Standard Operating Procedure CCTU/SOP030

Management of Trial Specific Equipment

1. Scope

This standard operating procedure (SOP) applies to equipment purchased, loaned or given for use in a specific Cambridge sponsored CCTU led clinical trial

2. Purpose

The purpose of this SOP is to provide a documented process for the responsibility and management of trial specific equipment to ensure it is maintained appropriately and meets general safety standards according to local policies.

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 Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge
Trial specific equipment	Any equipment acquired solely for use by the trial staff (e.g. a blood analyser or body scanner) or by trial participants (e.g. glucose analyser, blood pressure monitor, scales) within a particular trial

3.2. Abbreviations

Abbreviation	Meaning
PAT	Portable Appliance Testing

4. Undertaken by

Clinical Trial Staff managing equipment purchased, loaned or given for the duration of a Cambridge sponsored CCTU led clinical trial

5. Items Required

CCTU/FRM051 Trial Specific Training Log

CCTU/FRM043 Trial Specific Equipment Log

6. Summary of Significant Changes

It is the responsibility of CI and their trial team to ensure trial specific equipment specifically acquired (purchased, loaned or given) for their trial is managed according to local policies and procedures.

7. Method

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

Equipment may be purchased, loaned or given for use in a specific trial to ensure continuity across different departments or sites.

The procurement of trial specific equipment will be documented in the site agreement/protocol.

7.1. Safety

- Trial specific equipment may be purchased by the sponsor to be loaned or given to the coordinating centre for distribution to sites. It is then the responsibility of the coordinating centre to ensure it is safe for use before distribution
- Equipment received at sites direct from the manufacturer is managed by the local trial team according to local procedures
- Electrical equipment should have an identifier to indicate it is safe for use

  e.g. PAT testing sticker (in date), asset number, other according to local policy

7.2. Responsibility

- The coordinating site will assess any risk to the participant or to the integrity of the data in the trial level risk assessment
- It is then the responsibility of participating sites to follow local procedure to ensure:
  - Equipment is safe and fit for use
  - Equipment is validated and performs as expected
  - Equipment is calibrated
  - Routine maintenance is carried out

7.3. Training

Training must be recorded use CCTU/FRM051 Trial Specific Training Log.

PIs and their Site teams must ensure that users of trial specific equipment are trained appropriately, this also includes participants that use equipment at home e.g. lap tops I pads blood pressure monitors, glucose monitors,

7.4. Equipment Traceability

- Records must be kept for each piece of equipment.
- Use CCTU/FRM043 Trial Specific Equipment Log to record location (this includes participants if they are using equipment at home), maintenance calibration, safety and final disposal

- The equipment log and any associated paperwork should be maintained by the both the coordinating office and the site trial team and filed in the Trial Master File and Investigator Site File
- At the end of the trial the final destination of the equipment should be recorded as :
    - Returned to the sponsor
    - Donated to the site
    - Disposed/ destroyed
    - Other, specify

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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