevant parties within 12 months of the end of the study.
CI	CI or delegate	Fulfil obligations made to participants regarding the end of the study.
CI	CI or delegate	Fulfil the requirements of the Health Research Authority (HRA) regarding transparency of research results.

15.0 Development and Approval record for this Document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Management and Operations Group (RSMOG)	Professor Nigel Brunskill 	14/06/2024

16.0 Review Record

This table is used to track the changes made across document revisions.

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
June 2015	2	Diane Delahooke	Close Down checklist updated.
Oct 2016	3	Diane Delahooke	Logos changed, HRA reference, removal of old Appendix 3 and replaced with non-CTIMP close down checklist.
Sept 2021	3.1	Cat Taylor	Administrative changes
May 2024	4.0	Cat Taylor	<ul style="list-style-type: none"> • Update to SOP name • Major updates to add information which was previously included in SOP-1038 to make SOP 1038 'End of Study Reporting' Obsolete. • Major updates to add information which was previously included in SOP-1047 to make SOP 1047 'End of Sponsor Green Light Process' Obsolete. • Removal of RGO office address • No changes to appendices