North Bristol NHS Trust

Standard Operating Procedure

Maintenance of Research Equipment

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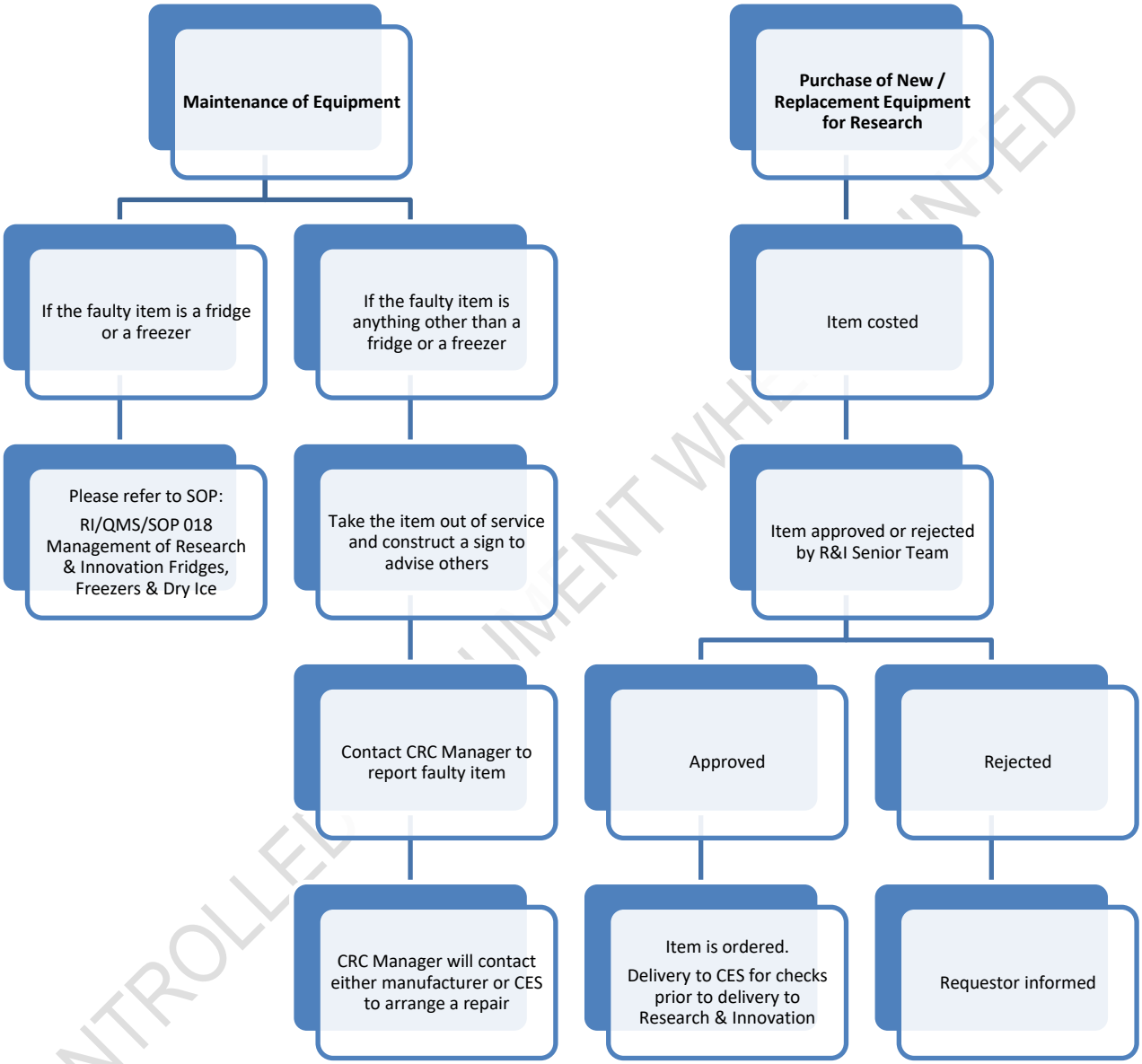
Document Version History

VERSION NUMBER	EFFECTIVE DATE	SUMMARY OF CHANGES SINCE THE PREVIOUS VERSION
1.0	31-05-11	N/A
2.0	08-02-16	SOP renamed, updated in line with new template and recoded from ISOP-F02
2.1	28-03-18	Updated to include reference to Datix system for accident and incident management
2.2	01-07-20	Updated flowchart, new hyperlinks to policies, greater clarity on wording

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT CHECKING IT IS THE LATEST VERSION

Current versions of all Research & Innovation SOPs and accompanying documents are available online. If you are reading this document in printed form, please check that the version number and date match the most recent version on the Research & Innovation website: www.nbt.nhs.uk/research

i. SOP Flowchart



1. PURPOSE AND SCOPE

The purpose of this SOP is to describe how equipment is maintained, calibrated and serviced for use in research at NBT.

The NBT trust policies on *Management of Medical Equipment* (CG27) and *Clinical Equipment Training* (CP 7a), available on the staff intranet, must be followed at all times. This SOP supplements these policies and governs the deployment, monitoring and control of Medical and Clinical Equipment associated to research, covering replacement and new items, whether purchased, donated, or hired.

The following items are not covered by this SOP:

- Staff Training - Although this SOP contains outline information on staff training, the NBT Clinical Equipment Training Policy (CP 7a) is the reference document for clinical and user staff training.
- Infection Control and Decontamination - Although this SOP contains information specific to medical equipment decontamination issues, the Overarching Infection Prevention and Control Policy (IC01) and Decontamination of Medical Devices and Endoscopes Policy (IC24) are the primary reference documents.
- All study related equipment not owned by NBT must be maintained and calibrated according to the manufacturer's recommendations.

2. DEFINITIONS/ABBREVIATIONS

Datix	NBT accident and incident management system
CE	Conformité Européene - European Conformity
CES	NBT Clinical Equipment Services department
CI	Chief Investigator
Clinical Equipment	The sub group of medical equipment which is used directly by clinical staff, in the monitoring, diagnosis or treatment of patients
CRC	NBT Clinical Research Centre
ICH GCP	International Conference on Harmonisation Guidelines for Good Clinical Practice
Medical Equipment	Equipment used in monitoring, diagnosis or treatment of patients in a direct or indirect manner (for example a centrifuge).
MEDUSA	NBT medical equipment management software package
NBT	North Bristol NHS Trust
PI	Principal Investigator
R&I	NBT Research & Innovation Office
SOP	Standard Operating Procedure
Sponsor	The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research

3. WHO SHOULD USE THIS SOP

This SOP applies to all investigators and research team members involved in studies sponsored or hosted by NBT.

Under ICH GCP, it is the responsibility of the CI/PI to ensure that the facilities and 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).

4. WHEN SHOULD THIS SOP BE USED

This SOP should be referred to during preparation of, and throughout the conduct of a research study sponsored or hosted by NBT.

It is the responsibility of the CI and PI to make sure that before any equipment is used, it meets the essential requirements of local trust 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 study start-up.

5. PROCEDURE

5.1. Requests for New or Replacement Equipment for Research

All new or replacement Clinical or Medical Equipment primarily used for research must be requested through NBT R&I.

All NBT owned equipment must be checked and logged on NBT's medical equipment management software package (MEDUSA), and an asset number and sticker placed on the item. This will be done by Clinical Equipment Services department (CES) prior to use.

All medical equipment purchased by NBT should be CE marked to indicate compliance with the Medical Devices Directive 93/42/EEC. NBT will not modify medical equipment in such a way as to influence its original CE registration, unless written agreement is obtained from the manufacturer or their agent. Any such agreement must be stored with the equipment records. Any modifications will be risk assessed and the assessment stored with the equipment records.

5.2. Training to Use Equipment

All members of staff must be trained and competent in any equipment that is used. The Staff Development department has the responsibility for providing training for Clinical and Medical Equipment.

NBT has a Clinical Equipment training co-ordinator, who may be contacted on EquipmentTraining@nbt.nhs.uk

Where non-standard study specific equipment is provided by a Sponsor or external party, any relevant training must be provided by that Sponsor or external party prior to use. This training

must be documented on your training record and site file. CES must be informed of any equipment in this category to ensure it complies with the NBT's infection control policies and any relevant Medicines and Healthcare products Regulatory Agency (MHRA) guidance.

It is the responsibility of the staff member to ensure they have been trained on any equipment prior to use and that they have updated their training record to reflect training received. The relevant band 7 study team leader is accountable for ensuring that their members of staff have been trained and are competent to use any equipment, and training logs have been updated.

5.3. Calibration

All equipment must be calibrated according to the manufacturer's recommendations, study protocols, and NBT requirements as appropriate.

A record of calibration must be maintained for all equipment, identifying which piece of equipment has been calibrated, by whom, and when. The calibration record must be available for inspection by the Sponsor, regulatory authorities and other relevant authorities.

Scheduled maintenance and calibration will be recorded on the NBT equipment management system (MEDUSA) for equipment that is maintained by CES. This system ensures that regular maintenance is scheduled and can be used to flag service due dates. Equipment managed by CES is labelled with the service due date. Equipment users should check that such equipment is in date for servicing and flag to CES where it is past the service due date.

Centrifuges, fridge and freezer temperature sensors are calibrated by an external company arranged by the Clinical Research Centre Manager annually.

5.4. Repairs

Should a piece of equipment become faulty, it is to be immediately taken out of service, and a visible sign displayed on the equipment "NOT TO BE USED, REPORTED TO the Clinical Research Centre Manager ON ……."

As per NBT policy, repair requests for equipment excluding centrifuges, freezers and fridges should be made to CES by phone and equipment should be sent to CES. This should be actioned by the Clinical Research Centre Manager.

5.5. Incident/Hazard Reporting

The Trust's accident and incident management system (Datix) procedure described in the Incident Reporting Policy CG01a sets out the requirements for all staff to follow in the event of a hazardous occurrence/adverse incident or near miss. This must be followed in all cases, so that incidents may be properly investigated and reported. Where applicable, the inventory or serial number of medical equipment should be recorded on the Datix incident form to aid investigation.

6. DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RI/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the Trust website (www.nbt.nhs.uk/research) and the Managed Learning Environment (MLE) system on the Trust intranet shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP. The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.

7. RELATED SOPS AND DOCUMENTS

- Medicines and Healthcare products Regulatory Agency
  Managing Medical Devices Guidance (April 2015)
  www.mhra.gov.uk

- Care Quality Commission
  CQC Standard - Outcome 11 – safety, suitability and availability of equipment
  www.cqc.org.uk

- The following NBT documents are available on the policy pages of the staff intranet:

  Management of Medical Equipment Policy (CG27)
  Clinical Equipment Training Policy (CP 7a)
  Decontamination of Medical Devices and Endoscopes Policy (IC24)
  Incident Reporting Policy (CG01a)

- The following R&I documents are available on the NBT website: www.nbt.nhs.uk/research

RI/QMS/SOP/018	Management of Research & Innovation Fridges, Freezers & Dry Ice