Dorset HealthCare University
NHS Foundation Trust

Standard Operating Procedure for Site Initiation Visits

Objectives	The aim of this SOP is to describe the purpose and procedure prior to, during and following Site Initiation Visits.
Scope	This procedure is applicable to all study personnel in Dorset HealthCare (DHC).
Responsibility	The initiation visit will be arranged by the study coordinator and the trial organisers/sponsor.
Related Document	RES SA 017 Study Files and Filing

1 Purpose

The purpose of this SOP is to document the process by which studies that have received approval are then initiated at the research site.

2 Introduction

An initiation visit will be performed for individual studies after the Ethics & HRA approval has been given and prior to the first patient being recruited into the study at that site. Initiation visits may be held for both commercial and non-commercial clinical trials. Prior to initiation visits, all health professionals involved in the study should familiarise themselves with the protocol and highlight protocol procedures that require clarification/discussion during the initiation visit.

During initiation visits the trial protocol, protocol procedures, important elements of running the trial, inclusion/exclusion criteria, case report form completion and sample collection should be discussed and queries clarified.

3 Training

New users must read and understand the contents of this SOP. Existing users must read and understand the revisions section.

4 Revisions

This is the second version of this SOP.

5 Procedure

An initiation visit will take place once full ethics & HRA approval has been granted and prior to the first patient being recruited into the study at that site.

5.1 Preparing for the Initiation Visit

- All approvals and regulatory documentation should be in place to open the study at site. This includes HRA approval and the capacity and capability agreement to run the study at site.

- Research teams should familiarise themselves with the trial protocol and make a record of any element of the protocol which is unclear and would need further clarification during the visit.
- All research team members working on the study, including the Principal Investigator and personnel from departments supporting the study should be informed that the initiation visit is scheduled and invited to attend.
- A room should be booked for the visit.
- The following documentation should be available:
    - CV of Principal Investigator, Sub-Investigators and all staff involved, including proof of ICH GCP training
    - List of laboratory reference ranges, signed and dated, and any accreditation certificates if applicable
    - Ethics committee letter of approval and composition of committee
    - Ethics approved Patient Information Sheet, Consent Form, and GP Letter – all on local headed paper
    - Current version of the trial protocol
    - Signed copy of the Indemnity Insurance

5.2 During the Initiation Visit

- The trial protocol, protocol procedures, inclusion/exclusion criteria, case report form completion and sample collection should be discussed and any queries clarified.
- Any documentation (e.g. Trust approval, delegation log, etc.) that is required by the pharmaceutical company/trial organisers/ sponsor that has not already been collected should be provided.

5.3 Following the Initiation Visit

- The pharmaceutical company/trial organisers/sponsor should submit a written report to the Principal Investigator summarising what has been discussed during the initiation visit.
- The written report should be filed in the Study Site File.
- A member of the research team should promptly address any outstanding actions that arose from the initiation visit.

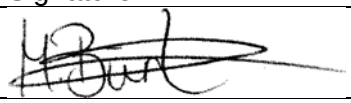
6 Appendices

There are no appendices to this SOP.

7 Review

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

Date reviewed: 12/04/2019 Date of next review: 12/04/2021

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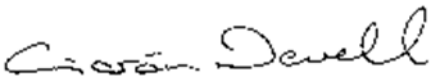
Dr Ciarán Newell		12/04/19
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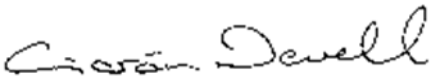
Dr Ciarán Newell		12/04/19