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

Document Number: R&D SOP085

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
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Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Version Number	Modification:
1.0	**New SOP**

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 or Royal Papworth House.
- The document also provides guidance to Royal Papworth Hospital Research staff for hosting a remote monitoring visit.

1 Purpose and Contents

a. The document defines the Trust's and Research & Developments (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 standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of a clinical trial that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of the trial subjects are protected').

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 patient confidentiality.

2 Roles & Responsibilities

a. This policy applies to all personnel that conducting 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 The Purpose of Monitoring

The purpose of monitoring a study is defined in GCP as ensuring that:

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

2. The reported trial data are accurate, complete and verifiable from the source documents.

3. The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

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 monitors Lorenzo card. The form must be signed and dated by the visiting monitor and Principal Investigator for the study.
2. The New IT User External form found here: http://papsvrintra/papworthonline/hr/index.asp?id=2070

b. The completed New User External form and FRM067 will be submitted, along with the external monitor's identity documents to the Human Resources Department where the access card and log in details will be provided. R&D has 3 Lorenzo cards available for monitors; 2 at Royal Papworth hospital and 1 at Royal Papworth house. The two cards at the hospital will be available from the Workforce Systems helpdesk based in the Admin area on the ground floor. The card at the house is located in the workforce office next to the reception desk on the ground floor.

c. The Lorenzo card 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 The spreadsheet must be completed detailing if the card is required at either Royal Papworth Hospital or Royal Papworth House.

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

e. The completed FRM067 will be uploaded to the monitoring section of the e-site file and a copy sent to the Monitoring & Audit Co-ordinator along with a list of the participants the monitor was scheduled to look at.

f. Royal Papworth staff must never share their access card or password.

g. Access to Lorenzo using the external monitor's card will be subject to an audit.

h. 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 Monitoring & Audit Co-ordinator in advance if access to the restricted monitoring file is required. The files must be deleted from the restricted monitoring file after the monitoring visit is complete.

i. 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 patient data in word documents

Use the following directions for providing patient 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 Lorenzo/other patient database PROVIDED the following takes place:

1. Screen shot the patient data to be used where **NO** patient identifiable information is visible
2. Copy and paste this information into a word document

3. Identify the word document with the patient's unique study Identification **ONLY**

b. Using FRM076 Remote Monitoring Form complete the "Declaration Form for the provision of anonymised patient 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 patient 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 patient 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 can be sent for the purpose of monitoring.**

1. The word documents should be sent with the second section of the form - "Declaration Form for the receiving of Anonymised patient 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 word documents.

4.3 Remote Monitoring – Live screen sharing of patient data

a. Clinical Trial Co-ordinators or Research Nurses can live screen share patient information from Lorenzo 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 patient 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 word document method as outlined in section 4.2.

b. During the visit:

1. The CTC/RN must only access the patients as agreed for the monitoring visit.
2. Under no circumstances should patient 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 following email template must be used to contact your monitor for the visit and a formal reply to this email must be received

Dear *Monitor*,

While the Trust remains unable to allow you on site to complete monitoring visits in person, we have been granted permission to complete monitoring visits by live sharing of our electronic patient notes.

The study co-ordinator will be using a Lorenzo card normally supplied for monitors to gain access to our medical notes, and will be using this card on your behalf so the card can be fully audited after the visit.

Please complete the form "Monitor's systems access and code of conduct" above so we have a record of when the remote monitoring visit took place.

Your formal reply to this email will be a record that you agreeing to the following:

a. Under no circumstances should you request patient data be accessed which is not related to the study subjects being monitored
b. The monitor must NOT record the monitoring visit
c. The monitor must NOT take photos during the monitoring visit
d. The monitor must NOT take screen shots during the monitoring visit

If further source documentation is requested after your remote visit this will be sent to you via an email in a word document with all patient identifiable information redacted.

If it is found that any recording/screen shots/photography of patient identifiable data has taken place this will constitute a data breach and your company may be liable for prosecution.

Yours sincerely,

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 either the Monitoring & Audit Co-ordinator or to R&D at randdadmin@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 (2018)
Key related documents:	Trust Research Policy Trust Policy DN1 Document Control Procedures

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

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

Review date:	June 2024

I certify the contents of this SOP has been reviewed and ratified

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Signed by Dr Ian Smith, Clinical Director of R&D

19th June 2021

Date

SOP Release Date: 25th June 2021