Dorset HealthCare University NHS Foundation Trust

Standard Operating Procedure Monitor Visits (External)

Objectives	This SOP is to explain the purpose and procedure for Monitor visits.
Scope	Applicable to all research study staff.
Responsibility	It is the main responsibility of the Principal Investigator to ensure this SOP is adhered to.
Related Document	None.

1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to explain what will happen and what is expected, ahead of, during and after a site visit from a Clinical Research Associate or 'Monitor' who is coming to evaluate the progress and documentation of a clinical study at Dorset HealthCare University NHS Foundation Trust.

2 Introduction

For some studies performed to ICH Good Clinical Practice standards, it is a requirement that a monitor appointed by the study organising body visits the trial site to ensure that the trial "is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirements." The purpose of this is to ensure the rights and well-being of trial subjects are protected.

An important part of a monitoring visit is comparing the entries in the case report forms with the original source documents (e.g. laboratory results, hospital notes, ECG printouts). This procedure is known as Source Document Verification (SDV).

The ICH GCP Guidelines encourage direct access to original source documents by Monitors in order to perform SDV and state that written information provided to subjects should include explanation that the Monitor will be "granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations."

This SOP describes the preparation for and the procedure to follow during monitoring visits.

3 Training

New users must read and understand this SOP before carrying out this procedure. Existing users must read and understand the Revisions section

4 Revisions

This is the second version of this SOP.

5 Procedure

Depending on the requirements of the study organising body, the first visit usually takes place soon after the first patient is enrolled. Depending on the study requirements, visits may take place approximately monthly to 4 monthly. Depending on the length of the study and its progress, this interval may be prolonged or shortened. Non-commercial and academic studies tend not to be monitored as frequently as commercially sponsored trials.

All relevant documents should be gathered together before the planned visit.

5.1 Preparation

There should be sufficient notification of monitoring visits, at least 4 weeks in advance for routine visits, particularly if a meeting with the PI is required at the visit.

The CRA should send an official email or letter before the visit outlining outstanding items which require action. Ensure that where possible, all outstanding items have been actioned prior to the visit.

All Case Report Forms (CRFs) and the site study file should be up to date including any outstanding corrections from the last visit.

Where possible, all source documents should also be available including those from other departments, e.g. Radiology, which may be relevant to the study.

A suitable work area should be set aside for the use of the Clinical Research Associate (CRA) during the visit.

Prepare any details of numbers of patients screened and enrolled in the study and of any other outstanding business requiring discussion.

5.2 During the visit

The CRA will normally require time to go through the CRFs and source documents alone with a meeting with the appropriate site staff afterwards to discuss any problems or outstanding business. Appropriate staff should make themselves available for such discussion.

The CRA may also wish to examine facilities at the study site and check storage of the study medication and drug accountability. If so, the appropriate arrangements should be made in advance and the CRA should be accompanied by a member of the research staff on visits to other departments.

If the visit is because of a serious adverse event, or some other specific purpose, the CRA should inform relevant personnel of any special requirements beforehand.

5.3 After the visit

It is the responsibility of the research team to promptly return the source data to the relevant departments.

Missing data should be obtained and corrections made promptly.

The CRA should (in line with GCP requirements) supply a report of the monitoring visit in a timely manner which should be actioned accordingly and stored in the site file.

The study file should be updated with a log of all visits made by the CRA.

6 Appendices

There are no appendices to this SOP.

7 Responsibilities

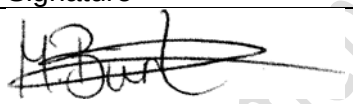
Monitoring visits are arranged by the monitor or CRA. The timing and frequency of monitoring visits are study specific and are clearly defined within each study protocol. The time of these visits will be agreed by the monitor with the principal investigator and/or other research staff, such as co-investigators and research practitioners, as appropriate.

It is the responsibility of the PI and/or research staff as delegated by the PI to gather the required documentation in preparation for the monitoring visit.

8 Review

This SOP should be reviewed every two years unless new guidance or legislation dictates a review any sooner.

Date reviewed: 12/04/19 Date of next review: 12/04/21

Written By	Signature	Date
Hazel Burt		12/04/19
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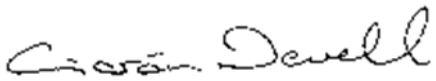
Dr Ciarán Newell		12/04/19
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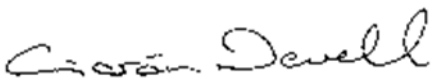
Dr Ciarán Newell		12/04/19