

**STANDARD OPERATING PROCEDURE**

|  |  |
| --- | --- |
| **Title** | Remote Monitoring |
| **Reference Number** | SOP-QMS-009 |
| **Version Number** | Version 0.2 |
| **Effective Date** |  |
| **Review Date** |  |

|  |  |
| --- | --- |
| **Author(s)** | Manjit Chohan, Quality Assurance Manager |
| **Reviewer(s)** | Jennifer Boston, Head of Research Governance and Quality |

|  |  |
| --- | --- |
| **Authorisation (Original signatures are retained by Research & Innovation)** | |
| Prof Stephen Ryder  Director of Research & Innovation | [Date] |
| Dr Maria Koufali  Managing Director of Research & Innovation | [Date] |

**USERS OF THIS STANDARD OPERATING PROCEDURE MUST REFER TO** [**WWW.NUH.NHS.UK/GUIDANCE-RESEARCHERS**](http://WWW.NUH.NHS.UK/GUIDANCE-RESEARCHERS)

**TO ENSURE THE MOST CURRENT VERSION IS BEING USED**

**UNCONTROLLED COPY WHEN PRINTED**

1. **Document History**

|  |  |  |
| --- | --- | --- |
| **Version Number** | **Effective Date** | **Reason for Change** |
|  |  |  |

1. **Introduction**

Whilst most monitoring is conducted on-site, there can be a requirement to facilitate remote monitoring. For example, during the current pandemic whereby social distancing is required, or if there is an oversees Sponsor and it is more practical to do any monitoring remotely.

Any deviation to any monitoring plans must be documented in the investigator site file. Any monitoring conducted must enable appropriate evaluation of the conduct of a trial.

1. **Purpose and Scope**

The purpose of this SOP is to provide guidance to Research and Innovation (R&I) personnel in the preparation and organisation of remote monitoring directed by an external Sponsor or Monitor.

1. **Responsibilities**

Sponsor is responsible for ensuring their trial is monitored effectively and appropriately. They are responsible for ensuring confidentiality of any data shared with them is maintained.

Principal Investigator and study team are responsible for facilitating the remote monitoring session and ensuring that the sponsor is aware of their responsibilities in this SOP.

1. **Definitions**

MS Microsoft

NUH Nottingham University Hospitals

PI Principal Investigator

R&I Research and Innovation

SOP Standard Operating Procedure

1. **Procedure**
   1. **Preparation of remote monitoring visit** 
      1. If there is a deviation from the study monitoring plan, the research team and/or PI will need to complete a file note to document this deviation and the reason for it.
      2. Once the remote monitoring date has been confirmed, the NUH PI/ study team must ensure all study personnel are aware of the agenda and schedule.
      3. The NUH study team should ensure a private room is available for the monitoring session. They must ensure the room has internet and appropriate IT access. Rooms can be booked through the R&I administration team.
      4. The Sponsor will need to request in advance the documentation they require to see for the monitoring session.
      5. The NUH PI/study team will organise staff to facilitate the sharing of the required documentation via MS teams and assist with any queries.
      6. NUH will issue the Sponsor/external monitor with a password.
      7. NUH study team must go through this SOP with the Sponsor/Monitor representatives present prior to starting the monitoring visit and ask them to confirm via signing and returning the training log TAFQ00702 that have read and understood the content of this SOP and their responsibilities.
   2. **During remote monitoring** 
      1. NUH study team should verify the identity of the Sponsor/Monitor representative on behalf of the sponsor and ask for password that was set in 6.1.6.
      2. Documentation can be shared between NUH and the Sponsor via MS Teams.
      3. NUH study personnel should only display documentation on MS teams that has been requested in advance by the sponsor, and must not deviate from the schedule.
      4. The NUH study personnel assisting with the monitoring session must remain online at all times.
      5. If breaks are involved during remote monitoring, all devices must be logged off securely. After each break the monitor will have to confirm the password each time.
      6. The Sponsor/Monitor must not record or print screen from the session on MS teams.
      7. The Sponsor/Monitor must only view the screen shared via MS teams in a confidential environment whilst the remote monitoring is ongoing.
      8. The Sponsor/Monitor must ensure that only individuals who have signed the training log (TAFQ00702) are present in the room whilst the monitoring session is ongoing.
   3. **After remote monitoring** 
      1. Ensure that all electronic devices used during remote monitoring have been logged off and switched off.
      2. Return any electrical equipment.
      3. The documentation requested and viewed by Sponsor/Monitor must be documented in the Investigator Site File.
2. **References and Associated Documents**

TAFQ00702-Remote Monitoring Training Log

TAFQ00803-Training attendance record

1. **Appendices**

**Not Applicable**