Portsmouth Hospitals University NHS Trust

Standard Operating Procedure (SOP)

Remote monitoring of research studies at PHU

For Completion by SOP Author	
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Document Author(s)	Toni Baker, Research Facilitator
Document Reviewer(s)	Beth Giddins, Research Facilitator Anna Cunnington, Research Support Officer Elaine Baddeley, Research Facilitator Kathy Blight, Pharmacist Chrissie Minnis, Pharmacist Mary Wands, Senior Clinical Trials Pharmacy Technician Mini David, Ophthalmology Research Nurse

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The definitive versions of all Portsmouth Hospitals University Trust Standard Operating Procedures (SOPs), templates and forms for research are online at https://www.porthosp.nhs.uk/research/

If you are reading this SOP in printed form then you are reading an uncontrolled document. You must therefore verify that the version number and date given below are the most recent, by cross-checking with the Trust research website before proceeding with implementation.

Portsmouth Hospitals University NHS Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This SOP has been assessed accordingly

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1. INTRODUCTION

Monitoring of research studies is necessary to ensure patient safety and data integrity. Monitoring can take place onsite or remotely depending on the needs of the study and the working environment.

Remote monitoring permits review of the study documentation without the Monitor having to physically attend the research site. This is particularly practical when site access is restricted or the monitor has a significant distance to travel.

2. PURPOSE

The purpose of this document is to describe the standard operating procedures for remotely monitoring studies conducted by Portsmouth Hospitals University NHS Trust (PHU)

3. SCOPE

This SOP relates to all hosted and sponsored research studies conducted at PHU that have a requirement for remote monitoring. All research staff involved in facilitating the remote monitoring session should be trained in this SOP.

The Trust recognises that some external sponsors, networks, funders and employers may require the use of their own SOPs for the good governance of research. In such cases it is the responsibility of the Portsmouth Hospitals University Trust user (including those individuals contracted to work on behalf of the Trust), to ensure that the external SOP is compatible with the procedure outlined below. If the external SOP contradicts the Trust's SOP then approval must be sought from a senior manager within the Research & Innovation Department at PHU.

In the event of an infection outbreak, flu pandemic or major incident, the Trust recognises that it may not be possible to adhere to all aspects of this document. In such circumstances, staff should take advice from their manager and all possible action must be taken to maintain ongoing patient and staff safety.

4. ABBREVIATIONS & DEFINITIONS

Abbreviation	Meaning
PHU	Portsmouth Hospitals University NHS Trust
PI	Principal Investigator
IT	Information Technology
SOP	Standard Operating Procedure

Term	Definition
PHU Study Team	The people involved in the conduct of a research project at PHU.
Monitor	The person delegated by the sponsor to undertake monitoring duties.
Sponsor	The organization that has ultimate responsibility for the initiation, management and financing of the research study

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5. DUTIES AND RESPONSIBILITIES

Role	Responsibilities
Monitor	• Advise PHU study team of documents required for monitoring ahead of the session • Sign the training log to evidence training in this SOP • Ensure remote monitoring takes place in a confidential environment • Follow the procedures in this SOP and not capture screenshots
Research Study Team	• Work with the monitor to coordinate the remote monitoring session • Provide the documents requested by the monitor • Ensure the identity of the monitor is verified at the start of each monitoring session • Ensure the monitoring session is disconnected at the end

6. PROCESS

6.1. Preparation of remote monitoring visit

6.1.1 If there is a deviation from the study monitoring plan (such as a late/missed monitoring visit), a member of the research team and/or PI will need to complete a file note to document the deviation and the reason for it.

6.1.2 Once the remote monitoring date has been confirmed, the PHU PI/ study team must ensure all study personnel are aware of the agenda and schedule. Consideration should be given to the length of the monitoring visit and schedule the visit over more than one day if both parties agree.

6.1.3 The PHU study team and the Monitor should ensure a private room is available for the monitoring session. They must ensure the room has internet and appropriate IT access.

6.1.4 The PHU study team and Monitor should agree which video conferencing platform to use. Ensuring it is secure and supported by both organisations for the purposes of sharing personally identifiable data. For example: Microsoft Teams. Note - PHU does not support the use of Zoom when sharing identifiable data.

6.1.5 The Monitor will need to request in advance the documentation they require to see for the monitoring session.

6.1.6 Confidential patient information may only be shared with the Monitor if this has been addressed in the patient information sheet and consent form.

6.1.7 Confidential information should be redacted if consent for it to be shared has not been given.

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6.1.8 The PHU PI/study team will organise staff to facilitate sharing of the required documentation via Microsoft Teams and assist with any queries.

6.1.9 PHU will issue the Monitor with a password that will be used to verify identity during the online session. The password can be any of the PHU study team's choosing.

6.1.10 The PHU study team must go through this SOP with the Monitor prior to starting the monitoring visit. The Monitor will be asked to confirm, via signing and returning the remote monitoring training log (appendix 1), that have read and understood the content of this SOP and their responsibilities. PHU staff should train and evidence SOP training in the usual manner.

6.2. During remote monitoring

6.2.1 At the start of the monitoring session the PHU study team should verify the identity of the Monitor and ask for password that was set in the steps above. (If the monitor is known to the study team then this step may be unnecessary).

6.2.2 PHU study team should only display documentation during the monitoring session that has been requested in advance by the Monitor, and must not deviate from the schedule.

6.2.3 The PHU study team assisting with the monitoring session must remain online at all times.

6.2.4 If breaks are involved during remote monitoring, all devices must be logged off securely. If there are any personnel changes when the session resumes then the password should be reconfirmed.

6.2.5 The Monitor must not record or take screenshots during the monitoring session.

6.2.6 The Monitor must only view the screen, shared during the session, in a confidential environment.

6.2.7 The Monitor must ensure that only individuals who have signed the remote monitoring training log (appendix 1) are present in the room whilst the monitoring session is ongoing.

6.3. After remote monitoring

6.3.1 Ensure all electronic devices used during the session have been logged off and switched off.

6.3.2 Return any electrical equipment.

6.3.3 Those present for the session and the documentation requested and viewed by Monitor must be documented in the Investigator Site File.

6.3.4 Within an agreed timeframe, the monitor should provide a monitoring report and an action plan for the study team to resolve any outstanding actions, if applicable.

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6.3.5 Record any chargeable monitoring activity on the study's finance template in EDGE so this can be invoiced appropriately.

6.4. Additional Notes

6.4.1 In the event of plans to use a previously untried or unapproved video platform or document sharing process this should be raised with the R&I office or IT department (as appropriate) to ensure data security levels are acceptable.

6.4.2 If the Monitor has an additional person/s attending the monitoring visit, they must be acting under the authority of the sponsor and read and follow this SOP.

7. TRAINING REQUIREMENTS

PHU study teams and external monitors conducting remote monitoring on research studies conducted by PHU must be trained in this SOP.

"The Research Dept., will endeavour to notify staff of SOP developments that may be relevant to them. SOPs are available on the Research department website. Updates on SOPs will feature in Research newsletters and communications and disseminate at local research meetings. It is the responsibility of all research active staff to ensure that they read the issued updates that may be relevant to them.

When a new SOP is authorised, or when an existing SOP is revised, self directed training must be carried out by all staff to which the SOP is relevant and this training documented in their training record. A template is provided to support this process. A study specific SOP training plan will be developed for investigators on high risk PHU Sponsored studies.

Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP when required. If clarification is needed then the trainee should approach their line manager and the SOP Controller who will arrange additional training. All staff should complete their training prior to the published implementation date which will normally be between 2-6 weeks after publication.

All staff are responsible for maintaining their own SOP Training Records and copies must be made available to line managers, the SOP Controller or study monitors on request."

8. REFERENCES AND ASSOCIATED DOCUMENTATION

Associated Documents

- Remote monitoring training log

Reference

- HRA Website
- Nottingham University Hospitals NHS Trust – SOP-QMS-009 Remote Monitoring

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9. VERSION HISTORY LOG

Version	Date Implemented	Details of Significant Changes
1.0	02/09/20	New document

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10. APPENDICES

10.1. Appendix 1

Remote Monitoring Training Log

Study title	
Sponsor	
PI	

I confirm I have been sufficiently trained and understand my responsibilities in the SOP: **PHTRD/SOP/21 Remote Monitoring of studies at PHU**

Print Name	Organisation	SOP Version & date	Signature	Date

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CONFIRMATION OF SOP TRAINING RECORD

A copy of this record may be kept in your personal training file to confirm your training in a specific SOP. If required by a study Sponsor a record may also need to be kept in the Trial Master Files (TMF) or Investigator Site Files (ISF)

SOP Details: To be completed by the SOP Controller	
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Personnel Details	
Name	
Job Title & Research Role	
Date of Training	
Nature of Training	Self Directed/Delivered by etc
Records of any meetings to clarify details in SOP	

Signatures
I confirm that I have read and consider myself to be sufficiently trained in the above Standard Operating Procedure with regards to my individual roles and responsibilities Signature of Trainee …… Date ……
I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities Signature of Trainer …… Date ……

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Additional Notes & Signatures
Signature of Trainer (where appropriate) I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities Signature of Trainer …… Date …….

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