SOP number	**53.013**	Version	**2.0**
Title	**Monitoring Clinical Research - For Cause Monitoring Visit**		

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SOP category	NHS GGC Sponsor Governance

Staff category

Staff Category	**R**	**A**	**C**	**I**
Lead Clinical Trial Monitor		x		
Clinical Trial Monitors	x			
Sponsor Research Co-ordinators			x	
Innovation Project Manager			x	
Innovation Contracts Manager			x	
R&I Sponsor Pharmacy			x	
Project Managers			x	
Research Governance Manager			x	
Chief Investigators				x
University of Glasgow Research Regulation and Compliance				x

1. Scope

This standard operating procedure applies to all NHS Greater Glasgow & Clyde Research Governance staff. The SOP also covers activity undertaken if contracted by an external Sponsor as detailed in SOP 53.014.

2. Purpose

The purpose of this SOP is to describe the procedures that will be used by the Clinical Trial Monitors (CTMs), acting on behalf of the Sponsor, to perform a For Cause Visit for non-commercial clinical trials, medical device trials and high-risk non-CTIMP studies, Sponsored or Co-Sponsored by NHS Greater Glasgow and Clyde (NHSGGC). A For Cause visit is a monitoring visit in response to alleged Non-Compliance with the protocol, GCP issue or process within the trial/study which has a potential impact on patient safety and/or data integrity. Anyone within the Sponsor team, Project Manager or trial site that may have concerns regarding a specific site should approach the CI, the Lead monitor, the Governance Manager and/or the Lead Pharmacist Clinical Trials to discuss trial/site issues – examples below.

Examples of a Non-Compliance/concern that might trigger a For Cause Monitoring Visit, may include, but is not limited to;

- Proof or suspected fraud relating to clinical trial documentation
- Continued data discrepancies or data backlog, where no site response is provided to data queries or a site plan to resolve data over a continuous time period
- Continued documented Non-Compliances of the protocol or patterns of the same Non-Compliance despite CAPAs in place
- Persistent or systematic Non-Compliance to GCP, the protocol or monitoring actions which has an impact on the safety and wellbeing of trial participants or compromises the integrity of the trial data
- Concerns over the ethical conduct of the study
- Failure to continually assess causality and expectedness in review of SAEs in accordance with the timelines defined within the protocol and associated legislation
- Consistent failure to report SAEs as defined by the protocol which impacts the safety of trial participants
- Poor PI oversight and continuous failure to respond to Sponsor communication
- Failure to provide IMP records and accountability
- Issues identified with laboratory samples which affects endpoints within the protocol
- Site requested visit

3. Procedures

The For Cause Visit is only deemed necessary if concerns are raised in regards to the safety of patients or the data of a particular site as outlined above. However, the For Cause Visit is a separate entity within the monitoring plan, Form 53.010A, and may only be deemed necessary after Sponsor stakeholder discussions.

The procedure for the For Cause Visit will depend on the area of Non-Compliance, however, the CTM will endeavour to conduct a full monitoring visit based on the costs attributed to the study, over an agreed time period depending on the seriousness of the Non-Compliance.

The monitoring visit will follow the same format as a standard Monitoring visit (SOP 53.004) but will be identified in Q-Pulse and the resulting documentation as a For Cause Visit, details from the visit will be followed up in the follow up letter and an actions resolution document which will then be filed within the monitoring section of the TMF. The follow up letter (Form 53.004H) and/or report will document the reason the visit was outside of the Monitoring Plan and the monitor will ensure the record on Q-Pulse identifies the reason for a For Cause Visit. The visit will be discussed at the next TMG if it follows within a reasonable timeframe or a post visit meeting may be scheduled with the CI, Lead Monitor, Sponsor Representatives, PM and may include the Research Governance Manager/Lead Pharmacist Clinical Trials. A decision will be made as to whether the site may continue recruitment in the trial and if the trial data can be used.

Conducting a For Cause Visit does not remove any pre-existing requirements within the monitoring plan, Form 53.010A, to conduct a normally schedule monitoring visit.

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
- Form 53.004H – Preliminary Follow Up Letter / Follow Up Letter

5. Related documents

- SOP 51.008 - Handling non-compliance with Good Clinical Practice (GCP) and/or the trial protocol in clinical research sponsored, co-sponsored or hosted by NHS Greater Glasgow and Clyde
- SOP 51.009 - Notification of Serious Breaches of Good Clinical Practice or the Trial Protocol for Clinical Trials of Investigational Medicinal Products
- SOP 53.002 - The Handling of Poor Quality and Fraud in Clinical Research
- Form 53.004B - NHS GG&C Research Governance Monitoring Risk Assessment
- SOP 21.003 - Sponsor IMP Management and Accountability
- SOP 21.010 - Destruction of Investigational Medicinal Products and Other Study Products

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	25/08/2022	First Release	N
2.0	21/10/2025	Annual review, new format including the RACI and minor changes	N