South Eastern Health and Social Care Trust

Standard Operating Procedures (SOP) Research and Development Office

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1.0	Sept 2007	Katrina Hughes	N/A
2.0	August 2011	Alison Murphy	Updated SOP to new format Removed guidance on ionising radiation equipment

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1. INTRODUCTION

It will be the responsibility of the Chief Investigator (CI) in a clinical trial to ensure that the equipment that they will utilise during the study is adequate for "the foreseen duration of the trial to conduct the trial properly and safely" (ICH GCP 4.2.3).

This will ensure that the "investigator has adequate qualifications and resources and remains adequate throughout the trial period, that facilities, equipment, and staff, are adequate to safely and properly conduct the trial and remain adequate throughout the trial period" (ICH GCP 5.18.4b).

This Standard Operating Procedure (SOP) will summarise equipment activities (such as maintenance, calibration and servicing) that should be undertaken and as such, will not be an exhaustive operating procedure on all aspects concerning all equipment in clinical trials as the South Eastern Health & Social Care Trust has extensive procedures concerning the management of equipment which should be adhered to.

2. OBJECTIVE

The purpose of this Standard Operating Procedure (SOP) is to describe how equipment is maintained, calibrated and serviced in clinical trials sponsored by South Eastern Health & Social Care Trust.

3. SCOPE

This SOP applies to clinical trials sponsored by South Eastern Health & Social Care Trust.

4. PROCEDURE

4.1 Inspection/Testing of Equipment

It is the responsibility of the Chief Investigator/Principal Investigator to make sure that before the equipment is used, it meets the essential requirements of the relevant EC directives as well as local Trust policies.

The equipment being used for research purposes should be inspected and tested by the relevant local department to ensure it meets the technical and safety requirements before trial start-up.

4.2 Management of Equipment

It is the CI/PI responsibility to ensure that the management of the equipment adheres to GCP and follows the requirements set out in the Medicines for Human Use (Clinical Trials) Regulations 2004. The CI/PI should also ensure that the departments whose equipment is being utilised follow the appropriate regulations.

The CI in conjunction with the appropriate department should:

a) Ensure timely maintenance and servicing of the equipment at the local site(s).
b) That the equipment is calibrated to appropriate and recognisable standards.

The department where the equipment is stored/used should also have an inventory detailing the following:

a) The name of the manufacturer
b) The serial number
c) The date of purchase or acquisition or installation
d) Records which detail contracted maintenance
e) Training records for members of staff who maintain the equipment

5. REGULATIONS, GUIDELINES, REFERENCES, SOP LINKS etc

ICH GCP (1996)

Medicines for Human Use (Clinical Trials) regulations 2004

SEHSCT Management of Medical Devices Procedures and Guidelines

SEHSCT Policy and Guidelines on Research and Medical Devices

6. APPENDICES

None