

Standard Operating Procedure

Title: STUDY FILES AND FILING		
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1. BACKGROUND

With the large volume of documentation required for each study a standard filing system is necessary. Each study should have a study file, and a designated member of staff responsible for maintenance and updating the file. Some sponsor companies may provide the Study File (also known as Investigator Site File or Trial Master 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.

2. PURPOSE

To describe the procedure for the filing of the study documentation.

3. OTHER RELATED PROCEDURES

SOP 002 Definition of Responsibilities
 SOP 005 Data Protection
 SOP 013 Archiving

4. WHEN

A Study File should be prepared as soon as possible after the first contact by the sponsor, or for studies where there is no external sponsor, as soon as an outline protocol is available. The file should be actively maintained and updated from this

STUDY FILES AND FILING	
REF: SOP 006	VERSION: 03

time until the study is formally closed. When it becomes available, the final report should be filed in the Study File.

5. WHO

The researcher who has been delegated the responsibility for the general 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.

6. HOW

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.

Should the investigator or the department decide not to participate in the study, the protocol and Investigator's Brochure should be returned to the external Sponsor (if applicable).

Each study will have an individual, specific Study File.

The Study File should be labelled with the protocol number but not the title of the study. The telephone number of the Sponsor and a contact name should also appear on the label, or on the cover of the folder.

The Study File, where applicable, will be divided into ten sections, as described below:

- Protocol
- Amendments
- Clinical Investigator Brochure (clinical trials only)
- The appropriate Research Ethics Committee documentation and correspondence e.g. approval letter(s) and interim reports.
- Trust approval
- Clinical Trial Authorisation, MHRA Correspondence and EudraCT Number
- Regulatory (may be sub-divided to contain the following documents:
 - Subject Identification List (list of all participants enrolled into the study)
 - Subject Screening Log (the list should also include those actively considered for the study but not entered, with reasons for non-entry where appropriate)
 - Decode envelopes (for blinded trials) may be stored in the Study File, but may be stored separately, e.g. at Pharmacy. The location of the decode envelopes should be noted in this section.
 - Financial agreement (if applicable)
 - Clinical Trial Agreement (if applicable)
 - Site Personnel Log (including specimen signatures, CVs, delegation/allocation of responsibilities)
 - Laboratory documentation (e.g. reference ranges, accreditation certificates)
 - Insurance and Indemnity (if applicable)

STUDY FILES AND FILING	
REF: SOP 006	VERSION: 03

- Patient Information Sheet /GP (to contain master copy of the approved Patient Information Sheet, Informed Consent Form and GP letter)
- Correspondence (including records of telephone and electronic correspondence and meeting notes)
- Serious Adverse Events (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 (often stored in a separate file)
- Drug accountability (shipping records, drug accountability logs etc. This section may be filed as a separate file in Pharmacy)
- Reports

A Study File may consist of more than one volume, and so should be labelled File 1, File 2 etc.

If any documents are filed separately from the Study File, then a note should be made in the Study File detailing where the documents are stored.

6.1. Filing source documents

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

Study data that is to be supported by source documents must be defined.

Source documents must be traceable. If documents are routinely stored separately from the patient notes, e.g. radiographs, and they belong to the source data, then a note should be made in the Study File or in the other source data, as to where the other documents are stored. If there are several such documents, it may be necessary to complete a table for each, documenting where they can be found.