Standard Operating Procedure (SOP)
Equipment Maintenance

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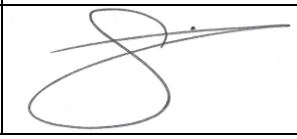
Signature of Authorisor:			

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SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1.0	Original Version	Lucy H H Parker
V2.0	Review of version 0.1 Updated Logo and Trust Name	Anika Kadchha
V3.0	Review and SOP format updated	Debs Rolfe
V4.0	Amendment of JREO to JRES. Addition of Associated JRES documents table. Update to all sections for clarity.	Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
	JRESWPD0023 General Research Definitions		

Contents

1. Background

It is essential that any equipment which is used in a clinical trial/study is fit for purpose, safe and accurate. Equipment used may be medical equipment for measuring trial parameters (eg: weighing scales, blood pressure monitors), laboratory equipment (eg: centrifuges and freezers for sample processing and storage) and pharmacy equipment (eg: fridges for IMP storage).

Equipment must be maintained for the duration of the study, according to the recommendations of the manufacturer and/or the requirements of the local organisation, to ensure that the study is conducted safely and correctly.

Staff using the equipment must receive documented training to ensure that they are using the equipment correctly and safely.

All departments involved in a study (eg: pharmacy, pathology, radiology) must have SOPs and records in place to demonstrate that their equipment is maintained to an acceptable level.

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

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

3. Scope

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for ensuring the appropriate maintenance of equipment used in studies sponsored by St George's.

This SOP focuses on equipment activities that the JRES may undertake as the Sponsor of a clinical trial and as such, does not cover all aspects concerning all equipment in clinical trials.

4. Definitions

For general research-related acronyms used in this SOP, refer to General Research Definitions Working Practice Document (JRESWPD0023).

5. Responsibilities

The Chief Investigator (CI) or Principal Investigator (PI) is responsible for ensuring that all equipment they will utilise during their study is adequate and fit for purpose.

It is also their responsibility to ensure that, before any equipment is used, it meets the requirements of any relevant UK legislation and local organisational policies.

It is the CI's responsibility to read and understand this SOP and to understand their responsibilities in relation to the maintenance of equipment.

6. Procedure

Inspection/Testing of Equipment

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 Radiology department at each research site.

Management of Equipment

The CI and/or PI, in conjunction with the appropriate department, should:

- Ensure timely maintenance and servicing of the equipment at the local site(s).
- Ensure 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 name of the manufacturer.
- The serial number.
- The date of purchase or acquisition or installation.
- Any contracted maintenance.
- Training records for members of staff who maintain or use the equipment.

Equipment Malfunction

It is important that the CI, in conjunction with the appropriate department, ensures that there are procedures in place to address equipment malfunctions, eg: the breakdown of a freezer where study samples are stored. These procedures should detail the process in the event of a malfunction and include:

- A back-up plan.
- Emergency contact numbers.
- How the event is to be assessed/investigated.
- Preventative measures to reduce re-occurrence.
- How the back-up plan is tested.

Documentation

Equipment service/calibration reports may be requested for audits and inspections and must thus be readily available and up-to-date. The location of such documentation must be referenced in the Investigator Site File.

7. References

ICH GCP and Clinical Trials Regulations.

8. Appendices

None associated with this SOP.