**Glasgow Clinical Trials Unit**
**NHS GG&C Clinical Research Facility**

**MANDATORY**

**GUI 57.001C: Remote Monitoring Visit**

The purpose of this guidance is to describe the host site remote monitoring process for GCRF. To ensure the confidentiality and sharing of data in accordance to NHS Greater Glasgow & Clyde Policies, NHS Scotland Confidentiality Code and General Data Protection Regulations.

**Procedure**

Microsoft Teams will be used to share applications on screen and as a document repository during remote monitoring visits (RMV). When arranging the visit date/time ensure the CRA/monitor can download and access the Microsoft Teams app. GCRF must create and own the Team and scheduled meetings, maintaining control and accountability of source. GCRF will set-up non-clinical access to the study record on EDGE ensuring no participant identifiable data can be viewed.

Remote monitoring visits must be appropriately resourced, the ability to complete independent QC/QA by GCRF team must be taken into consideration and agreed prior to contract sign-off and site green light.

Monitors/CRA will be able to view and control Clinical Portal (EMR) through shared application on Teams. GCRF must receive confirmation from CRA/monitor that the RMV will be conducted in a private area, Form 51.001B. Research participants must have consented to allow third party to view medical records. Health Research Authority (HRA) confirms site does not need to seek further consent from participants unless the PIC/ICF mentions where SDV will take place i.e. named physical site.

## 1 Preparation

i. Discuss and agree the remote monitoring requirements with CRA/monitor i.e. essential documents, critical data points for SDV. RMV should take no longer than 2 hours, not including site preparation time, if more is required then an onsite visit should be scheduled.
ii. Once date/time agreed check LOWS (laptop on wheels) is available, book through reception.
iii. Create meeting on Outlook, click **Teams Meeting** icon. Add all attendees.
iv. Create remote MV folder on EDGE (RMV – *Date of visit*– *Lead Study Nurse Name*). Scan and upload essential documents and source required for visit.
v. The following identifiable participant documents must be shared on screen during RMV – screening/enrolment log, AE log, SAE report, paper CRF, paper worksheets, IMP accountability log.
vi. Request EDGE RMV account access from Information Systems Manager (ISM) or Administration Manager.
vii. Add the assigned EDGE RMV account as a user to the study record.
viii. The monitor may request to review non-identifiable documents (delegation log, training log, GCP, CVs (ensure no home address details), current version of PIS/ICF, R&D approvals, MV log, temperature log) prior to the RMV. Create a Team for the study on Microsoft Teams. Create folder within Team for RMV and upload required non-identifiable documents. Confirm documents are available to view and download prior to visit.
ix. Send Form 57.001B to CRA/monitor for review and signature. Electronic signature is accepted so long as the form has been returned by CRA/monitor email account.

## 2 Share and control of Clinical Portal screen

i. Check PIS/ICF for any mention of SDV. If physical location of SDV is mentioned i.e. SDV will be conducted on hospital premises, verbal consent from participants must be sought to complete SDV remotely. Verbal consent must be documented in Clinical Portal.
ii. Request monitoring account from Nurse Manager or Administration Manager.
iii. Create and share worklist with account following GUI 57.001B.

## 3 During

i. Using LOWS, login to Teams, the assigned EDGE RMV account and assigned Clinical Portal account minutes prior to RMV to ensure there are no issues with access.
ii. Work through the EDGE RMV file structure with the CRA/monitor.
iii. Share the Desktop and grant the CRA/monitor control of the screen.
iv. Request CRA/monitor download a file to ensure access working.
v. Ensure microphones are muted when SDV can be completed in the background.
vi. Review of EMR – Share Clinical Portal application. If CRA/monitor has not accessed Clinical Portal previously, train how to access shared worklist and where information and documents can be found. Share the application with the CRA/monitor and grant control of the screen.
vii. At the end of the visit. Stop sharing all applications.
viii. Follow GUI 57.001A section **At the end of Visit**. Confirm with CRA/monitor worklist has been adhere to.
ix. End the meeting.

## 4 After

i. Remove assigned EDGE RMV account from study record.
ii. Remove study worklist from Portal account.
iii. Once received upload RMV report to relevant folder on EDGE.
iv. Remove CRA/monitor from RMV Team if notified no longer working on the study.

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