STANDARD OPERATING PROCEDURE (SOP)

SOP Number: NCP/R&D_009

SOP Title: Study Files and Filing

Role	Name	Signature	Date
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Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	10-Aug-15	Initial Version – Version Number -1	
2	27 – May-16	Version reviewed – Version Number - 2	

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the procedure for the filing of study documentation.

1.2. With the large volume of documentation required for each trial, a standard filing system is necessary. Documentation for each study should be kept in a specific study file with a dedicated member of staff responsible for maintenance and updating the file. Some sponsors may provide the study file (also known as Investigator Site File or Trial/Site Master File) for specific studies.

1.3. 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 provided".

1.4 Whilst demonstrating compliance with ICH-GCP, the filing of study documents in an orderly, timely manner also greatly assists the smooth running of the study and any future audit or inspection.

2. DEFINITIONS

RN – Research Nurse

RF – Research Facilitator

ISF – Investigator Site File

IB – Investigator Brochure

ICH-GCP – International Conference on Harmonization - Good Clinical Practice

Non-CTIMP/CTIMP – Non/Clinical Trial Investigational Medicinal Product

3. PROCEDURE and RESPONSIBILITIES

3.1 The Research Nurse/ Research Facilitator (RN/RF) and/or other designee(s) as documented on the Site Responsibility Log must ensure that the study file(s) are established and properly maintained.

3.2 A study file should be prepared as soon as possible after the first contact by the sponsor or for trials where there is no external sponsor, 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. When it becomes available, the final report should be filed in the study file.

3.3 Specific space should be allocated for the filing of prospective studies, where protocols, Investigator Brochures (IB) and early correspondence can be stored when they are first produced or received by the department. The filing system should be segmented so that individual trial documentation remains separate, to avoid misfiling/ loss of documents and correspondence.

3.4 Should the Principal 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).

3.5 If the study is to be processed, a study file will be established and all accumulated material should be transferred to the study specific file.

3.6 The Study File should be labelled with the protocol number, UKCRN Study ID No., MREC No., SSA No., R&D No., and other information as determined by the study sponsor. The telephone number of the sponsor and a contact name should appear on the inside cover of the folder.

3.7 The Study file should be divided into sections as set out in NCF-R&D_014 – Investigator Site File (ISF) Template – non-CTIMP or NCF-R&D_015 – Investigator Site File (ISF) Template – CTIMP. A study file may consist of more than one volume and so should be labelled File1, File 2, etc. If any documents are filed separately from the ISF, then a note should be made in the ISF detailing where the document is stored.

N.B. For some studies, they may provide their own Investigator Site File index and this should be used on a study specific basis.

3.8 It is the responsibility of the identified RN/RF and/or designee to ensure that all essential documents have been collated prior to study initiation and that the study file is maintained throughout the study. The documentation required may differ between industry supported research and academic research, with the level of documentation required for each study being determined by the sponsor. This SOP refers to the current minimum standard of documentation as outlined in ICH GCP; Section 8.2, 8.3 and 8.4 (see NCF-R&D_021 – Study File Essential Document Listing).

3.9 All correspondence (including written and electronic documents and correspondence and records of all telephone contacts and minutes/ notes of study meetings) should be retained. However, only critical documents/correspondence should be stored in the Investigator Site File as a hard copy. Source documents and trial related data from clinical trials with investigational medicinal products (CTIMP) or medical devices must be stored for a minimum of 15 years. Please refer to NCP-R&D_004 – Study Closure and CP-R&D_011 – Archiving for more information.

3.10 The ISF should be retained in a secure place, with restricted access in accordance with the requirements of the Data Protection Act and this SOP. Restricted access may vary according to location, but should always be inaccessible to non-Trust staff, patients, etc., and ideally only to be accessible to those working on the study and listed on the delegation of duties log, i.e. locked away in a filing cabinet.

3.11 It is the responsibility of the investigator to maintain a list of appropriately qualified persons to whom the Principal Investigator has delegated significant trial related duties (ICH GCP; Section

4.1.5). This should indicate the nature of duty being delegated, person delegated to (with signature), and date of start and finish of delegated duty. The list should include Sub-Investigators, Research Nurses/Research Facilitators etc. This should be updated as and when there are any changes in personnel, or delegation of duties. Each change is to be signed by the Principal Investigator. The delegation log is attached to form NCF-R&D_014 – Investigator Site File (ISF) Template – non-CTIMP or NCF-R&D_015 – Investigator Site File (ISF) Template – CTIMP. Further information on delegation of study responsibilities can be found in NCP_R&D-010 – Delegation of Study Responsibilities.

3.12 Source documents are the original documents related to the trial, to medical treatment and the history of the subject, e.g. the patient's medical record, laboratory reports, subject diaries, x-ray films, etc. Source documents must be traceable. If documents are routinely stored separately from the patient notes, 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 (Location of Source Data form).

4. SUPPORTING MATERIAL and ATTACHMENTS

The following documents can be used in conjunction with this SOP:

SOPs

NCP-R&D_004 – Study Closure
CP-R&D_011 – Archiving
NCP-R&D_010 – Delegation of Study Responsibilities

Forms

NCF-R&D_021 – Study File Essential Document Listing
NCF-R&D_014 – Investigator Site File (ISF) Template – non-CTIMP
NCF-R&D_015 – Investigator Site File (ISF) Template – CTIMP

5. TRAINING

5.1 All R&D staff are required to read and understand the content within this SOP. Staff should sign to confirm that the SOP has been read and document this within the R&D SOP file. When a SOP is updated or each 2 years (as appropriate), staff will be notified and will need to re-read and sign against the SOPs within the R&D SOP file.

5.2 Individual members of staff should retain their own training records in their Professional Development Portfolio, which should be available for inspection. These should contain a record of all training events undertaken, with appropriate certificates or conference programmes. A central log of staff training should be retained within the centre.

6. REFERENCES

Department of Health Research Governance Framework for Health and Social Care

https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition

The Medicines for Human Use (Clinical Trials) Regulations 2004
http://www.legislation.gov.uk/uksi/2004/1031/contents/made

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
http://www.legislation.gov.uk/uksi/2006/1928/contents/made

Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006, Statutory Instrument 2006/2984
http://www.legislation.gov.uk/uksi/2006/2984/contents/made

Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008, Statutory Instrument 2008/941
http://www.legislation.gov.uk/uksi/2008/941/pdfs/uksi_20080941_en.pdf

Medicines for Human Use (Marketing Authorizations Etc.) Amendment Regulations 2008, Statutory Instrument 2008/3097

http://www.legislation.gov.uk/uksi/2008/3097/made

Medicines for Human Use (Advanced Therapy and Miscellaneous Amendments) Regulations 2010, Statutory Instrument 2010/1882
http://www.legislation.gov.uk/uksi/2010/1882/pdfs/uksi_20101882_en.pdf

NIHR Research Support Services Framework, May 2011

http://www.nihr.ac.uk/policy-and-standards/framework-for-research-support-services.htm

Government GCP Guidance

https://www.gov.uk/good-clinical-practice-for-clinical-trials