Standard Operating Procedure			**53.008**
Accompanied and Training Visit Process			
Version	**2.0**		
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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			

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 Lead Clinical Trial Monitor (CTM) / Research Governance Manager will adhere to when conducting an accompanied visit with a clinical trial monitor. The Lead CTM will primarily carry out the visits, however the RGM or a delegated experienced CTM will provide cover as required. The process should ensure the standard of monitoring carried out by the monitor(s) within Research and Innovation is consistent. The Lead CTM will accompany the CTM on a monitoring visit for the purpose of assessing performance and / or using the visit as a learning opportunity for the CTM, this can either be on-site or via a remote method such as MS Teams.

5. Procedures

The process will involve the Lead CTM carrying out an accompanied visit for either - a new staff member or for – training purposes. The flow of the process is detailed below in Figure 1.

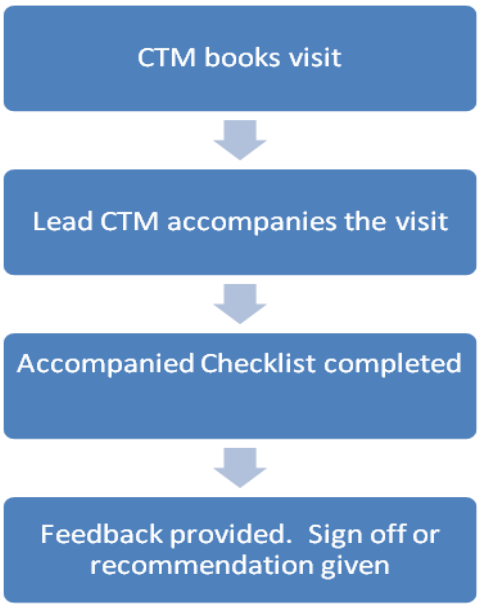

Figure 1 – Accompanied Visit Process Flow

The Lead CTM will identify if the monitor requires an accompanied visit for performance or training purposes. The CTM will schedule a routine monitoring visit (preferably a routine monitoring visit) in line with the monitoring plan and a local location should be prioritised to minimise travel costs associated to the trial.

5.1. Accompanied Performance Visit

The Lead CTM will accompany the CTM for a monitoring visit in which they will review performance in the following areas –

- Monitor compliance with the monitoring plan, SOPs and protocol
- Visit preparation
- On site conduct
- Site staff interaction
- PI Feedback
- Visit follow up
- Visit feedback

5.2. Accompanied Training Visit

The Lead monitor will identify any area(s) where training is required and accompany the monitor for a monitoring visit in which the training will be given as detailed below –

- Pre- training plan
- Visit preparation
- On-site training
- Post visit
- Visit feedback

On completion of an accompanied visit the Lead CTM, or RGM/delegated experienced CTM, will complete the Form 53.008A. Accompanied Visit Checklist and provide this to the monitor. This will then be filed within the individuals training file, a copy retained by the Lead CTM and a copy shared with the Research Governance Manager for oversight. Depending on the outcome of the visit, the Lead CTM will either sign off the checklist or provide a recommendation for further training.

This process will be part of the on-going induction process for new CTMs and will comply with the monitoring SOPs and regulations.

6. Referenced documents

- FORM 53.008A: Accompanied Monitoring Visit Checklist

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	10/03/2023	Change of author as per the Process development SOP, formatting and a remote method added.