St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

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Standard Operating Procedure (SOP)
Equipment Maintenance

SOP Chronology		
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V1.0	Original Version	Lucy H H Parker
V2.0	Review of version 0.1 Updated Logo and Trust Name	Anika Kadchha

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1. Background

This Standard Operating Procedure (SOP) will focus on equipment activities (such as maintenance, calibration and servicing) that the JREO may undertake as Sponsor of a clinical trial and as such, will not be an exhaustive operating procedure on all aspects concerning all equipment in clinical trials. This will be the responsibility of the Chief Investigator (CI) in the 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 (see ICH GCP 4.1,4.2, 5.6) and remain adequate throughout the trial period, that facilities, including laboratories, equipment, and staff, are adequate to safely and properly conduct the trial and remain adequate throughout the trial period."(ICH GCP 5.18.4b). The CI should also ensure that the various departments that will be used (e.g. radiology, pathology) have SOP's in place to ensure that equipment being used is maintained to an appropriate level.

2. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JREO acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

The purpose of this Standard Operating Procedure (SOP) is to describe how equipment is maintained, calibrated and serviced in clinical trials sponsored by St George's.

4. Definitions

None applicable to this SOP.

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5. Responsibilities

It is the Chief Investigator's responsibility to read and understand this SOP and to understand their responsibilities in relation to maintenance of equipment used in a research study.

6. Procedure

6.1 Inspection/Testing of Equipment

It is the responsibility of the Chief Investigator to make sure that before the equipment is used, it meets the essential requirements of the relevant European Commission (EC) directives (http://ec.europa.eu/atwork/applying-eu-law/index_en.htm) as well as local Trust and SGUL or SGHT 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.

Ionising radiation equipment must have a critical examination of the radiation safety features before trial start-up. This is the responsibility of the Principal Investigator at the research site.

Ionising radiation equipment must also have a risk assessment carried out prior to its use. This assessment must be completed by the relevant department in the Trust, and approved by the appropriate Radiation Protection Adviser and a manager from the department in which the equipment is to be used.

6.2 Management of Equipment

It is the CI's 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 should also ensure that the departments, whose equipment is being utilised, follow the appropriate regulations. The CI/ Sponsor should ensure the study team are trained to use the trial related equipment prior to the SIV.

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.

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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

6.3 Equipment Malfunction

a. It is important that the CI in conjunction with the appropriate department ensures that there are procedures in place to address equipment malfunctions e.g. breakdown of freezers. These procedures should detail the process in the event of malfunction and include: A back-up plan
b. Emergency contact numbers
c. How the event is to be assessed/investigated
d. Preventative measures to reduce reoccurrence
e. How the back-up plan is tested

7. References

International Harmonisation Conference on Good Clinical Practice (GCP) (1996)
Medicines for Human Use (Clinical Trials) Regulations 2004
http://ec.europa.eu/atwork/applying-eu-law/index_en.htm)

8. Appendices

None applicable to this SOP.

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