Standard Operating Procedure			**53.013**
Monitoring Clinical Research – For Cause Monitoring Visit			
Version	**1.0**		
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1. SOP Category
NHS GG&C Sponsor Governance

2. Staff Category
- Sponsor Research Coordinators
- R&I Lead Clinical Trial Monitor
- R&I Clinical Trial Monitors
- R&I Sponsor Pharmacy
- R&I Research Governance Manager
- R&I Lead Pharmacist Clinical Trials
- R&I Project Management Unit
- GU Project Managers
- Innovation Project Manager
- Innovation Contracts Manager
- Principal Investigators

3. Scope
This standard operating procedure applies to all NHS Greater Glasgow & Clyde Research Governance staff.

4. 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 (GG&C). 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 or the project manager 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 prior to arranging a site visit.

Examples of a non-compliance that might trigger a For Cause Monitoring Visit, may include, but is not limited to;

- Proof of Fraud relating to clinical trial documentation
- Continued data discrepancies
- Continued documented non-compliances of the protocol
- Persistent or systematic non-compliance to GCP or the protocol 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.
- Failure to provide IMP records and accountability.

5. 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 53.004, 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 over an agreed time period depending on the seriousness of the non-compliance. The monitoring visit would follow the format of standard Monitoring visit SOP (53.004) and details from the visit would be followed up in the follow up letter and an actions resolution document. 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 would ensure the record on Q-Pulse, identifies the reason for a For Cause Visit. A post visit meeting would be scheduled with the CI, Lead Monitor and may include the Research Governance Manager/Lead Pharmacist Clinical Trials and a decision would 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 53.004A, to conduct a normally schedule monitoring visit.

6. Referenced documents

- SOP 53.004 - Monitoring Clinical Research - Site Monitoring Visit
- Form 53.004A - Monitoring Plan for a Clinical Trial of an Investigational Medicinal Product
- Form 53.004H – Preliminary Follow Up Letter / Follow Up Letter

7. 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
- Form 53.004L - Site Close Out Report
- Form 53.004O - End of Trial Monitoring Document Reconciliation
- Form 51.016F - CTM File Index
- SOP 21.003 - Sponsor IMP Management and Accountability
- SOP 21.010 - Destruction of Investigational Medicinal Products and Other Study Products

8. Document History

Version	Date	Description
1.0	25/08/2022	*First Release*