Southern Health NHS Foundation Trust

STANDARD OPERATING PROCEDURE (SOP)

SOP Number: NCP/R&D_006

SOP Title: Getting Ready for Site Inspection SOP

Role	Name	Signature	Date
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SOP Review Date			Effective date stamp

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	01-Dec-2012	Initial Version	28-Aug-2012
2		Template updated to include additional sections and further guidance in preparation of SOPs	

1. PURPOSE AND CONTEXT

1.1 This Standard Operating Procedure (SOP_ describes the process for preparing the Trust and related departments for an MHRA inspection

2. DEFINITIONS

- **MHRA:** Medicines and Healthcare Regulatory Agency. Executive agency of the NHS responsible for ensuring that medicines and medical devices work and are acceptably safe.
- **GCP Inspectors:** People responsible for ensuring trials are conducted to UK Clinical Trials Regulations.
- **CI –** Chief Investigator
- **PI –** Principal Investigator
- **CAPA** – Corrective and Preventative Actions

3. PROCEDURE and RESPONSIBILITIES

3.1 Inspections are necessary from regulatory authorities to conduct an official review of documents, facilities and records that are related to the studies managed at Southern Health NHS Foundation Trust (SHFT). This SOP seeks to explain the actions that will need to take place if the Trust is notified of a pending inspection.

3.2 The R&D Director will be notified of a planned inspection and will notify the rest of the R&D team. A liaison contact for the course of the inspection will be identified to co-ordinate communication between the R&D Department and the GCP Inspector.

3.3 The table below describes the actions which will need to be taken in preparation for an inspection. The Inspection Preparation Checklist (NCF-R&D_017) should be used during this process.

	Responsibility	Undertaken by	Activity
1	R&D Director	R&D Director/Manager	• Receive notification of inspection visit • Identify scope of inspection and alert relevant CI/PI/Sponsor/Trust board/R&D Team and other related departments • Identify liaison contact within the team • Set up an inspection file for all correspondence and information to be stored • Set up Inspection Preparation Check List (NCF-R&D_017) • Prepare pre-inspection dossier and send to regulatory board
2	R&D Manager	R&D Manager/R&D Office/CI/PI/other as required	Form steering committee to meet regularly:- • Identify deadlines • Discuss inspection requirements in detail with CI/PIs • Identify and book any rooms or equipment required • Identify any training requirements • Identify key areas to review prior to inspection and allocate to appropriate team member and as appropriate use Audit Self-Completion Forms (NCF-R&D_005)
3	R&D Manager	R&D Manager	• Work with CI/PI other to ensure that study files/departments are ready as directed by steering committee • Gather a list of documents including SOPs, organizational chart, training records and the relevant Trial Master File/Investigator Site Files.
4	R&D Manager	Liaison Contact	Receive confirmation of inspection date • Work with inspectors to draw up timetable including what areas will be inspected • Alert steering committee • Confirm logistics of inspection (room bookings, equipment, accommodation, catering requirements etc.)
5	R&D Manager	Liaison Contact	• An open meeting will be held with the GCP Inspectors, R&D Director/Manager and Liaison Contact to provide an outline of the R&D's processes and study portfolio.

5	R&D Office	All identified personnel	• Be present at inspection – staff are reminded that they should only answer questions which are within their job role.
6	R&D Director	R&D Director/Manager	Receive inspection report • Identify response required and deadline • Identify and alert CI/PI/departments required to respond • Identify response lead • Disseminate to interested parties with a Lessons Learnt meeting to discuss the results and actions that need to be taken
7	R&D Director	Manager/R&D Office/CI/PI/other departments	• Request from relevant parties feedback on any findings and any planned actions
8	R&D Director	R&D Director/Manager	Send response (CAPA) report to inspectors within the required deadline. • Disseminate copies to R&D staff and other linked services
9	R&D Director	R&D Director/Manager	Receive GCP Inspection Statement from the regulatory board • Disseminate to all interested parties
10	R&D Office	R&D Director/Manager	• Implement agreed actions and time-based follow up based on GCP Inspection Statement recommendations.

4. SUPPPORTING MATERIAL and ATTACHMENTS

SOPs

- NCP R&D_003 – Monitoring

Forms

- NCF-R&D_005 – Audit Self-Completion Form
- NCF-R&D_017 – Inspection Preparation Checklist

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 the SOP is updated staff will be notified and will need to re-read and sign against the SOPs within the R&D SOP file.

5.2. As applicable, training will be given in relation to study specific documents and will be documented in the site file.

6. REFERENCES

Department of Health Research Governance Framework for Health and Social Care
http://www.dh.gov.uk/en/Aboutus/Researchanddevelopment/Researchgovernance/DH_4002112

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.mhra.gov.uk/home/groups/clin/documents/websiteresources/con033682.pdf

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

Good Clinical Practice Guide (Grey Book)

14.4 Quality Assurance