South Eastern Health and Social Care Trust

Standard Operating Procedures (SOP) Research and Development Office

Title of SOP:	Maintaining a Site File
SOP Number:	25
Version Number:	2.0
Supercedes:	1.0
Effective date:	August 2013
Review date:	August 2015

Author:	Alison Murphy, Research Manager Endorsed by Paul Carlin
Approved by:	Dr David Hill
Signed:	
Date:	O1 August 2013

Version History:

Version No.	Date	Author	Reason of Change
1.0	Sept 2007	Katrina Hughes	N/A
2.0	Aug 2011	Alison Murphy	Updated to reflect new SOP layout

Table of Contents

1. INTRODUCTION

Under ICH Good Clinical Practice (GCP), Chief and Principal Investigators have a responsibility to maintain an accurate, up to date site file for each research project. The Trust considers it Good Clinical Practice for all research to comply with this standard.

2. OBJECTIVE

The objective of this SOP is to give Principal Investigator's guidance on the content of a research project site file. The Principal Investigator should also refer to the current guidance from the regulatory authorities, such as MHRA and RECs.

3. SCOPE

The Primary focus of the SOP is clinical trials of investigational medicinal products (CTIMPs) that fall under the remit of the Medicines for Human Use (Clinical Trials) Regulations 2004 (called "Clinical Trials Regulations"). However, it is also relevant for other clinical investigations that may have an impact on the safety and well-being of human participants.

It applies to Principal Investigator's within the Trust site, to ensure that a site file is maintained for each research study they are participating in. If the sponsor of a research study should have SOP's to cover a specific trial then these should be followed.

4. PROCEDURE

An investigator site file should contain the following documents.

4.1 Study Protocol

- A copy of the final approved protocol (version and date)
- A copy of the final approved participant information sheet (version and date)
- A copy of the final approved participant consent form (version and date)
- A copy of any approved amendments to protocol, information sheet or consent form (version and date)
- Adverts for recruitment *
- A copy of the study assessment tools (questionnaires, diaries etc) *
- Information for GPs or consultants (version and date)*
- Letters of invitation to participants (version and date)*

4.2 Independent Scientific Review

- Direct evidence of independent scientific review

4.3 Ethics

- The Ethics Committee Approval letter
- All correspondence with the committee(s)
- Composition of reviewing committee(s)

4.4 Regulatory Documents

- MHRA (for medicinal health care products and devices) until 30th April 2004: CTC/CTX/DDX, from 1st May 2004: CTA
- ARSAC
- Other statutory approvals

4.5 Research Department

- The Director of Research Final Permission Letter
- Indemnity arrangements: Trust, clinical trials insurance, ABPI
- Sponsorship agreement
- Serious adverse events: procedure for notification
- Data Protection: arrangements for participant identifiable data
- Health and safety requirements
- Intellectual property rights

4.6 Financial Management

- Contract/financial agreement*
- Confirmation of grant award*
- Trust finance approval
- Research Project Resource Assessment Form (RAF)
- Financial tracking*

4.7 Investigator and Research Team

- Local Principal Investigator CV (signed and dated)
- Co-investigators CVs and training record signed and dated (including research nurses/co-ordinators, pharmacists, research associates)
- Signature Log of all members of the research team
- List of tasks and responsibilities delegated to co-investigators
- Honorary contract/letter of authority for non-Trust staff

4.8 Project Management

- Membership of project steering group*
- Standard Operating Procedures for trial specific tests/interviews/ focus groups and the processing of study material/data
- Data management arrangements/security of data storage/ list of personnel authorised to access data, electronic or paper
- Laboratory Accreditation certificate*
- Normal laboratory values*
- Procedures for treatment allocation and decoding *
- Record of Serious Adverse Events

4.9 Participant Information

- Originals of consent forms signed by trial participants and Investigator
- Participant screening log
- Participant recruitment log
- Record of retained body fluids/tissue samples
- Record of tapes and transcripts of interviews and focus groups

4.10 Data Collection

- Blank copy of data collection sheet/interview schedule

4.11 Correspondence

- All other trial related correspondence

4.12 Study Closure

- Recruitment summary
- Archiving arrangements
- Dissemination: plans for/record of

4.13 Monitoring and Auditing

- Plan of study
- Record of internal monitoring
- Monitoring reports supplied to Research Department, Ethics Committee, Funding organisation and Sponsor
- Final Study Report

4.14 Research Governance Compliance

- Declaration of Helsinki
- ICH Good Clinical Practice (GCP) booklet

5. REGULATIONS, GUIDELINES, REFERENCES, SOP LINKS ETC

IICH (1996). Guidelines for Good Clinical Practice – ICH Harmonised Tripartite Agreement, Section 8.

6. APPENDICES

None