

**Salford Royal NHS Foundation Trust &  
Standard Operating Procedure:  
Study Files – Sponsor Files**

**SOP Number:** SOP 016

**Effective Date:** 30.10.07

**Version Number & Date:** Version1

**Review Date:** 30.10.08

**Superseded Version Number & Date (if applicable):**

**Author:** Dr Lloyd Gregory

**Approved by:** Martin Gibson

**Position:** R&D Lead

**Position:** R&D Director

**Signature:**

**Signature:**

**Date:** 30.10.07

**Date:** 30.10.07

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**Summary of Key Points**

1. This SOP is designed to outline the procedure for the establishment and maintenance of sponsor files where Salford Royal NHS Foundation Trust has taken on the role of sponsor as outlined in the Research Governance Framework for Health and Social Care 2005.
2. This SOP covers all non-commercial clinical trials of investigational medicinal products (CTIMPs) sponsored by Salford Royal NHS Foundation Trust.
3. Principal investigators for all other non-commercial research sponsored by Salford Royal NHS Foundation Trust should ensure that a copy of all regulatory approvals is provided to the Trust's R&D Lead. All other project specific documentation should be filed to facilitate audit or monitoring.
4. Sponsor files should be established as soon as an outline protocol is available.
5. Sponsor files should be actively maintained for the duration of the study.
6. Sponsor files should be located in a secure place with restricted access.

7. At the end of the study the sponsor file should be archived appropriately (see SOP R&Dxx– Retention of Research Data). Archiving of sponsor files should be separate from archiving of co-ordinating site and study site files.
8. Any or all of the documents in the sponsor files may be subject to, and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies).

## **1.0 Introduction**

Salford Royal NHS Foundation Trust hosts research under a number of scenarios whereby the Trust is able to undertake a variety of research management/administrative roles - sponsor, co-ordinating centre or participating site. Each of these roles carries varying levels of responsibility for the collation of essential documentation to evaluate the conduct of the research. Essential documentation is stored in study files relevant to the level of Trust involvement in the study – sponsor files, lead or co-ordinating site master files, participating site files. A flow diagram indicating the requirements for study file documentation for research hosted by the Trust is given in Appendix 2. SOPs relating to the establishment of lead or co-ordinating site master files (R&D008a) and participating site files (R&D008b) are also available.

This SOP has been produced in accordance with the requirements of Research Governance Framework 2005 and ICH GCP Guidelines. The SOP will outline the procedures regarding the establishment and maintenance of sponsor files for CTIMPs where Salford Royal NHS Foundation Trust has taken on the role of sponsor. Documents contained within the files enable both the conduct of a clinical trial and the quality of the data produced to be evaluated by the relevant regulatory authority (Medicines for Health Regulatory Authority - MHRA).

### **1.1 Purpose**

To describe the establishment of sponsor files for CTIMPs where Salford Royal NHS Foundation Trust is the sponsor.

### **1.2 Scope**

Non commercial clinical trials of investigational medicinal products (CTIMPs) sponsored by Salford Royal NHS Foundation Trust where the Trust is acting as sponsor. For all other Trust sponsored research an R&D file comprising evidence of relevant regulatory approval will be established.

### **1.3 Responsibilities**

The Research Governance Officer is responsible for the establishment and maintenance of sponsor files. The research practitioner responsible for the general organisation of the study e.g. research nurse, trial administrator or trial co-ordinator is responsible for the provision of documentation relevant to the sponsor file. The principal investigator retains overall responsibility for the content and provision of all study files and documentation.

It is the responsibility of the Research Governance Manager to ensure that the necessary research staff are trained and aware of their responsibility to adhere to the procedures outlined.

It is the responsibility of all research personnel to read and follow the procedures prior to any research study commencing within the Trust.

### **2.0 Procedure**

#### **2.1 Compiling and format**

Sponsor files should be prepared 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 available, and prior to archiving, the final report should be filed in the sponsor file.

Documentation should be ideally established in A4 lever arch files and divided into related sections. A suggested method for sectioning is outlined in Appendix 1. All relevant material should be transferred to the appropriate sections. Where there are a large number of external sites sections may be sub-divided for each study site.

The study file should be labelled with the following information – Study drug name, name of principal investigator and the Trust R&D identification number.

#### **2.2 Maintaining a sponsor file**

It is the responsibility of the Research Governance Manager or designee to ensure that all essential documents have been collated and that the sponsor file is maintained throughout the study.

If any documents are filed separately from the sponsor file then a note should be made in the sponsor file detailing where the document is stored.

If a sponsor file consists of more than one volume the volumes should be labelled numerically with the number of existing files also indicated e.g. File 1 of 2.

Each volume should include a contents page which should be updated regularly and in cases where the sponsor file consists of more than one volume the contents of all volumes should be listed in Volume 1.

Some of the documents contained in the file will be original documents. Therefore, the study file should be located in a secure place with restricted access. Restricted access may vary according to location but should always be inaccessible to patients and non-Trust staff and ideally only accessible to staff working on the study and listed on the delegation of duties log i.e. in a locked filing cabinet or access controlled area.

At the end of the study the sponsor file should be archived appropriately (see SOP R&Dxx – Retention of Research Data). Archiving of sponsor files should be separate from archiving of co-ordinating and study site files.

Any or all of the documents in the sponsor files may be subject to, and should be available for, audit by an independent auditor and inspection by the regulatory authority(ies).

### 3. Glossary

ICH Good Clinical Practice (ICH GCP)  
Standard Operating Procedure (SOP)

### 4. Appendices

Appendix A: Suggested lay out of filing system for study file

Compiled by Linda Dack August 2007

### Related Documents

1. Department of Health's Research Governance Framework  
([www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en](http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en))
2. ICH Harmonised Tripartite Guideline for GCP (E6)  
([www.emea.eu.int/pdfs/human/ich/013595en.pdf](http://www.emea.eu.int/pdfs/human/ich/013595en.pdf))
3. Salford Royal NHS Foundation Trust SOPs R&D – Retention of research data; R&D – Agreements with study site collaborators; R&D – Sponsor and Investigator; R&D – Study files – Lead or co-ordinating centre master files; R&D– Study files – participating site files

## Appendix 1 –

### Suggested Layout For Sponsor Files For CTIMP Where Salford Royal NHS Foundation Trust Is The Study Sponsor.

<b>Documentation</b>		<b>Notes</b>
Contents page		
Study Centre contact sheet (Salford Royal NHS Foundation Trust only)		This sheet contains the contact details of all study staff
<b>Section 1 - Study Protocol</b>		
Copy of final protocol		Must be signed and dated by the Principal Investigator
Protocol amendments		
Investigator brochure and updates		To document that relevant and current scientific information about the investigational product has been provided.
Financial agreement		This may be part of Trust Clinical Trial Agreement or individual study site agreement.
<b>Section 2 - Patient Information</b>		
<b>Master copies of:</b>		
Patient Information sheets		Include all approved versions, including superseded versions. Must be on Salford Royal NHS Foundation Trust headed paper
Consent forms		
Invitation letters		
Questionnaires		
Advertisements		
Copy of GP letter		
Any related correspondence		
<b>Section 3 - Ethics</b>		
Application for ethical approval		Include site specific assessments from participating sites
Letter of approval from REC		Include copies of approval letters from participating sites
Notification and approval of protocol amendments from REC		
REC composition and constitution		
Ethics reports - annual reports, safety reports, final report on study closure		Include any reports from participating sites
Any related correspondence		
<b>Section 4a - Regulatory Approval</b>		
Clinical Trials Authorisation application and approval		If a clinical trial which commenced prior to 1 May 2004 include a copy of your DDX application and authorisation letter together with a copy of the letter from the MHRA transferring the DDX to a CTA
GTAC application and approval		
Clinical Trials Agreement		
Evidence of insurance and indemnity		
Study site agreements		Include copies of agreements with all study sites
Sponsor letter		
Any other relevant agreements e.g. material transfer agreements, confidentiality agreements		
Any related correspondence		

<b>Section 4b - NHS Trust / University Approval</b>	
Trust R&D application and approval letter	Include approval letters from all participating sites
University R&D application and approval letter (where applicable)	
Evidence of peer review	
Any intellectual property reports	
<b>Section 5 - Pharmacovigilance</b>	
Master randomisation list	
Sample SAE reporting form	
Copy of reporting procedures	This may be included in the protocol
Completed SAE forms	If not included in the Case Report Form
Copies of all correspondence to sponsor, MHRA and ethics regarding SAEs	
<b>Section 6 - Patient Documents</b>	
Not relevant – information stored in study site files	
<b>Section 7 - Data Collection</b>	
Sample Case Report Form (CRF)	Include copies of all previously approved CRFs
Completion guidance for CRF	
Location of source data form	To enable the location of source documents
<b>Section 8a - Laboratory - clinical</b>	
Not relevant – information stored in study site files	
<b>Section 8b - Laboratory - pharmacodynamic (PD) and pharmacokinetic (PK)</b>	
Not relevant – information stored in study site files	
<b>Section 9 - Study site staff (Salford Royal NHS Foundation Trust staff only)</b>	
CV's	Signed and dated
Study delegation log	Details individual responsibilities in the management and conduct of a study. Is signed and dated by both the individual and the principal investigator
Copies of any honorary contracts	
<b>Section 10 – Pharmacy</b>	
De-coding procedures for blinded trials	This information should be filed and maintained in a "Pharmacy File" in the Pharmacy department during the trial. At the end of the study it may be archived with the study files.
Certificate of analysis / QP release of unlicensed products	
Stability data	
Instructions for storage, handling and sample of label	
Drug despatch forms	
Temperature logs	
Drug accountability records	
Records of drug destruction	
Pharmacy signature log	
Study specific procedure	
Any related correspondence	
<b>Section 11 - Monitoring and Audit</b>	
Site initiation report	Include reports and correspondence from all study sites.
Monitoring log	
Audit reports inc. data monitoring committee reports	
Any related correspondence	
<b>Section 12 – Other</b>	
Current ICH-GCP guidelines	
General correspondence	