

SOP number	53.007	Version	3.0
Title	Unblinded Monitoring Process		

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SOP category	NHS GGC Sponsor Governance			
Staff category				
Staff Category	R	A	C	I
R&I Lead Clinical Trials Monitor		X		
R&I Clinical Trials Monitor	X			
R&I Research Governance Manager	X			
R&I Lead Pharmacist Clinical Trials			X	
R&I Pharmacovigilance			X	
R&I Sponsor Pharmacy			X	
Chief Investigator			X	

1. Scope

This procedure applies to NHSGGC Research Governance Clinical Trial Monitors (CTM). CTMs may monitor trials out with the NHSGGC Sponsor team, however agreements with external Sponsors must be made in writing prior to the use of this SOP for monitoring on behalf of external Sponsors. (Please refer to SOP 53.014).

2. Purpose

The purpose of this SOP is to describe the process the Clinical Trial Monitors (CTM) will adhere to when monitoring a blinded trial whilst being unblinded. The procedure will be used by the CTMs, acting on behalf of the Sponsor, to monitor non-commercial/commercial clinical trials, including CTIMPs, high risk non-CTIMPs and medical device investigations which are Sponsored, Co-sponsored by NHS Greater Glasgow and Clyde (NHSGGC) or a non-GGC Sponsor. The process is designed to ensure the CTM(s), Lead CTM and Research Governance Manager maintain the blind, whilst adhering to the R&I SOPs for monitoring clinical trials, escalating and reporting any issues / non compliances.

3. Procedures

3.1. Blinded Monitoring Process

The CTM will perform their monitoring visit in accordance with SOP 53.004, following the visit the CTM will write a report which will be reviewed by the Lead CTM or Research Governance Manager. Once the report is approved, the CTM will send a follow up letter to the Principal Investigator (PI), location staff and relevant Sponsor representatives. This process is outlined in Figure 1.

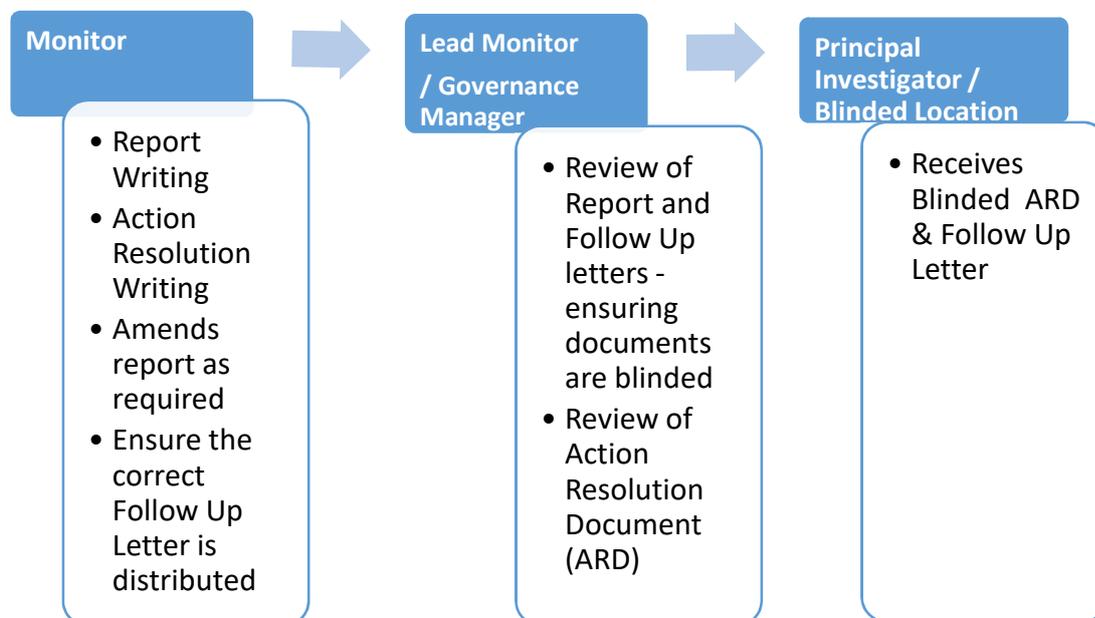


Figure 1 – Blinded Monitoring Process

3.2. Unblinded Monitoring Process

In certain scenarios it may be necessary for the CTM to be unblinded throughout the trial or at times when safety issues occur e.g. potential serious breach. The decision to use an alternative CTM or to unblind the trial CTM (exceptional circumstances) will be taken by the appropriate decision makers which may include the Research Governance Manager, Lead CTM, Lead Clinical Trials Pharmacist, CI and PV Manager, for example, and will be documented in the Sponsor Risk Assessment (Form51.004A) and Monitoring Risk Assessment (Form53.010B). The CTM will perform their unblinded visit, the unblinded information will remain confidential and secure. The CTM must ensure they do not communicate any unblinded study information with the PI, research location staff and Sponsor representatives whilst on-site, via email or through any other means of communication and the trial duration. The CTM will write their unblinded report and submit for review and approval to the Lead CTM or Research Governance Manager, ensuring to flag the report/email contains Unblinded Trial Information. Once the report is approved the CTM will send an unblinded Action Resolution Document (ARD) and follow up letter to the nominated unblinded research location staff (e.g. nominated location staff, location pharmacist etc.), clearly indicating that the contents contain unblinded information which must remain inaccessible to blinded members of the location staff. The CTM will also send a blinded follow up letter to the PI to apprise them of the recent monitoring visit. The pharmacist/site/CTM will agree on follow up letter storage and ensure a separate filing system is either in place if agreed during set up or posthumously in the case of an urgent unblinded visit. This information will be detailed in a filenote (Form 51.016M).

The recipients of the unblinded information/blinded information must be defined and documented in the monitoring plan and a clear storage arranged.

Careful reviewing will be undertaken to ensure the blinded follow up letter contains no unblinding information and the entire process will comply with the monitoring SOPs and regulations. This process is detailed below in Figure 2.

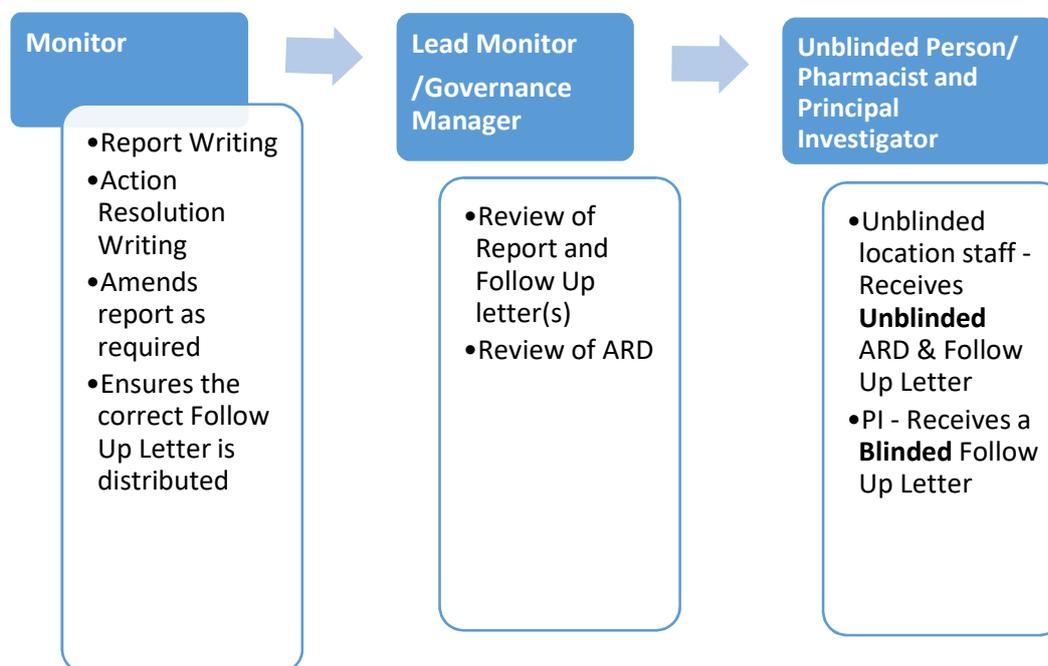


Figure 2 – Unblinded Monitoring Process

3.3. Exceptions

In the case that there are differences within trials and how the unblinded CTM should perform their monitoring tasks versus a blinded CTM, this will be detailed in the specific trial monitoring plan. For example, a CTM who is unblinded throughout the duration of the trial or a CTM who becomes unblinded at a certain stage of the trial due to quality issues.

If Lead CTM is the unblinded CTM then the Research Governance Manager will review the report and sign off.

3.4. Security of Documentation

The electronic report in Q-Pulse and associated documents saved in the shared drive will have a clear title stating **Unblinded Trial Information**. The CTM will set up a locked folder/password protected on the R&I shared drive and the Lead CTM will also be able to access. The Lead CTM will remain unblinded for these types of trials to ensure oversight of monitoring reports. The printed follow up letter and ARD will be enclosed in an envelope where the seal has been signed and dated and then filed in the TMF.

4. Referenced documents

- SOP 53.004 - Monitoring Clinical Research – Site Monitoring visit
- Form 53.010A - Monitoring Plan for a Clinical Trial of an Investigational Medicinal Product/Medical Device Investigation
- Form 53.010B - NHSGFC Monitoring Risk Assessment
- Form 53.004H - Preliminary Follow Up Letter/Follow Up Letter
- Form 51.016M - TMF/ISF Filenote
- Form 51.004A - Risk Assessment Tool

5. Related documents

- N/A

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	11/12/2018	Release of first Version	No
2.0	06/12/2022	Update of author as per the Process development SOP, formatting, filing location and addition of Form reference.	No
3.0	19/02/2026	Periodic review, wording and updated template	No

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