| SOP number | **57.001** | Version | **10.0** |
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| Title | **Managing a Monitoring Visit** | | |

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| SOP category | 57 - NHSGGC Clinical Research Facility - Administration |
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Staff category

| Staff Category | R | A | C | I |
|---|---|---|---|---|
| Nursing | X | | | |
| Administration | X | | | |
| Clinical Research Fellow | X | | | |
| Local Clinical Trials Pharmacy | X | | | |
| GCRF Manager | | X | | |
| Principal Investigator | X | | | |
| GCRF Associate Director | | | | X |
| Senior R&I Manager | | | | X |

## 1. Scope

This procedure applies to all Glasgow Clinical Research Facility (GCRF) staff, Principal Investigators (PI) and study teams supported by GCRF.

## 2. Purpose

To describe the procedure to be followed when preparing, coordinating and participating in a commercial or non-commercial sponsor monitoring visit, either onsite, remote or central monitoring.

## 3. Procedures

### 3.1. Routine Monitoring

The method, frequency and type (onsite/remote) of monitoring will be determined by the Sponsor, and discussed with the study team at location selection/initiation visit or as part of the study set-up communication.

Monitoring visits will be agreed in advance however staff may need to rearrange dates in instances when the facility cannot accommodate visits i.e. not given adequate notice or other monitoring visits arranged.

### 3.2. Triggered Monitoring Visit

There are events that may trigger a monitoring visit e.g. protocol non-compliance, high or low number of adverse events, higher or lower than expected recruitment numbers, IMP

management issues, drug errors. These events may result in further visits providing additional support to resolve issues.

The Research Nurse Manager and GCRF QA Lead must be notified as soon as additional monitoring visits have been requested.

### 3.3. Preparation

The study lead nurse or designee will liaise with sponsor representative, co-ordinate local resources and ensure the following are completed for onsite monitoring visits:

- Trigger monitoring workflow on EDGE.
- Confirm date, time and plan with monitor, relevant study team members.
- Book a monitoring desk using the room booking process, GUI 57.004B.
- Ensure all relevant documentation and files are available including those requested by the monitor, whilst maintaining sponsor confidentiality.
- If required request Clinical Portal access following GUI 57.001A.
- Complete Clinical Portal account details on Form 57.001B.
- Ensure all paperwork up-to-date.
- Ensure outstanding actions from previous visits have been resolved.

Follow GUI 57.001C to prepare and manage a remote monitoring visit (RMV).

### 3.4. During the Onsite Monitoring Visit

On arrival, the monitor will:

- Sign the visitors' book
- Be orientated to the department and advised on emergency exits and procedures.

The visit will be conducted in the designated workspace and the monitor provided with the relevant documentation and Clinical Portal access as detailed on Form 57.001B. During the visit the monitor must comply with NHSGGC policy on access to electronic and paper health records.

The study lead nurse or designee will supervise and support the monitoring visit, resolve queries and co-ordinate other departmental meetings as necessary.

The Principal Investigator (PI)/Co-Investigator should be available on the day of the visit to clarify any details or queries raised by the monitor.

At the end of the visit the monitor will meet with the appropriate study staff to discuss their findings and the action points that need to be resolved, setting an agreed timeline for completion. The monitoring visit date, time spent with the monitor and attendees must be recorded in the EDGE study record.

Any safety, data quality or regulatory findings identified during the visit must be escalated to the PI, Research Nurse Manager and Quality Assurance Lead. On leaving each day the monitor will sign out of the CRF in the visitors' book.

### 3.5. Following Monitoring Visit

All source records and files must be held in a secure location until returned to the appropriate department/storage areas.

The study lead nurse will provide a verbal report to Research Nurse Manager highlighting areas that need to be addressed.

The study lead nurse or designee will aim to resolve all action points raised during the visit within 14 working days. Missing data and corrections must be completed promptly following a visit. Any action unresolved within 14 working days must be reported to GCRF Research Nurse Manager.

The sponsor monitoring report must be reviewed by Research Nurse Manager and escalated to GCRF Manager, Lead Nurse and QA Lead as appropriate.

Study team must update the EDGE Monitoring Workflow, file a copy of the monitoring report in the Investigator Site File and upload to EDGE.

### 3.6. Access to Electronic Health Records (EHR)

NHSGGC electronic patient record system is Clinical Portal which provides a full audit trail of any events. Investigator access and viewing of results in Clinical Portal will be included in the audit trail. A patient's participation in research and any supporting documentation will be recorded on Clinical Portal.

Access to NHSGGC Clinical Portal for a user external to the clinical study team will be requested by the study lead nurse and granted access by a member of the GCRF Management Team. Each monitor account has an inactivity timeout set to a maximum of 30 minutes and the account will disable after 30 days.

Following GUI 57.001A and GUI 57.001B, the study lead nurse will add the external user account to the relevant work list on Clinical Portal. The monitor accounts do not have the ability to deviate from the shared worklist, therefore the monitor cannot access patient health records out with the study.

### 3.7. Observed monitoring or technical support

There may be a requirement for the study sponsor to observe a participant clinical visit or a member of the sponsor team to attend a participant clinical visit to provide technical support, training and advice to the GCRF team. Form 57.001C Clinical Visit with Study Staff External to NHSGGC Checklist should be completed by GCRF team.

The participant must consent to the external visitor being present during the visit; the GCRF team must use Form 57.001D to consent the participant. Copy must be given to the participant, another filed in the participant research record and uploaded to participant health record on Clinical Portal.

If the participant does not wish to consent to observed monitoring practice or technical support/training the study sponsor and Research Nurse Manager must be notified immediately. If the participant does not wish to consent to an observed monitoring visit,

the participant's clinical visit should continue as normal with GCRF staff only present. If the participant does not wish to consent to observed technical support/training further, discussions with study sponsor is required as their attendance may be a protocol requirement for the clinical visit to take place

## 4. Referenced documents

- Form 57.001B: Clinical Portal External User
- Form 57.001C: Clinical Visit with Study Staff External to NHSGGC Checklist
- Form 57.001D: Consent Form for Observed Clinical Visit
- GUI 57.001A: Clinical Portal Access for External Users in GCRF
- GUI 57.001B: Creating and sharing Worklist on Clinical Portal
- GUI 57.001C: Remote Monitoring Visit
- GUI 57.004B RGCRF Room Booking

## 5. Related documents

- Form 57.001E: Informed Consent Quality Check
- NHS Scotland Code of Practice: Protecting Patient Confidentiality

## 6. Document history

| Version | Date | Description | Retrospective Implementation |
|---|---|---|---|
| 1.0 | 30/09/2009 | Release of version 1 | No |
| 2.0 | 30/06/2014 | Change of author, substantial amendments to provide clearer guidance on preparing, conducting and follow-up to a monitoring visit New form created to support SOP (Form 17.019A) | No |
| 3.0 | 14/03/2016 | Addition of audits<br>Introduction of GUI 17.019A Addition of section 5.4 Minor changes | No |
| 4.0 | 15/07/2016 | Restructure of SOPs<br>Change of SOP number from 17.019 to 57.001 | No |
| 5.0 | 27/02/2018 | Addition to types of monitoring visits<br>Minor admin changes<br>Removed audit reference, now covered in SOP 57.008. | No |
| 6.0 | 20/09/2018 | Addition of observed monitoring practice<br>Addition of Form 57.001C and Form 57.001D | No |
| 7.0 | 26/08/2019 | Minor changes to add responsibility to section 5.3, to remove the verbal report timeline from section 5.5 | No |
| 8.0 | 11/09/2020 | Addition of:<br>GUI 57.001C Remote Monitoring Visit<br>Form 57.001 Informed Consent Quality Check | No |
| 9.0 | 28/09/2022 | Removal of 'Recently searched patients' process.<br>Addition of EDGE workflow and MV date<br>Form 57.001A obsolete | No |
| 10.0 | 10/04/2026 | Change of author and released by.<br>Transfer to new SOP template<br>Addition of RACI<br>Minor admin changes | No |