Imperial College London

Research Governance
and Integrity Team

NHS
Imperial College Healthcare
NHS Trust

Equipment Maintenance

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Author: Susana Murphy, Research Regulatory Facilitator	
Approved by: Keith Boland, Senior Clinical Trial Manager	Date:

Version	Date	Reason for Change
Version 1.0	31 May 2007	
Version 2.0	24 Jun 2008	Annual review
Version 3.0	08 Feb 2010	Formation of Joint Research Office
Version 4.0	14 Jul 2011	Annual review
Version 5.0	03 Dec 2012	Annual review
Version 6.0	18 Feb 2015	Scheduled review
Version 7.0	25 Oct 2017	Scheduled review
Version 8.0	19 Oct 2020	Scheduled review Templates removed and administrative changes to SOP

		JRCO name change to RGIT
Version 9.0	12 Feb 2024	3yr SOP review

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1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe how equipment is maintained, calibrated and serviced in clinical trials sponsored by Imperial College London or Imperial College Healthcare NHS Trust.

2. INTRODUCTION

This SOP will focus on equipment activities (such as maintenance, calibration and servicing) that Imperial College London or Imperial College Healthcare NHS Trust 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. It is the responsibility of the Chief Investigator (CI) in the clinical trial to ensure that the equipment that (s)he 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).

The CI will ensure that the "investigator has adequate qualifications and resources (see 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 (GCP 8.2.12, 8.3.6, 8.3.7) level.

3. PROCEDURE

3.1. Inspection/Testing of Equipment

It is the responsibility of the Chief Investigator (CI) to ensure that before the equipment is used, it meets the essential requirements of the relevant Ethics Committee (EC) directives as well as local trust and Imperial College London or Imperial College Healthcare NHS Trust policies (which can be found via Source Trust Intranet)

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. The PI or delegate in the research team should obtain calibration records annually or as specified by the local department SOP.

Examples of research equipment includes; investigational product, storage thermometer, biological specimen storage thermometers, blood pressure cuffs, ECG machines.

Ionising radiation equipment must have a critical examination of the radiation safety features before trial start-up. This is the responsibility of the CI.

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. Examples of ionising radiation equipment include; CT scanners, X-ray and DEXA scanners.

All new equipment must be calibrated before its use and should be fit for use. All existing equipment should be calibrated at least annually or as specified by the local department SOP.

3.2. Management of Equipment

It is the CI's responsibility to ensure that the management of the equipment adheres to Good Clinical Practice (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 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.

3.3. 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 e.g. breakdown of freezers. These procedures should detail the process in the event of malfunction and include:
   a. 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.

4. REFERENCES

[Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6(R2): Step 4](#)

[Medicines for Human Use (Clinical Trials) Regulations 2004](#)