Document Title: Monitoring Research Studies – External Monitors & Remote Monitoring

Document Number: R&D SOP085

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Summary of Amendments

Version Number	Modification:
1.0	New SOP
2.0	Wording updated in section 4.3 to clarify remote monitoring via live screen sharing
3.0	Amended for the location of Lorenzo cards for external monitors
4.0	Section 4.1 Wording updated and clarification for provision of documents to access to a Smartcard card for monitoring EPR. Reviewed for changes in regards to the new clinical trial R3 regs.

Key Related Documents	FRM067 Monitor Systems access and code of conduct FRM076 Declaration Form for the provision of Anonymised Patient Data TPL058 External monitor letter for sharing participant data Trust Policy DN001 Document Control Procedures

Key Points of this Document

- This document sets out the roles, responsibilities and procedures to be followed by external monitors involved in the monitoring of Non-Sponsored Royal Papworth research studies.
- It aims to provide clear guidance for the documents and processes that must be followed when hosting an external monitor at Royal Papworth Hospital.
- The document also provides guidance to Royal Papworth Hospital staff for hosting a remote monitoring visit.

1 Purpose and Contents

a. The document defines the Trust's and Research & Development's (R&D) procedures for the monitoring of Royal Papworth NHS Foundation Trust Non sponsored research studies.

b. It documents the purpose of monitoring as described in Good Clinical Practice (GCP: a risk-based, quality-focused process that uses a combination of methods like centralised monitoring, remote oversight, and targeted on-site visits to ensure participant safety and data integrity).

c. The document contains the guidance on how monitoring visits should be scheduled, performed and documented as to comply with the Trust-wide policies on Information Governance and participant confidentiality.

2 Roles & Responsibilities

a. This policy applies to all personnel that conduct research at the Trust.

b. Staff involved in the hosting of external monitors or the provision of documents for remote monitoring must following the guidance set out in section 4.

c. Copies of any templates used can be found on the Research and Development website: https://royalpapworth.nhs.uk/research-and-development/information-researchers/standard-operating-procedures-2

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with it may result in disciplinary procedures.

4 Procedure

4.1 Process for External monitors – Monitoring on site

Guidance for external monitors from outside the Trust:

a. Non-Royal Papworth sponsored studies using external monitors must complete:

1. The Systems access and Code of Conduct FRM067 will be sent in advance of any monitoring visit. This will allow access to a monitor's smartcard. The form must be signed and dated by the visiting monitor and Principal Investigator for the study.
2. A smartcard New External User form should be completed, it can be found here: https://staff.royalpapworth.nhs.uk/workforce-info-for-employees-smartcards
This form needs to be signed off by a Royal Papworth Hospital Manager and the "Smartcard Position" should be "R&D Monitor" The "Smartcard position end date" should be the date your monitor finishes their visit. Cards will be deactivated after this date. This form will need to be completed at each monitoring visit.

b. The completed Smartcard new external user form and FRM067 will be presented, along with the external monitor's identity documents to the workforce systems helpdesk based in the admin area on the ground floor, Royal Papworth Hospital. Upon an external monitor first requesting an R&D Monitors smartcard, the individual will need to complete the necessary ID check where the following documents will be requested:

3 Forms of photographic ID/proof of UK address documents are required - originals seen and copies taken, dated and signed.

3 original documents should be presented, one from each section.

Please note: Proof of Address should be dated within the last 3 months.

ID 1 - Photographic	Passport (current)
	Driving License (current)
	HM Armed Forces Identity Card (UK)
	eVisa (accessed online via Home Office View & Prove service)

	BRP Card (up to 18 months after expiry date)
	PASS Accredited ID Card
	Photo endorsement with proof of ID
ID 2 – Photographic or Proof of UK Address	Passport (current)
	Driving License (current)
	HM Armed Forces Identity Card (UK)
	eVisa (accessed online via Home Office View & Prove service)
	BRP Card (up to 18 months after expiry date)
	PASS Accredited ID Card
	Photo endorsement with proof of ID
	Utility Bill (excluding a mobile phone bill) (dated within last 6 months)
	Financial Statement (dated within last 6 months)
	Benefit Statement from DWP
	Confirmation from Electoral Register
	HMRC Tax Notification (but not a P45 or P60)
	Local Authority Tax Bill (Council Tax etc) (dated within last 6 months)
	Local Council Rent Card/Tenancy Agreement
	Mortgage Statement from a recognised Lender
ID 3 – Proof of UK Address	Utility Bill (excluding a mobile phone bill) (dated within last 6 months)
	Financial Statement (dated within last 6 months)
	Benefit Statement from DWP
	Confirmation from Electoral Register
	HMRC Tax Notification (but not a P45 or P60)
	Local Authority Tax Bill (Council Tax etc) (dated within last 6 months)
	Local Council Rent Card/Tenancy Agreement
	Mortgage Statement from a recognised Lender

c. Once the external monitor has completed this process their ID will be kept on file so this process will not be necessary for the next monitoring visit. (Helpdesk will be able to check their records to see if the ID presented has previously been accepted). ID will be valid for a maximum of 2 years.

d. R&D has 3 Monitors Smartcards available for monitors to use.

e. The Monitors smartcard must be booked in advance by accessing the spreadsheet located: S:\shared\R&D\Meeting Rooms and Clinic Bookings\Meeting Room & Clinic Bookings\Lorenzo Monitoring Card Booking Spreadsheet.xlsx

f. The study team will provide training for the monitor.

g. The completed FRM067 will be uploaded to the monitoring section of the e-site file and a copy sent to papworth.randdqa@nhs.net along with a list of the participants the monitor has viewed.

h. Royal Papworth staff must never share their own Smartcard or password.

i. Access to Lorenzo using the external monitor's Smartcard will be subject to an audit.

j. If Non-Royal Papworth sponsored studies are using the Royal Papworth eTMF site file structure a **COPY** of the files will be uploaded to N:\Shared\RESTRICTED MONITORING to prevent access to other files, this must be arranged with the QA Manager in advance if access to the restricted monitoring folder is required. The files must be deleted from the restricted monitoring folder after the monitoring visit is complete.

k. If monitoring from Quality Controlled print outs of electronic health records (EDMR) then these data become the source data and must be kept as source along with the monitoring documents. Print outs must be anonymised with the patient study ID, signed and dated by the person making the copies. This will be applicable to any of the systems required apart from Lorenzo (Monitors from outside the Trust using the Lorenzo cards **DO NOT** have access to any of the external links located on Lorenzo).

4.2 Remote Monitoring – for the provision of participant data PDF documents

Use the following directions for providing participant data for monitoring purposes or for SAE reporting where the data needed for an SAE report cannot be transcribed into the relevant SAE reporting documents and further information is required.

a. Monitors from outside the trust can be provided with "screen shots" of information from EPR/other participant database PROVIDED the following takes place:

    1. Screen shot the participant data to be used where **NO** participant identifiable information is visible.
    2. Copy and paste this information into a word document.
    3. Identify the word document with the participant's unique study Identification **ONLY.**

b. Using FRM076 Remote Monitoring Form complete the "Declaration Form for the provision of anonymised participant data for the purpose of remote monitoring" with:

    1. The details of the study (title, PO No., REC No.).
    2. Provide the name, job title and company of the person requesting this data.
    3. Explain the purpose of the data required.
    4. List the data sets being sent.

5. The person providing the requested data must complete their name, date and signature (or confirmation email) on the form.

c. Once the above has been completed, send the word document and FRM076 to another member of the department (independent of the study) to check the documents for participant identifiable data.

d. If any identifiable data are found the word document will be rejected and deleted/destroyed and the process of producing the anonymised participant data must begin again.

e. If no identifiable data are found the reviewing Study Co-ordinator/Research Nurse must complete their name, date and signature (or confirmation email) on the form.

f. If wet ink signatures cannot be obtained, the forms should be completed electronically. The form and all correspondence should be filed in the monitoring section of the site file along with the completed monitoring form/word document.

g. **Following completion of the forms the word documents MUST be converted to a PDF file and only then can it be sent for the purpose of monitoring.**

1. The PDF documents should be sent with the second section of the form - "Declaration Form for the receiving of Anonymised participant data for the purpose of remote monitoring".
2. Complete this form with the details of the study and the name and details of the person receiving the PDF documents.

4.3 Remote Monitoring – Live screen sharing of participant data

a. Clinical Trial Co-ordinators or Research Nurses can live screen share participant information from the EPR with Monitors from outside the Trust using Teams ONLY if the following takes place:

1. FRM067 must be completed by the Monitor. Please tick the box to state that you intend to complete the visit remotely via live screen sharing.

2. The Clinical Trial Co-ordinator or Research Nurse must complete their name on the FRM067 where indicated.

3. The Monitor must print their name, sign and date under the declaration that the participant data will not be recorded / copied in any way that will allow the data to be accessible to the Monitor after the session is concluded.

4. The Study Co-ordinator or Research Nurse must use one of the Monitor's Lorenzo cards and not their own Lorenzo card. (This will allow for the card to be fully audited after the visit).

5. Any other data required will be sent to the monitor via the redacted PDF document method as outlined in section 4.2.

b. During the visit:

1. The CTC/RN must only access the participant as agreed for the monitoring visit.

2. Under no circumstances should participant data be assessed which is not related to the study being monitored.

3. The Monitor must not record the monitoring visit.

4. The Monitor must not take photos during the monitoring visit.

5. The Monitor must not take screen shots during the monitoring visit.

c. The email template (TPL058 Monitor letter for sharing participant data) must be used to contact your monitor for the visit and a formal reply to this email must be received.

d. Please file all documents and correspondence for the visit in your site file.

e. All monitoring reports for Royal Papworth Sponsored and Non-sponsored studies must be submitted to papworth.randdqa@nhs.net to save for sponsor oversight review at the QA meeting.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken.

SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter.

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Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

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