

Standard Operating Procedure CCTU/SOP030

Management of Trial Specific Equipment

1. Scope

This SOP applies to equipment purchased, loaned or given to be used in Cambridge Sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs) or other research sponsored by the Trust and coordinated by the CCTU.

2. Purpose

The purpose of this SOP is to provide a documented process detailing who is responsible for the management of specific equipment.

3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

3.1. Definitions

Term	Definition
Cambridge Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH); or the University of Cambridge (UoC); or jointly by CUH and UoC OR Sponsored by: Cambridge University Hospitals NHS Foundation Trust (CUH) or CUH jointly with the University of Cambridge or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge

3.2. Abbreviations

Abbreviation	Meaning
PAT	Portable Appliance Testing

4. Undertaken by

Any staff using equipment loaned or given for the duration of a clinical trial

5. Items Required

CCTU/FRM043 Trial Specific Equipment Log
Trust procedure Media ID 8585 Management of Medical Devices

6. Summary of Significant Changes

Clarification that it is the responsibility of the Trial team to ensure that any trial specific equipment is logged with and passed by clinical engineering before use.

7. Method

The following sections provide a description of the processes to be followed when implementing this document's procedures.

7.1. Responsibility

- Trial specific equipment given, purchased or loaned for a specific trial is the responsibility of the team conducting that trial
- All equipment should go through the trust medical device procurement process
- Before use trial specific equipment must be registered with clinical engineering and passed as safe to use
- Refer to Trust procedure Media ID 8585 Management of Medical Devices
- It is the trial team's responsibility to ensure that trial specific equipment is serviced appropriately and records are kept
- It is every user's responsibility to ensure that any equipment they use has been passed by Clinical Engineering and has an up to date maintenance record
- Normally a sticker with the date of the last maintenance check and the date of the next check due date is visible on the equipment
- In exceptional circumstances equipment may be purchased and sent directly to sites outside the Trust e.g. GP surgeries. This equipment would not require standard clinical engineering checks. It is the responsibility of the trial team to source this equipment from an approved supplier in accordance with the protocol

7.2. Equipment Log

- A log with a description, serial number, location, date received, date of maintenance/calibration and a record of planned preventative maintenance should be kept
- Use Trial Specific Equipment Log CCTU/FRM043
- It is the trial team's responsibility to keep an equipment log for each piece of equipment they are responsible for
- The Trust keeps a medical device asset register
- Information from the register can be obtained via Clinical Engineering

7.3. Records

- Equipment records can be accessed from Clinical Engineering on request
- The equipment log and any associated paperwork for trial specific equipment should be maintained by the trial team and filed in the Trial Master File and Investigator Site File

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring Compliance and Effectiveness

As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators

This process forms part of a quality management system and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

9. References

The Institute of Clinical Research, Abbreviations used in Clinical Trials.
MHRA, Good Clinical Practice "Grey Guide"

10. Associated Documents

Clinical Engineering pages on connect

11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

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