South Eastern Health and Social Care Trust

Standard Operating Procedures
(SOPs)
Research and Development Office

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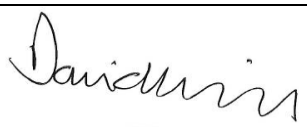
Signed:	
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Version No.	Date	Author	Reason for Change
1.0	Oct 2007	Katrina Hughes	N/A
2.0	July 2011	Alison Murphy	Updated to new SOP format

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1. INTRODUCTION

An audit is:
"*a systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor's Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirements."*
(ICH GCP 1.6)

Audit of research within the Trust is a function of research governance. It enables the Research Office to assess the conduct of research in the Trust, and to identify potential and actual problems and address the training needs of research staff. Throughout the audit, general information exchange between the auditor and the institution being audited is acceptable and essentially is used as an evaluation tool. This ensures that research conducted within the Trust continues to be of a high standard and we continue to provide a supportive and proactive service to Trust research staff. It also ensures that the safety of our patients and service users is maintained.

An audit is an informal planned process and can take place prior to, during or after the patient recruitment phase. An internal audit is often undertaken prior to an external inspection.

There are two types of Audit; Routine Random Active Project Audit and For Cause Audit. This SOP covers For Cause Audit, There is a separate SOP for Routine Random Active Project Audit (SOP 06)

For Cause Audit occurs when the Trust identifies a need for a study to be inspected by the Trust due to suspicion of significant contractual or regulatory non-compliance, scientific misconduct or fraud.

2. OBJECTIVE

This SOP describes the For-cause Project Audit procedures of South Eastern Health and Social Care Trust Research Office (SEHSCT). This SOP specifically describes the processes for selecting those studies identified as requiring a for-cause project audit. This SOP also describes the requirements and timelines for investigators to respond to these types of audit reports and implement corrective actions.

3. SCOPE

This SOP applies to all research projects taking place within the South Eastern Health & Social Care Trust

4. PROCEDURE

4.1 Selecting projects for For-Cause Project Audit

For-Cause Project Audit or triggered Audit can take place for the following reasons:

- When there is reason to believe that a trial is not being conducted in accordance with the stipulation made by an Ethically and Research Governance approved protocol

- That Regulations/Legislation are not being adhered to

- At the request of a senior member of staff as part of an official Trust Investigation or as that investigation, for example at the request of one of the following:
  Clinical Risk Department
  Research and Development Committee
  Trust Board
  Senior Management Team

- Triggered by the occurrence of a SAE

- To facilitate an audit by a Competent Authority (the MHRA or research Ethics Committee) who has concerns for patient safety or grounds to suspect that improper practices are occurring at a site. Under these circumstances, a "triggered" inspection will take place whereby inspectors have the legal right of entry to inspect premises at any time without notification.

- When it is reasonably believed patient safety is at risk.

- As part of an investigation onto fraud or misconduct under the Trust Policy.

- Any other reason that causes concern that can not be foreseen.

4.2 Initiating the Audit

A letter will be sent to the Chief/Principal Investigator for the trial informing them of the intention to audit the project, stating that this is a triggered audit, the reason why it is occurring, and at the request of which body or individual.

A follow-up phone call should be made a few days after sending the letter, to confirm receipt of letter and awareness of audit. During the call, questions can be answered and a date arranged to conduct the audit. Suitable accommodation should be identified and booked i.e. a space to review all documents etc. It must be made clear to the Researcher that participation is mandatory.

4.3 Conducting the Audit

From this point onwards the SOP 06 pertaining to Routine Random Project Audit should be followed.

5. REGULATIONS, GUIDELINES, REFERENCES, SOP LINKSS ETC.

Department of Health Research Governance Framework for Health and Social Care 2—5 (2nd Edition)

UK Clinical Trials (Medicines for Human Use) regulations 2004;

ICH GCP Guidelines 2006

Linked to:
SOP06 Routine Random Project Audit
SOP23 Notification of Serious Breaches of GCP

6. APPENDICES

None