



**UNIVERSITY OF LEICESTER
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH SUPPORT OFFICE
STANDARD OPERATING PROCEDURES**

**University of Leicester (UoL) Research Governance Office
SOP S-1024 UoL**

Version 3.1, September 2021

**Study Closedown and End of Study Reporting for Research
Sponsored by the University of Leicester.**

OFFICE BASE

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Effective Date: October 2021

1. INTRODUCTION

This Standard Operating Procedure (SOP) describes the procedures for reporting and documentation requirements for the closure of research sponsored by the University of Leicester (UoL). The document covers closure as defined in the protocol, along with early termination for safety, ethical or logistical reasons and closure of individual sites in Multi-centre studies.

The outcome is that the Sponsor is able to confirm study closure

2. SCOPE

This SOP applies to all research sponsored by the University of Leicester.

3. PROCEDURE

Trial closure should be performed as defined in the study protocol and in accordance with regulatory requirements and Good Clinical Practice guidelines (GCP) as appropriate. Any planned changes to the closure of a study should be submitted as a Substantial Amendment to the HRA, REC, appropriate regulatory bodies and the NHS Trust R&D/R&I in accordance with SOP S-1026 UoL (Amendments SOP).

The objective of trial closure is to ensure that:

- The rights and wellbeing of all participants have been protected
- All essential documents have been stored appropriately in the Trial Master File (TMF) and Investigator Site Files (ISF)
- The correct approved version of the protocol was used and adhered to
- IMP accountability has been carried out
- Any SAEs, and SUSARs have been reported appropriately
- DSURs have been submitted
- Source Data Verification (SDV) has been undertaken
- Monitoring has been performed as described in the study monitoring plan
- All contractual requirements have been met
- Any outstanding queries between the Sponsor and sites are resolved
- A study close-out report is produced

Plans for close down should be included in the monitoring plan and discussed during the Sponsor Risk Assessment and Green Light Process and detailed in SOP S-1003, S-1011, S-1025, S-1026 and S-1007.

Archiving is covered in the Archiving SOP S-1032 UoL.

3.1 Planned closure

It is expected that the definition of planned study closure will be outlined in

the study protocol. The end of study would usually be described as the last visit of the last patient or the final follow-up completion and data collection. Plans for closing the study should be discussed during the Sponsor Risk Assessment and Green Light Process, and included in the monitoring plan.

Final analysis of the locked database should occur after a study close down report has been completed. In cases of unblinding for randomised studies, written approval will be required in accordance with the SOP S-1035 UoL. It is the responsibility of the Sponsor to ensure that study closure tracking and study end dates are maintained on the database. The aim is to support the production of an accurate overview and reporting of research activity sponsored by the UoL.

It is the responsibility of the Chief Investigator to discuss study closure with the Sponsor and to complete relevant required documentation. The Sponsor will ensure that the regulatory authorities and REC receive completed documentation within 90 days in accordance with required timelines.

Where required, a study close down visit will be performed. The site close down report (Appendix 1) must be completed and site close down visit logs (Appendix 2) completed and filed in the site file.

For Non-CTIMP studies, the Study Closedown checklist (Appendix 3) must be completed and signed by the Chief Investigator/Principal Investigator and a copy sent to the Sponsor and a copy filed in the TMF/ISF.

Database lock, validation and cleaning, must be done in accordance with SOP S-1036 Data Management process for research Sponsored by UoL.

3.2 Premature Termination / Early Closure

As Sponsor, the UoL has a legal responsibility to notify the Competent Authority (MHRA), HRA and Research Ethics Committee (REC) as relevant that a study has terminated early at a site within 15 days of the termination, irrelevant of reason. It may also be necessary to notify the following:

- 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

Research can be terminated prior to the planned closure date or event because of:

- Unsafe events attributed to the Study IMP (Investigational Medicinal Products)
- Poor toleration of the IMP
- Slow recruitment
- Sponsor decision
- Investigator decision
- Regulatory decision (e.g. MHRA)

It is essential that the CI discuss the process with the Sponsor to ensure that appropriate documentation is completed and submitted within the required timelines.

3.2.1 Multi-centre studies

Closure of multi-centres must be documented and retained in the Investigator Site Files (ISF) and within the site section of the Trial Master File (TMF).

Confirmation of closure must include the justification of the closure, the number of participants still receiving treatment and the proposed management of those participants where appropriate.

A letter thanking the site for their contribution with an overall summary of the participants must be sent by the CI. The correspondence must include a reminder that the PI will be required to comply with any future audits or inspections of the closed study. There must be an agreed plan to resolve any financial balances, and information about the publication process.

The expectation will be that archiving of site study documentation be managed by the individual site. This will be discussed at the initial set up of the study along with the process to be used, and individuals responsible for close down of individual sites.

3.3 Final Report

A report of the study findings, negative and / or positive must be produced within one year of the closure date.

UoL as Sponsor will track this date using the database and will remind the investigator at least 30 days prior to the due date.

4. ARCHIVING

Essential Documents must be archived in accordance with the Archiving SOP S1032 UoL. Details of what documents are regarded as 'essential' are detailed in the SOP S-1015 UoL.

5. RESPONSIBILITIES

	Responsibility	Undertaken by	Activity
1	Chief Investigator (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.
2	CI	CI / PI	Discuss with Sponsor regarding study conclusion or extension requirement. Complete required documentation.

	Responsibility	Undertaken by	Activity
3	Sponsor	Research Governance Manager or their delegate	Maintain the relevant database/s with the end date and study status related to closure or extension based on information from the CI and set reminders for final reports
4	Sponsor / CI	CI	Inform the regulatory authorities and the REC, and all other relevant parties as necessary copying in the Sponsor to all correspondence.
5	Sponsor	Research Governance Manager or their delegate	Ensure that all relevant parties are informed within the required timelines.
6	Sponsor	Trial Monitor or their delegate	Finalise the study files ensuring all necessary documents are present in TMFs / ISFs and ensuring all end of study procedures are completed.

6. MONITORING AND AUDIT CRITERIA

Key Performance Indicators	Method of Assessment	Frequency	Lead
All research sponsored by UoL has appropriate Risk Assessment	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity.	Research Governance Manager or their Delegate

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

7. 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:	13/10/2021

8. REVIEW RECORD

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.

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Sept 2021	3.1	Cat Taylor	Administrative changes