Research and Development

Royal Devon University Healthcare NHS Foundation Trust

WORK INSTRUCTION

WI19 – Monitoring
Version 3

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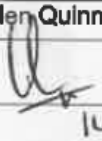
Signature	
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Controlled document

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It is the responsibility of all users of this Work Instruction to ensure that the correct version is being used. If you are reading this in a paper format please go on-line to confirm you have the latest version.

DISCLAIMER

This generic R&D Work Instruction (WI) must be followed unless a study specific SOP/WI exists.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author**	**Reason**
1.0			Previously archived and combined with S19.
2	21 September 2022	Lizzy Gordon, Lead Nurse Clinical Trials	Reinstated to add detail on remote monitoring and use of EPIC for monitors.
3	13 December 2023	Lizzy Gordon, Lead Nurse Clinical Trials	Updates to Royal Devon referencing and website links. Combined Northern and Eastern process.

Associated Trust Policies/ Procedural documents:	S19 Monitoring Monitor plan Risk Assessment
Key Words:	R&D Monitor Clinical Trial WI EPIC

In consultation with:

- Research & Development – Quality Assurance Group (QA)
- Research & Development Governance and Oversight Group (GOG)

Contents

1 INTRODUCTION

The conduct of Research is a co-operative undertaking between the Sponsor and Chief Investigator (CI). Each is responsible for ensuring that the conduct of the research conforms to the Protocol and adheres to the applicable laws and regulations as driven by the Department of Health's UK Policy Framework for Health and Social Care Research and the Medicines for Human Use (Clinical Trials) Regulations. The Royal Devon University Healthcare NHS Foundation Trust (hereafter termed as 'the Trust') has a responsibility for oversight of research conducted on its premises or which it sponsors. Consequently, the Research & Development Department (R&D) undertakes to monitor research conducted when the Trust is acting as a research sponsor and to facilitate the monitoring of hosted research studies undertaken by external study monitors.

2. PURPOSE

This Work Instruction is designed to accompany the R&D Standard Operating Procedure on Monitoring (S19) and provide additional detail on remote monitoring options and guidance on the use of the Trust IT systems for monitors.

3. SCOPE

This WI is applicable to all research (both Clinical Trial of an Investigational Medicinal Product (CTIMP) and non-CTIMPs) sponsored or hosted by the Trust or, when the commitment to monitor has been delegated to the Trust by a non-commercial Sponsor.

4. DEFINITIONS & ABBREVIATIONS

CI	Chief Investigator
CIMD	Clinical Investigation of a Medical Device
CRDT	R&D Clinical Research Delivery Team
CRO	Clinical Research Organisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
GOG	R&D Governance Oversight Group
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
PS	R&D Professional Services Team
R&D	Research & Development
REC	Research Ethics Committee
Royal Devon	Royal Devon University Healthcare NHS Foundation Trust
SOP	Standard Operating Procedure
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate

5. DUTIES AND RESPONSIBILITIES OF STAFF

The **Chief Investigator** (CI)/ **Principal Investigator** (PI) or their delegated Research Team Members have responsibility for conducting the Research according to the approved Protocol, complying with procedures necessary to secure the quality of every aspect of the trial, ensuring that all documentation is in an appropriate and secure location and enabling monitoring activities to be undertaken at the study site. They must ensure that all findings and any Corrective Action Preventative Action (CAPA) plans are addressed.

The **R&D Clinical Research Delivery team (CRDT)** will facilitate any requests to monitor which are made in accordance with the Protocol or monitoring plan, complying with the any relevant Trust Guidance or Policy, this Work Instruction and the associated SOP.

For Trust Sponsored studies, the **R&D Professional Services Team (PS)** will, as part of the Sponsorship process for Research, conduct a risk assessment, the outcome of which will determine the type (e.g. on-site, central monitoring, management groups, recruitment etc) and amount (e.g. number of visits, what is being checked) of oversight required for a particular study. The risk assessment will be revisited, if necessary, prior to approval and/or during the study. A scheduled monitoring plan may then be developed to reflect this. Monitoring will be delegated to appropriately trained members of the R&D Office or, if applicable, to other suitable external parties e.g. a Clinical Trials Unit (CTU) or independent monitor.

The Study Monitor is responsible for conducting the monitoring visit in accordance with the Monitoring Plan, any relevant Trust Guidance or Policy, S19 and this WI (unless otherwise agreed and delegated) and regulatory requirements. Only Monitors with adequate training and experience may conduct monitoring activities.

The **Sponsor** retains overall responsibility and must have oversight of the monitoring process. This includes reviewing monitoring reports/monitoring letters and advising of appropriate CAPA to be taken where necessary. The Sponsor will be responsible for the delegation of monitoring to other parties when applicable. This will be documented in writing.

6. PROCEDURES

Those members of staff responsible for arranging monitoring visits and overseeing monitors on the day of their visit must familiarise themselves with the R&D Monitoring SOP S19.

On-site monitoring is only to be authorised where deemed essential. Sponsor requests for monitoring must be made through the PI or Research Team Lead who will consider the rationale for the request. All requests must be in line with approvals as documented in the Study Protocol and patient information. Record on 'Request for on-site Monitoring table' – Appendix 1 which should be filed in the site file.

Where possible a single room should be booked for the monitor to use, for the purposes of privacy and confidentiality this must not be shared office space.

Northern services have a designated spare room (Chichester House, Suite 4, Room 2) that can be used for monitoring visits. Liaise with the Rosemoor admins via rduh.research-northern@nhs.net regarding availability.

Once agreed, enter the visit on Outlook 'Monitoring' Calendar detailing the location.

ID badges must be requested from all external monitors on arrival and must be worn by the monitor throughout the visit. Only those employed by the Sponsor or CRO for the purpose of monitoring to be permitted on site.

All visitors to the Eastern site must be issued with a visitor badge/sticker by the relevant member of the CRDT when the monitor signs in. See Appendix 2 for a template sign in sheet.

At the Northern services site all monitors must be taken to Facilities to sign in and receive a visitor's badge.

All visitors must sign out on departure.

All time spent with a monitor during their visit by any member of staff must be recorded on EDGE). See Tip Sheet 3 for details.

6.1 Arranging Guest Accounts on the Trust Network for Monitors–see Tip Sheet 1

6.2 Creating Batch Releases for Monitors on EPIC – see Tip Sheet 2a

6.3 Creating PDF Batch Releases for Monitors – see Tip Sheet 2b

6.4 Updating an existing Batch Release – see Tip Sheet 2c

6.5 On the day of Monitoring – see Tip Sheet 3

6.6 Reactivating Guest Accounts – see Tip Sheet 4

7. DISSEMINATION AND TRAINING

7.1 This WI and associated templates and forms will be uploaded to the Royal Devon website shortly after having been released.

7.2 All staff whose activities are subject to this WI must ensure that they take time to read and understand the content of this WI.

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS WI

8.1 In order to monitor compliance with this WI, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	On-site monitoring is only to be authorised where deemed essential and in line with approvals as documented in the Study Protocol and patient information	Review completed 'Request for on-site Monitoring table' and Protocol in ISF.
2.	All time spent with a monitor during their visit by any member of staff must be recorded on EDGE	Visits recorded on EDGE using assigned template.

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the Royal Devon website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

Royal Devon University Healthcare NHS Foundation Trust

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APPENDIX 1 – On-site Monitoring Request Form

	Request for on-site Monitoring	Tick if aware of request
Name of Study		
R&D Number		
Principal Investigator		
Team Lead		
Justification for onsite Monitoring Visit		
Preferable date(s)		
No. of monitoring staff		

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APPENDIX 2 - Visitor Sign in Sheet

Visitor Sign in Sheet

For use for all external visitors (excluding patients and participants)

Date	Name	Purpose of Visit/Who Visiting	Time In	Sign In Signature	Time Out	Sign Out Signature