Dorset HealthCare University NHS Foundation Trust

Standard Operating Procedure for 'Pre-study' Monitor Visits

Objectives	To outline the procedure and purpose of a pre-study Monitor visit.
Scope	This SOP is for all staff members involved in study set-up.
Responsibility	It is the Principal Investigator's responsibility to ensure this SOP is adhered to.
Related Document	RES SM 004 Site Initiation Visits RES SM 005 Site Staff Responsibilities RES SM 006 Use of Investigator's Brochure RES SA 017 Study Files and Filing

1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to explain what's expected of a pre-study visit from a Sponsor, or Sponsor's representative (Monitor), ahead of setting up and opening a clinical study at Dorset HealthCare University NHS Foundation Trust. This SOP describes the procedure for site staff to follow for visits by the Monitor before official study start, i.e. before recruitment of the first patient. Included in this procedure are visits made by all representatives of the Sponsor to the study centre.

2 Introduction

There will be at least one Clinical Research Associate (CRA or 'Monitor') assigned by the Sponsor to monitor the study. Monitors are often biological science graduates, sometimes medical doctors, sometimes with nursing qualifications. The Monitor's activities may range from visiting study centres to designing the study and writing the protocol, to training staff at the department and subsequently writing the study report. In some cases, a specialist set-up team will deal with set-up and hand over to a CRA once the study starts.

From the Sponsor's side there are several aims of the pre-study visits. These include:

- To introduce the study to the Principal Investigator and their team.
- To ensure that the Principal Investigator and their team have enough time, interest and experience to perform the study to the standard required.
- To assess the facilities and meet all individuals that might have some involvement with the trial, including those in other departments.

It is also an opportunity for the Principal Investigator to assess both the Sponsor and the study.

In multi-centre studies there may be an Investigator's meeting planned at an external venue. A Principal Investigator (or delegated representative) from each centre must attend. The aim of the Investigator's meeting is to ensure a unified approach to the study protocol and documentation. Any outstanding or controversial points can be discussed.

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

Who is present will depend on the stage of the study. For the initial pre-study visit, only the Principal Investigator need be present, although the more members of the study team are present, the better. The Principal Investigator must be present for at least part of one pre-trial meeting.

There is normally, but not always, a study initiation meeting (or meetings) arranged to inform the entire study staff about the study and documentation – here, as many as possible of the staff who will be involved in the study must attend, i.e. the Principal Investigator, Sub-Investigators, the Study Site Co-ordinator (if there is one), pharmacist, radiologist and any nursing, laboratory, technical or administrative staff. These meetings may be in the form of a teleconference.

This must be carried out before enrolment of the first patient, but the exact schedule will vary.

- At pre-study meetings (usually the initial meeting) the main task is for the Principal Investigator and/or other staff to assess acceptability and feasibility of the study protocol.
- Other salient points include discussion and agreement about division of the responsibilities according to GCP. For example, submission to the Ethics Committee, insurance arrangements, publication agreements and financial agreements.
- The scope of the trial will also be discussed so that site staff can estimate the requirements of the study regarding staff, facilities, financing etc.
- Projected timelines for the start of the study must be discussed; communications from sponsor sites about projected study start dates must be established in order to maintain a good portfolio without conflicting studies.
- Written notes must be made for all meetings and kept in the Study File.
- In the course of the pre-study visits Sponsors require to be provided with the following documentation (this list is not exhaustive):
    - Curriculum vitae of the Principal Investigator and Sub-Investigators and evidence of GCP training.
    - Signed confirmation of protocol (signed protocol signature page) plus any amendments.
    - List of laboratory reference ranges and details of Quality Control/Quality Assurance Schemes.
    - Any necessary registration documents, e.g. to national or hospital authorities.
    - Financial agreement.
- The following documentation must be received from an external Sponsor before the start of the study:

- At least one copy of the Investigator's Brochure or equivalent in the case of a CTIMP (see SOP RES/020: Investigator's Brochure). In a Phase IV study the data sheet information may be provided instead.
- At least one copy of the study protocol.
- Examples of the patient information and consent forms.
- An example of the CRF.
- A contract detailing the terms and conditions for performing the trial, including the financial agreement.
- Documentation of the insurance or indemnity arrangements for the study of letter of indemnity must be discussed and agreed

• Recruitment rates must be discussed and agreed with the Monitor and a recruitment strategy decided upon.

• Emergency contact telephone numbers must be obtained from the Monitor, particularly in double blind trials, so that contact is possible 24 hours a day, where required.

6 Appendices

There are no appendices to this SOP.

7 Responsibilities

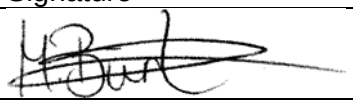
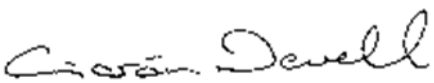
It is the responsibility of the study CRA/Monitor to visit the Principal Investigator and the study site before, during and at the end of a clinical trial.

The Monitor will be working to the Sponsor's SOPs and there may be more than one pre-study visit planned to each centre. Exactly how many visits will vary according to Sponsor and the study.

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
Reviewed By	Signature	Date
Dr Ciarán Newell		12/04/19
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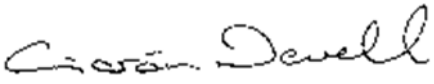
Dr Ciarán Newell		12/04/19