Standard Operating Procedure			**53.007**
Unblinded Monitoring Process			
Version	**2.0**		
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Approved by	Caroline Watson	Signature	Date
Released by	Julie Brittenden	Signature	Date

1. SOP Category

NHS GG&C Sponsor Governance

2. Staff Category

Staff Category	R	A	C	I
Lead Clinical Trials Monitor	X	X		
Clinical Trials Monitors	X			
Research Governance Manager	X			
Lead Pharmacist Clinical Trials			X	
Pharmacovigilance Safety Manager			X	
Sponsor Pharmacy			X	
Chief Investigator			X	

3. Scope

This procedure applies to the Monitoring Team within the Research Governance Department of NHS Greater Glasgow and Clyde Research and Innovation.

4. 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 Clinical Trial Monitors, acting on behalf of the sponsor, to monitor non-commercial clinical trials, including CTIMPs, high risk Non-CTIMPs and medical device studies which are Sponsored, Co-sponsored by NHS Greater Glasgow and Clyde (GG&C) or a non-GG&C sponsor. The process is designed to ensure the monitor(s), Lead CTM and Research Governance Manager maintain the blind, whilst adhering to the Research and Innovation SOPs for monitoring clinical trials, escalating and reporting any issues / non compliances.

5. Procedures

5.1. Current Blinded Monitoring Process

The CTM will perform their monitoring visit in accordance to 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), site staff and Sponsor representatives. This process is outlined in Figure 1.

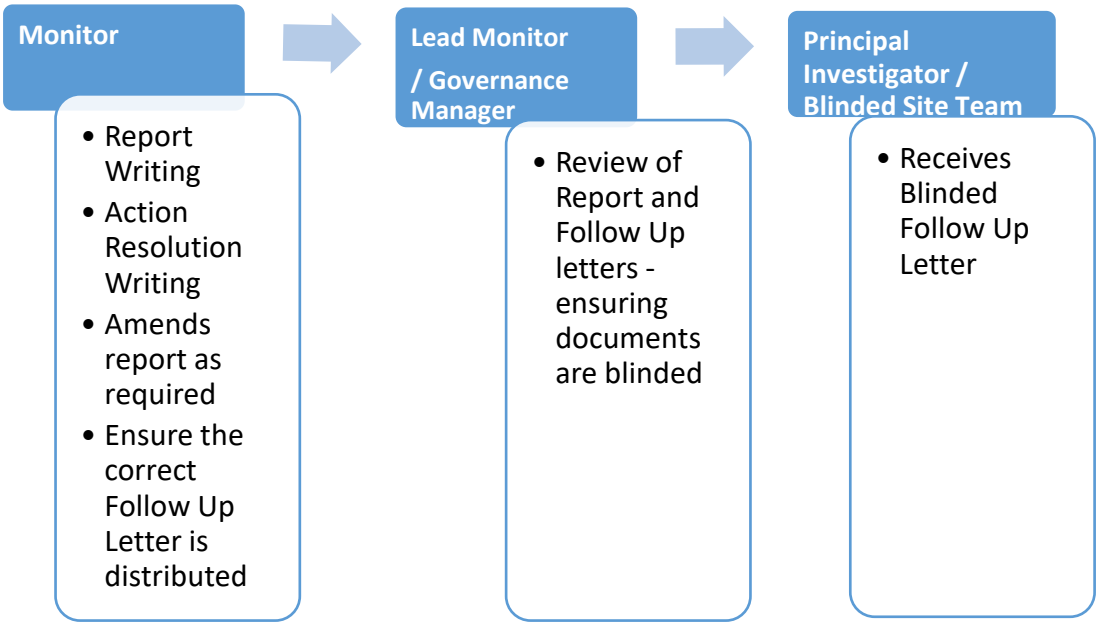

Figure 1 – Blinded Monitoring Process

5.2. 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 i.e. 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. 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, site staff and sponsor representatives whilst onsite, 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 follow up letter to the nominated unblinded site staff (e.g. nominated site staff, site pharmacist etc.), clearly indicating that the contents contain unblinded information which must remain inaccessible to blinded members of the site 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 53.005J.

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.

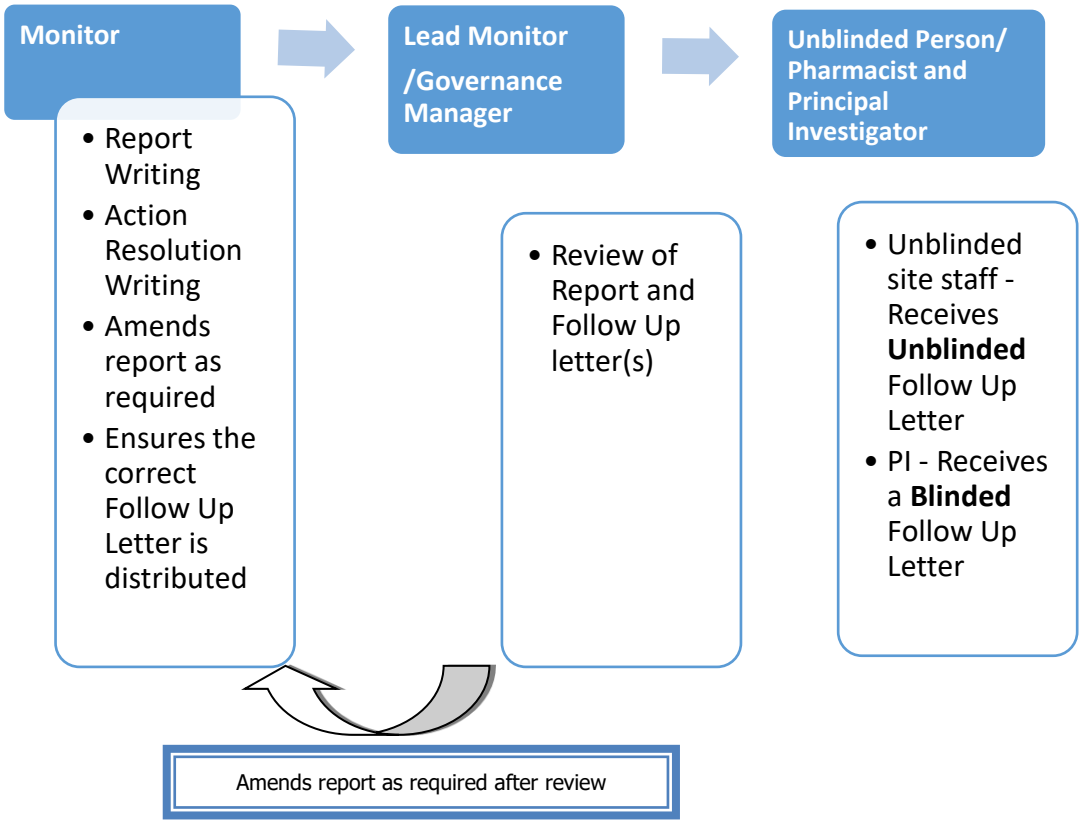

Figure 2 – Unblinded Monitoring Process

5.3. Exceptions

In the case that there are differences within trials and how the unblinded CTM should perform their monitoring tasks, 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 monitor then the Research Governance Manager will review the report and sign off.

5.4. 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 on the R&I shared drive and the Lead CTM will also be able to access. No unblinded information can be entered into the monitoring record or associated findings in Q-Pulse, they must only be referenced but contained in the secure folder in the common drive. The printed report will be enclosed in an envelope where the seal has been signed and dated and then filed in the TMF.

6. Referenced documents

- Form 53.004A: Monitoring Plan
- Form 53.004H: Preliminary Follow Up Letter/Follow Up Letter
- Form 53.005J: Filenote Template

7. Related documents

- SOP 53.004: Monitoring Clinical Trials

8. Document History

Version	Date	Description
1.0	11/12/2018	Release of first Version
2.0	06/12/2022	Change of Author as per Process Development SOP, formatting and removal of old form.