SOP number	**56.004**	Version	**3.0**
Title	**Project Management Trial Site Close-Out**		

Prepared by Signature	Lynsey Gillespie Date
Approved by Signature	Lynn Prentice Date
Released by Signature	Julie Brittenden Date

SOP category	56 NHS GG&C Sponsor Project Management Unit

Staff category

Staff Category	**R**	**A**	**C**	**I**
Project Management Unit	X			
Heart Failure Project Manager	X			
Robertson Centre for Biostatistics (RCB) Project Manager	X			
GCRF Manager		X		
Head of Clinical Trials for Heart Failure Group (University of Glasgow)		X		
Director of Operations RCB		X		
Sponsor Research Coordinator				X
Chief Investigator				X
R&I Systems Manager				X
Senior R&I Manager				X

1. Scope

This procedure applies to Project Management Unit (PMU) staff and study specific Project Managers (PM). Accountability of this SOP differs as detailed in the RACI. This SOP does not cover studies coordinated by Cancer Research UK Clinical Trials Unit, Glasgow.

2. Purpose

To describe the procedures that will be used by the project managers (PM) acting on behalf of the Sponsor to close out participating sites for all studies sponsored or co-sponsored by NHS GG&C (with University of Glasgow), and project managed by either PMU or a study specific PM. If project management functions are performed on behalf of a non-GGC Sponsor, this SOP will also be used, on agreement with the Sponsor.
Formal close out of participating sites 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 participating site teams when their last patient 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 Site Close Out Monitoring Visit (SOP 53.012) and pharmacy close out procedures if applicable.

Where a study site closes early for any reason the same procedures will apply and close out should be tracked to completion, with the site 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 Site Close-Out Checklist, and request that this is completed by the participating site trial team.

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

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

4. Referenced documents

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

5. Related documents

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

6. Document history

Version	Date	Description
1.0		First release
2.0	23/09/2019	Minor change to staff category
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

This SOP is a controlled document. The current version can be viewed on the GCTU website.
Any copy reproduced from the website may not, at time of reading, be the current version.