

Glasgow Clinical Trials Unit Standard Operating Procedure

SOP number	56.004	Version	4.0
Title	Project Management Trial Location Close-Out		

Prepared by	Lynsey Gillespie
Approved by	Lynn Prentice
Released by	Jesse Dawson

SOP category	56 NHS GG&C Sponsor Project Management Unit			
Staff category				
Staff Category	R	A	C	I
Project Managers	X			
GCRF Clinical Research Manager		X		
Sponsor Research Coordinator				X
Chief Investigator				X
Principal Investigator				X
R&I Systems Manager				X
Sponsor Pharmacy				X
Clinical Trial Monitors				X

1. Scope

This procedure applies to Project Management Unit (PMU) staff, Innovation Project Managers, Robertson Centre for Biostatistics (RCB) Project Managers and study-specific Project Managers undertaking project management activities on behalf of the Sponsor. This SOP does not cover studies coordinated by Glasgow Oncology Clinical Trials Unit, Glasgow.

2. Purpose

To describe the procedures that will be used by Project Managers acting on behalf of the Sponsor to close out participating locations for studies Sponsored or Co-Sponsored by NHSGGC (with University of Glasgow), and managed by PMU, RCB, Innovation or a study specific PM. Where project management activities are performed on behalf of a non-NHSGGC Sponsor, this SOP can also be used, on agreement with the external Sponsor.

Formal close out of participating locations is necessary to verify that the trial has been conducted in compliance with GCP guidelines and to ensure that the investigator site file (ISF) is complete prior to archiving.

3. Procedures

The PM will be notified by local study teams when their last participant last visit (LPLV) has been conducted and this will trigger the PM close out procedure. The PM will liaise with the relevant Sponsor teams to agree a timeline for close out activities as this will also trigger the Close-Out Monitoring Visit (SOP 53.012) and pharmacy close out procedures if applicable.

The PM will also liaise with the data centre, as applicable, to confirm that all data queries have been resolved prior to initiating site close-out.

Where a study location closes early for any reason the same procedures will apply and close out will be tracked to completion, with the local study team made aware that final documents such as the End of Trial Notification will require filing prior to archiving.

3.1. Close Out Checklist

When notified of the LPLV the PM will initiate Form 56.004A Location Close-Out Checklist, and request that this is completed by the local study team. All applicable checklist items must be completed and marked 'Yes' prior to return; any items that cannot be marked 'Yes' will be discussed with the PM or monitor and resolved where appropriate.

The PM will liaise with relevant Sponsor teams and data centre, as applicable, to confirm that all close out activities (monitoring, pharmacy and data management) are complete.

On completion of all actions in relation to close out, the PM will email the participating location confirming all necessary arrangements are in place to officially close using the location close out email template (Form 56.004B).

In accordance with UK GDPR principles, personal data must not be retained longer than necessary. If participant consent forms have been uploaded to the data centre, the PM or monitor will, following receipt of the Close-Out Checklist from all participating Locations and completion of database lock, contact the data centre to arrange removal of the uploaded consent forms from the server.

4. Referenced documents

- Form 56-004A – Location Close Out Checklist template
- Form 56.004B – Location Close out email template
- SOP 53.012 – Monitoring Clinical Research – Location Close Out Monitoring Visit

5. Related documents

- SOP 22.026 – Closure of a clinical trial – pharmacy process

Glasgow Clinical Trials Unit Standard Operating Procedure

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	17/10/2016	First release	No
2.0	23/09/2019	Minor change to staff category	No
3.0	21/08/2023	Change to staff category to include external PM Change to close out checklist Addition of close out email template Update to SOP template v2.0 Addition of RACI matrix	No
4.0	19/10/2026	Terminology changes as per updated regulations	No

This SOP is a controlled document. The current version can be viewed on the R&I website, GCTU website and R&I's Q-Pulse account.

Any copy reproduced from the website may not, at time of reading, be the current version.