

Standard Operating Procedure

<b>Title: PRE-STUDY SITE FILE CHECK</b>		
<b>REF: SOP 014</b>	<b>Version: 04</b>	<b>Issue No: 1</b>
Template Source: Merseyside & Cheshire Cancer Research Network		Date: 18/02/05
Reviewed by: Professor Rod Owen		Date: 05/11/2009
Approved by: Dr M J Maxwell		Date: 21/05/07
Due for Revision		Date: 05/11/2012
This SOP is effective from:		Replaces: Version 03 (21/05/07)

## 1. BACKGROUND

Each study should have a study file in which to file the study specific documents collected before, during and after the active phase of the study. ICH Good Clinical Practice guidelines define the study documents to be filed during a clinical trial as *“those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced.”* Careful filing of such essential documents is a mandatory component of GCP, ensuring regulatory compliance prior to enrolling patients in a research study.

## 2. PURPOSE

To describe the procedure for the checking that essential pre-study documentation is complete and in the site file before patient recruitment activities commence.

## 3. OTHER RELATED PROCEDURES

SOP 002	Definition of Responsibilities
SOP 004	Submission to a Research Ethics Committee
SOP 005	Data Protection
SOP 006	Study Files & Filing
SOP 013	Archiving

## 4. WHEN

A Study File should be prepared as soon as it is known that the study will be progressed. All study related documentation should be filed in this file in a timely manner. This may include, but is not limited to, communication with the sponsor, the draft or final protocol, correspondence with hospital departments regarding the set-up of the study, ethics committee submissions etc. Section 8 of the ICH-GCP Guidelines comprises a list of ‘Essential Documents’ and should be consulted.

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All appropriate approvals (including Clinical Trial Authorisation from the MHRA, Main Research Ethics Committee, Site Specific Assessment from a Local Research Ethics Committee and the host NHS Trust) must have been received before any prospective subjects are approached for their potential consent to participate in the study.

## 5. WHO

The researcher who has been delegated the responsibility for the general organisation of the study must ensure that the necessary files are established and documents compiled.

## 6. HOW

Each trial will have an individual, specific study Site File. The Site 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 person conducting the pre-study check should use a Pre-Study Site File Checklist, and complete the form with the study title, and then indicate with a tick (✓) in the appropriate column whether the document is present or missing from the Site File. Some of the documents listed on the checklist may not be required for all studies, for example a study that does not involve an investigational medicinal product would not require a Clinical Trial Authorisation from the MHRA. In such cases, the tick should be placed in the column marked N/A (Not Applicable).

Documents that must be present in the study site file before the first potential subjects can be approached are:

- Investigator's Brochure / Summary of Product Characteristics<sup>1</sup> (as applicable)
- Signed current protocol and amendments
- At least one blank Case Report Form
- At least one blank study form e.g. randomisation form
- Subject information sheet and consent form
- Copy of advertisement for recruitment

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- Signed financial agreement or contract<sup>3</sup>
- Insurance statement (included in mCTA)
- Form of Indemnity (included in mCTA)
- REC approval letter
- Trust R&D approval letter (or completed Trust Approval Form)
- Authorisation from MHRA
- Curriculum vitae for:
  - Principal Investigator
  - Co-investigator(s)
  - Research Practitioner(s)
- Completed Delegation of Authority log<sup>3</sup>
- Completed Sample Signature log
- Normal value ranges for local laboratory
- Accreditation certificate for local laboratory
- Instructions for handling investigational product<sup>1</sup>
- Shipping records for investigational product<sup>1</sup>
- Drug accountability forms<sup>1</sup>
- Decoding procedures for blinded trials<sup>1</sup>
- Documentation that the site has been “activated” or initiated by the sponsor and is ready to recruit subjects

Note:

- 1 May (also) be stored in a separate Pharmacy study file
- 2 For commercial trials the mCTA (or CRO version of mCTA) is mandatory
- 3 Delegation of Authority log may also serve as a Sample Signature log

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The Research Practitioner and the checker should sign and date the checklist, and this should be filed at the front of the Site File.

If there are any ticks in the column labelled "MISSING" the study must not be started until the relevant documents have been collected. The Research Practitioner must make every effort to obtain the missing documents with the minimum delay. Once obtained and filed, an appropriate staff member should repeat the pre-study Site File check, and another checklist used and completed.

If there are no ticks in the "MISSING" column, and the checker has verified the not applicable status of any documents marked as such, the study is opened, and potential subjects may be approached.

## PRE-STUDY SITE FILE CHECK LIST

STUDY TITLE: \_\_\_\_\_  
 \_\_\_\_\_

DOCUMENT	PRESENT	MISSING	N/A
Investigator's Brochure or Summary of Product Characteristics			
Signed current protocol and amendments			
At least one blank Case Report Form			
At least one blank study form e.g. randomisation form			
Patient information sheet (as approved by REC)			
Patient informed consent form			
Copy of advertisement for recruitment			
Signed financial agreement or contract			
Signed study agreement between site and sponsor			
Insurance statement			
Form of Indemnity			
REC approval letter			
Trust approval letter (or TAF)			
Authorisation from MHRA			
Curriculum vitae for:			
Principal Investigator			
Co-investigator(s)			
Research Practitioner(s)			
Completed Delegation of Authority log			
Completed Sample Signature log			
Normal value ranges for local laboratory			
Accreditation certificate for local laboratory			
Instructions for handling investigational product			
Shipping records for investigational product			
Drug accountability forms			
Decoding procedures for blinded trials			
Documentation that the site has been "activated" or initiated by the sponsor and is ready to recruit subjects			

### STUDY SITE FILE CHECKED BY:

RESEARCH PRACTITIONER			CHECKER		
<b>Name</b>	<b>Signature</b>	<b>Date</b>	<b>Name</b>	<b>Signature</b>	<b>Date</b>