University Hospitals Plymouth NHS Trust

Work Instruction

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Title:	On-Site Monitoring Visits during COVID-19		
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Signature:		Effective Date:	May-2022
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1. Purpose

To describe the procedure and staff responsibilities required to accommodate an on-site Monitoring Visit (MV) organised within University Hospitals Plymouth (UHP) during COVID-19 pandemic.

2. Scope

This Work Instruction (WI) applies to all staff and monitors that organise and participate in internal and external MVs for UHP hosted studies.

3. Responsibilities

Sponsor

- Provide Personal Protective Equipment (PPE) and relevant testing kits for the monitor in line with national and local guidelines.

Monitor

- Act as the main line of communication between the sponsor and the investigator/ site.
- Comply with the national and local guidance in regard to PPE and other measures (including testing requirements and travel restrictions) designed to stop the spread of COVID-19 (SARS-CoV-2).
- Notify the Principal Investigator (PI) and relevant research nurse and administration team for the requirement of an on-site MV. A minimum of 4 weeks' notice is required, where possible to ensure availability of participant's medical records and the availability of the PI or other site staff.

Principal Investigator

- Facilitate monitoring access for the study.
- Ensure that all essential documents/ source data/ participant information is available for inspection at MVs.
- Receive monitoring reports.
- Act on any issues identified in the monitoring reports, as appropriate.
- Respond to monitor requests for completion/ correction of data.

Trust (Host)

- Respond to essential monitoring requests.
- Co-ordinate trial management to facilitate central, remote and/ or site monitoring.
- Facilitate MVs and allow access to study related documentation.
- Act on any issues identified in the monitoring reports, as appropriate.

4. Documents needed for this WI

- None.

6. Equipment and skills

- R&D monitoring calendar (where visits are booked by R&D Office).

7. Related documents

- Standard Operating Procedure (SOP) QA2 Monitoring.
- WI2 Remote Monitoring Visits.

8. Definitions

CRF: Case Report Forms are data collection tools provided by the sponsor on which clinical data is recorded for each participant. This can be paper or electronic (eCRF).

Hosted Research: Studies conducted at UHP, sponsored by an outside organisation.

ISF: Investigator Site File is a file used by the site to organise and collate all essential documentation required to conduct the study.

Monitor: Individual appointed by the Sponsor to perform site visits to check the trial is conducted, recorded and reported in accordance with the protocol, SOPs, Good Clinical Practice (GCP) Guidelines and the applicable regulatory requirements. The purpose is to protect the rights and well-being of trial participants.

MV: Monitoring Visit, the monitor will evaluate the way the study is being conducted and perform source document verification.

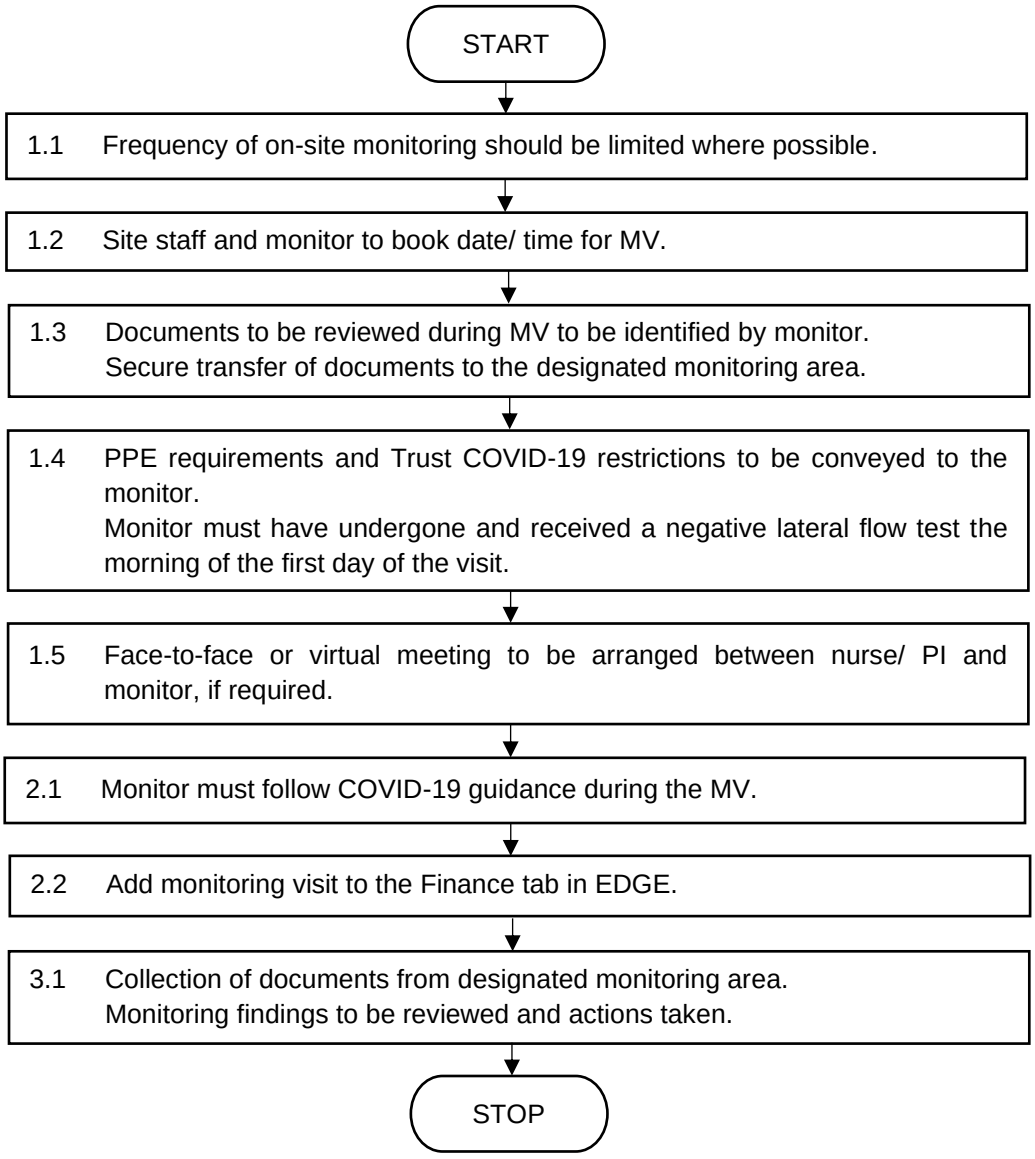
SDV: Source Data Verification involves checking the original data record against what is transferred onto the CRF/ database.

Source Documents: Defined in International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) GCP (1.51) as all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data should be accurate, legible, contemporaneous, original, attributable, complete and consistent. Source data may be both electronic and on paper. Examples of source documents where source data may be located include:

- paper-based medical records
- laboratory reports
- participant diaries
- nurses' notes

- dispensing logs
- test results such as (ECG) print-outs, x-ray images, radiological reports

7. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1.0	**Organising a Monitoring Visit**	
1.1	Frequency of on-site monitoring should be limited where possible due to the reduced monitoring availability. Site Selection Visits (SSVs), Site Initiation Visits (SIVs), any training, facility tours, and where appropriate Close Out Visits (COVs) should be completed remotely. Visits to the main hospital building by monitors/ CRAs are permitted for Pharmacy MVs.	Monitor, research team and administration team.
1.2	Contact made by monitor to the relevant team to organise an on-site MV. Oncology, Haematology and Pharmacy to organise own MV, for all other disease areas MV requests must be sent to the R&D administration team at plh-tr.rdmonitoring@nhs.net . Availability of desk space to be checked by the administration team and booking made on the monitoring calendar. The administration team must ensure the Research Nurse is aware of the visit. On-site monitoring visits are permitted at 'COVID Safe' locations. Confirmation of booking i.e. visit date, time and location to be sent to monitor. Details of the MV will be recorded on the monitoring calendar to ensure the appropriate number monitors are on site at any one time.	Monitor, administration team, and Pharmacy Clinical Trials.
1.3	A list of all source documents required to meet the aims of the MV must be identified by the monitor before the visit. This list must be supplied 7 working days in advance of the visit. Documents identified should be collated and made available for the MV by the administration team. Secure transfer of documents including medical notes (notes bag) on the day of the monitoring visit, if required.	Monitor, administration team and Pharmacy Clinical Trials.

Step	Action	Responsibility
	Documents may include: • ISF • Participants medical notes/ source data • Relevant nursing documents/ source data • Up to date CRF/ eCRF • Internet access is available Monitoring may be performed remotely *via* MS Teams or scanned copies/ photographs may be sent by email. Please refer to the remote monitoring WI. Any documentation/ images sent by email must not contain identifiable patient information.	
1.4	Inform monitor of PPE requirements and need to follow Trust policy on COVID-19 restrictions. Monitor must have received a negative lateral flow test on the morning of the first day of the visit. Monitor required to bring their own surgical mask and refreshments; however, there are various fast-food outlets close by. Monitor must not attend the MV if they have any symptoms of COVID-19, a cold or 'flu like' illness beforehand or received a positive lateral flow test result. The research team reserve the right to turn the monitor away on the day for any reason.	Administration/ reception team and monitor.
1.5	Monitor may have face-to-face contact with the research team or PI, but a virtual meeting is preferred.	Clinical research/ administration team.
2.0	**During the Monitoring Visit**	
2.1	Monitor's own surgical mask must be worn at all times during the MV. Regular hand hygiene throughout the visit following the PHE recommended guidance. When using lift/ stairs, follow all social distancing measures clearly labelled. Similarly make way at exits, entrances and frequently used doors. Food and drink may be consumed by the monitor at their allotted station but this is done so at their own risk. Monitor required to clean their allotted station after use where wipes are supplied. Toilet facilities are available to the monitor.	Monitor, and administration/ clinical research team.

Step	Action	Responsibility
2.2	Add monitoring visit to the Finance tab in EDGE.	Administration team.
3.0	**Post-Monitoring Visit**	
3.1	Study related documentation and medical notes must not be left in the monitoring room overnight. Collection required by 1700 at the latest. Review findings and complete any remedial actions.	Administration/ clinical team.

10. Changes from last revision

Minor changes including the removal of the requirement to complete a confidentiality agreement, per monitor per study.