Dorset HealthCare University NHS Foundation Trust

Standard Operating Procedure for Study Files and Filing

Objectives	The objective of this SOP is to ensure the set-up and maintenance of Investigator Site Files.
Scope	Applies to all research study staff.
Responsibility	The Principal Investigator has overall responsibility to ensure the set-up and maintenance of Investigator Site Files.
Related Document	None.

1 Purpose

The Purpose of this Standard Operating Procedure (SOP) is to detail the expected contents of the Investigator Site Files for research projects being set up at Dorset HealthCare University NHS Foundation Trust.

2 Introduction

With the large volume of documentation required for each trial a standard filing system is necessary. Each study should have an Investigator Site File and a designated member of staff responsible for maintenance and updating the file. Study organising bodies should provide the site file for specific studies.

ICH Good Clinical Practice guidelines define the study documents to be filed as “those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced.” As well as demonstrating compliance with ICH Good Clinical Practice, filing study documents in an orderly, timely manner also greatly assists in the smooth running of the study and any future audit or inspection.

This SOP describes the procedure for the filing of the study documentation.

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

5.1 An Investigator Site File (ISF) should be prepared as soon as possible after the first contact by the study organising body or, for trials where there is no external study organising body, as soon as an outline protocol is available. The file should be actively maintained and updated from this time until the trial is formally closed.

5.2 One copy of any superseded document should remain in the Site File, with a line through it. The date the document was superseded and the latest version of the document should be stated on the document. For example, Protocol superseded on 24/07/2009 by Protocol version 2 dated 20/07/2009. Where possible the superseded document should be placed in a plastic wallet until archiving.

5.3 When it becomes available, the final report should be filed in the Site File.

5.4 Specific space will be allocated for the filing of prospective studies, where protocols, investigator brochures and early correspondence can be stored when they are first produced or received by the department.

5.5 Should the investigator or the department decide not to participate in the study, the protocol and investigator's brochure should be destroyed or returned to the external study organising body (if applicable).

5.6 Each trial will have an individual Site File which will contain (but not necessarily in this order):

- Version log
- Protocol
- Amendments
- Clinical Investigator Brochure
- MHRA approvals/documentation (if applicable to the study)
- MREC documentation and correspondence
- Local R&D documentation, correspondence, HRA approval letter, and ongoing HRA approval letters for amendments, and letter confirming capacity and capability
- DDX / CTX (Doctors & Dentists Exemption Certificate, or Clinical Trials Exemption Certificate, as applicable)
- Regulatory documents, such as:
  - (i) Subject Identification List (list of all patients enrolled into the study)
  - (ii) Subject Screening Log (the list should also include those actively considered for the trial but not entered, with reasons for non-entry where appropriate
  - (iii) Decode envelopes (for blinded trials) or a note of their location. IVRS envelopes (containing access codes) should not be stored with the site file. Each researcher should keep their decoded documents in a separate, secure location (no-one else should have access to the code). Many trials however, come with specific sections in the site file for the storage of such material. In this case a password protected spreadsheet must be kept of individual codes and the paper copy destroyed
  - (iv) Financial agreement
  - (v) Signed Clinical Trial Agreements
  - (vi) Site Personnel Log (including specimen signatures, CVs, GCP certificates, delegation of responsibilities)
  - (vii) Laboratory documentation (e.g. reference ranges, accreditation certificates)
  - (viii) Insurance and Indemnity
- Approved Patient Information Sheet, Informed Consent Form and GP letter.

- Correspondence (including records of telephone and electronic correspondence and meeting notes).
- SAEs (completed serious adverse event forms if not included in the CRFs).
- Blank Case Report Form or data collection form.
- Completed, signed, original informed consent forms (a copy of each patient's signed informed consent form should also be filed in the patient's medical record).
- Completed CRFs (usually stored in a separate file).
- Drug accountability (This section may filed as a separate file in Pharmacy).
- Reports.

5.7 A study file may consist of more than one volume and should be labelled File 1, File 2, etc.

5.8 If any documents are filed separately then a File Note should be made in the study file detailing where the document is stored. (File Notes may be printed on hospital headed paper, with the full protocol title, name of PI and the title of the documents e.g. CRFs. The exact location of the documents is then typed in. The location could be just next to the Site File, on another shelf, or in a different department. (For example the Drug Accountability Log is stored in the Pharmacy Department. The File Note is then signed and dated).

5.9 Filing source documents:

5.9.1 Source documents are the original documents, data and records e.g. the patient's medical record, laboratory reports, subject diaries, X-ray films, etc.

5.9.2 Medical test results may be held on secure electronic databases – these records will not routinely be printed out since they are secure, retrievable and any changes will be documented (audit-trailed) i.e., the fulfil the criteria for source documents as required by ICH GCP.

5.9.3 Source documents must be traceable. If documents are routinely stored separately from the patient notes and they belong to the source data, a note should be made in the study file as to where the other documents are stored.

6 Appendices

There are no appendices to this SOP.

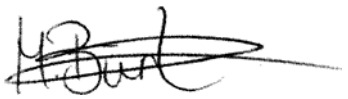
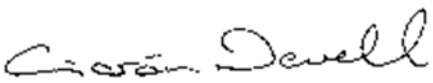
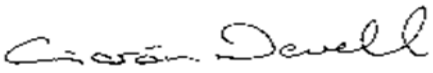
7 Responsibilities

The Principal Investigator has overall responsibility for the site study documentation. The Research Nurse or Data Administrator who has been delegated the responsibility for organisation of the study, together with the person assigned to setting up and monitoring the study file, must ensure that the necessary files are established and properly maintained.

8 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
Reviewed By	Signature	Date
Dr Ciarán Newell		12/04/19
Authorised By	Signature	Date
Dr Ciarán Newell		12/04/19