SOP 331 Remote Monitoring of Studies

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
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Description of changes:	Addition of procedure for NNUH sponsored studies hosted at other sites

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies printed from the website are only valid on the day of printing.

1. Contents

2. Definitions of Terms Used / Glossary

CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HRA	Health Research Authority
ISF	Investigators Site File
NNUH	Norfolk and Norwich University Hospital
PI	Principal Investigator
REC	Research Ethics Committee
R&D	Research and Development
SOP	Standard Operating Procedure

3. Objectives

This SOP describes the process and responsibilities for the remote monitoring of clinical trials which the Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) sponsors or participates in, both in relation to Clinical Trials of an Investigational Medicinal Product (CTIMPs) and Device Trials.

4. Scope

Monitoring is an integral process in the Quality Control (QC) of a trial. Monitoring ensures that a trial it is conducted, recorded, and reported in accordance with the trial protocol, applicable SOPs, policies, GCP, and the applicable regulatory requirement(s) (section 1.38 ICH Guideline for Good Clinical Practice E6 (R2), dated 9 November 2016.)

According to the principles of ICH GCP (section 5.18.1, ICH Guideline for Good Clinical Practice E6 (R2), dated 9 November 2016.) the purposes of trial monitoring is to verify that:

- The rights and well–being of human subjects are protected.

- The reported trial data are accurate, complete and verifiable from source documents.
- The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

Monitoring is part of a multi-factor approach to ensure the quality of research for all NNUH sponsored CTIMPs and Device Trials.

5. Purpose

This SOP describes the process to be followed regarding situations where onsite monitoring may not be possible and follows the guidance provided by MHRA and HRA.

6. Procedure for Sponsors requesting access to NNUH for monitoring

Research sponsors shall contact the PI and / or the research team to discuss arrangements for monitoring visits on a study-by-study basis. The Sponsor must ensure that the PI is informed of any necessary amendment to the study protocol to facilitate alternative monitoring arrangements.

While it is the responsibility of the Sponsor to ensure appropriate submission and approvals of study documentation, the PI should always review any changes and discuss this with R&D if deemed necessary.

It is recommended that all research Sponsors should consider the extent and nature of monitoring that would be proportionate to each specific research study while striking a balance between appropriate oversight and the capacity of the trial site to avoid any extra burden alternative measures may present.

6.1. Remote monitoring

Monitoring allows an overview of study progress, any potential issues in trial conduct, changes to the protocol, trial participants status etc. and may be done onsite or remotely. Remote monitoring visits including phone calls, video links, emails etc. to enable the Sponsor to monitor the progress in collaboration with the PI and the research team and are feasible at NNUH.

It is the responsibility of the PI and the research team to ensure appropriate arrangements, outlined below are in place to facilitate remote monitoring:

- Video conferencing should be conducted via Microsoft Teams, this is the current approved system and use of any other system may require additional approvals from NNUH Digital Health and Information Governance and might delay remote monitoring.

- The Sponsor should provide a copy of an appropriate procedure (e.g. Sponsor SOP) to support remote monitoring and its associated activities. Any queries regarding this process should be directed to R&D rdoffice@nnuuh.nhs.uk

- The monitor responsible for the conduct of the visit is known to the research team and the PI. Alternatively, you must ensure that all requests for such visits are received from a source know to you.

- Ensure that remote monitoring is conducted in a safe and private location.

- Ensure that any correspondence / documents generated as a result of this visit are appropriately filed in the ISF.

It is the responsibility of the Sponsor to confirm in writing compliance with the following rules of the visit prior to the remote visit taking place:

- Taking screen shots, printing, emailing or downloading of any records during screen sharing is not permitted

- Video recording is not permitted

- The monitor will inform the research team / PI of any personnel present in the room during remote monitoring. Any personnel involved with the remote monitoring must be familiar with the study, and fully trained in GCP to ensure compliance with regulatory requirements, and patient confidentiality.

- The PCs used during this activity by all parties involved must be password protected, with adequate security in place (e.g. firewall)

- The PCs will not be left unattended and accessible by anyone other than the monitor during this monitoring activity.

It is the responsibility of the PI to ensure that the above arrangements are in place.

6.2. Remote review of source data

Remote source data verification (SDV) will only be considered for current studies where patients have consented for sharing of their personal information. The remote SDV shall focus specifically on the quality control of critical data (e.g. primary end point) and important safety data.

Review of electronic patient's medical records by the monitor via any of the Trust Electronic Health Records (EHR) is not possible and it cannot be approved.

In absence of remote access to EHR, the PI should determine if the current situation at the site allows sharing of pseudo anonymised copies of trial related source documents with the Sponsor.

The PI and the research team must ensure that:

- The Sponsor has provided an appropriate procedure to outline the extent and nature of remote monitoring tasks.

- Patient identifiable data must not be shared electronically without explicit patient consent to proceed. The PI must ensure that any changes to the study consent are clearly documented and approved by the REC/HRA (where applicable).

- When agreeing to provide anonymised source data, the PI must consider if this is appropriate, and the research team must ensure that all patient identifiable data is redacted.

- Monitors agree in writing that adequate measures will be put in place to maintain patient confidentiality at all times, and that reviewing of patient records is conducted in private, and not public places.

- Data sharing platform is adequate and secure. It is recommended that Microsoft Teams is used for video and they are carried out in private. For emails only use an email address that an exchange of communication has already taken place with.

- Any requests to provide data by post or courier must be resourced by the Sponsor and assurance given that confirmation of receipt of data will be issued by the Sponsor.

6.3. Alternative Arrangements

NNUH acknowledges that remote monitoring might not be possible where any or some of the above conditions cannot be guaranteed by the Sponsor. It is recommended that in such cases the Sponsor contacts the Research Office via email: rdoffice@nnuh.nhs.uk, clearly marking the email with 'Alternative monitoring arrangement' to:

- Postpone monitoring activities until the site monitoring is allowed

- Provide a proposal for any alternative arrangements to be reviewed and approved by the Research Office. These requests will be reviewed in liaison with support departments.

7.0 Procedure for NNUH sponsored studies hosted at other sites

For NNUH sponsored studies monitoring may take place by on-site visits or by centralised / remote monitoring as per SOP 330. Details of monitoring approach, including remote monitoring will be summarised in the monitoring plan. Access for remote monitoring should be in line with MHRA and HRA guidance and take into consideration policies of individual sites.

8. References and Related Documents

References
https://www.hra.nhs.uk/
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

SOP No.	SOP Title
SOP 330	Monitoring Clinical Trials of an Investigational Medicinal Product and Device Trials

9. Approval

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10. Reason for new version and Training Implication

This SOP replaces the previous version number V1

Changes made	
Reason	• to include procedure for NNUH sponsored studies hosted at other sites.
Training Implication	**Yes**
Actions required	• Additional training may be required • Matrix to be updated