SOP number	**53.014**	Version	**1.0**
Title	**External Sponsor Monitoring Arrangement**		

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Approved by Signature	Caroline Watson	Date
Released by Signature	Julie Brittenden	Date

SOP category	NHS GG&C Sponsor Governance
Staff category	

Staff Category	R	A	C	I
Research Governance Manager		X		
Clinical Trials Monitors	X			
Lead Clinical Trial Monitor	X			
Sponsor Research Co-ordinator			X	
Commercial Research Co-ordinator			X	
R&I Director			X	

1. Scope

This procedure applies to NHS Greater Glasgow and Clyde Research Governance.

2. Purpose

The purpose of this SOP is to describe the process for detailing the agreed monitoring processes and documentation when the NHSGGC Clinical Trial Monitors (CTM) have been requested to monitor a trial/investigation on behalf on an external Sponsor or when NHSGGC are the UK Co-ordinating centre.

3. Procedures

Non-NHSGGC Sponsors can request their trial or clinical investigation to be monitored by the NHSGGC CTMs on their behalf. In the event the request is made, the Co-Ordinator will contact the Lead CTM who will then ascertain whether this is achievable in terms of resource and the logistics of the trial/investigation and any issues will be escalated to the Research Governance Manager and R&I Director.

3.1. Considerations

The Lead CTM/CTM will discuss with the external Sponsor the requirements such as

- SOP use - NHS R&I monitoring SOPs or external Sponsor processes
- Monitoring plan format
- Report and Follow Up letters, action resolution templates
- Reporting timelines
- Communication pathways
- Non-compliance reporting
- External Sponsor liaison and interaction – TMG/Reviewer
- The Quality Management System - NHSGGC (Q-Pulse) or Sponsor developed
- Training

3.2. Documenting Agreements

The decision shall be documented in an External Sponsor Monitoring Process Arrangement Form and completed by the Lead Clinical Trial monitor and then signed by both the Lead CTM and/or NHS Research Governance Manager and the external Sponsor Representative. The form must be filed in section 5 of the CTM section the TMF and/or Q-Pulse.

The arrangement of monitoring processes between NHSGGC and the external Sponsor will be captured within the Research contract, such as the Model Agreement for Non-Commercial Research, between the two organisations. Items listed within section 3.1 will be covered within the contract. This will also include monitoring, and staff costs.

3.3. Decision to Proceed

The final decision on whether or not to act on behalf of the external Sponsor will be made by the Research Governance Manager based on the discussions outlined in Section 3.1 and documented as per Section 3.2.

4. Referenced documents

- FORM 53.014A - Sponsor Engagement Form

5. Related documents

- SOP 53.004 - Monitoring Clinical Trials
- SOP 53.012 - Close Out
- SOP 53.015 - Site Compliance Visit

6. Document history

Version	Date	Description
1.0	29/04/2024	First Release