1. Introduction

Research Space at the University Hospitals of Leicester (UHL) supports the conduct of a broad range of clinical trials, which often require the use of both clinical and non-clinical equipment.

Planned Preventative Maintenance (PPM) of all high risk medical devices and laboratory equipment is a regulatory and statutory requirement in order to prevent deterioration that could threaten the safety of participants and staff. For some devices, regular calibration is also required to ensure that healthcare readings used to inform clinical care, or that are reported for research purposes, are accurate.

To ensure participant and staff safety and the integrity of study results, it is essential that all Research Space equipment is correctly maintained and that users are aware of required actions in the event of equipment failure or malfunction.

The aim of this Standard Operating Procedure (SOP) is to outline the local processes and procedures required to ensure that any Research Space equipment used for sample processing or the generation, measurement or assessment of clinical or research data, is regularly inspected, maintained and, where necessary, calibrated.

2. Responsibilities

The Research Space Management Team (RSMT) is responsible for:

- authorising the procurement, maintenance, repair, replacement, disposal and use of Research Space medical devices and laboratory equipment in line with Trust policies and procedures
- oversight of processes related to operating, maintaining and/or cleaning of Research Space equipment
- monitoring compliance with this SOP

All users of Research Space equipment are responsible for:

- ensuring they are adequately trained, and have the required authorisation, before operating any Research Space equipment
- checking and cleaning equipment before and after use
- reporting damaged, malfunctioning, unsafe or out-of-service equipment to the Research Space administration team (RSA)
- performing routine equipment maintenance, or cleaning tasks, as delegated by the RSMT or Laboratory Supervisor

The Laboratory Supervisor is responsible for:

- ensuring research staff have completed a laboratory orientation and relevant online training before starting any work within Research Space laboratories, including individual equipment training where required

- regular oversight of all Research Space laboratory equipment to ensure it is being used, cleaned and stored as per UHL Policy and manufacturers' recommendations
- organising and/or carrying out routine cleaning and maintenance of Research Space laboratory equipment, as per manufacturers' recommendations and Trust / local policy and documenting where required
- ensuring laboratory equipment that is faulty or out of calibration is labelled appropriately
- reporting any issues to the RSMT

The Research Space administration (RSA) team are responsible for:

- actively maintaining an asset register of all clinical / non-clinical equipment and medical devices owned by or on loan to Research Space
- reporting damaged or malfunctioning equipment to the RSMT
- maintaining a record of equipment calibration, maintenance and repair, and providing copies as required
- proactively checking and organising regular service and calibration of all relevant Research Space equipment in line with Trust / local policies and procedures and / or manufacturer recommendations and study protocols
- arranging the procurement of new laboratory equipment and medical devices
- arranging repair, replacement or disposal of damaged or malfunctioning equipment (where authorised by the RSMT)
- ensuring equipment or medical devices that are faulty or out of calibration are labelled appropriately

The study Chief/ Principal Investigator is responsible for:

- ensuring that all relevant study approvals are in place before equipment is used
- ensure any loan equipment is serviced and maintained in accordance with the protocol and UHL policy, and provide evidence where requestedensuring all study team members:
    - are familiar with all relevant policies and procedures
    - are appropriately trained and formally delegated to all tasks requiring the use of Research Space equipment
- maintaining oversight of all study team members and taking corrective action in the event of lack of compliance with this SOP

  See the following linked documents for further information; RS-SOP5000, RISOP C-2003, RISOP S-1010

3. Scope

This SOP applies to the Research Space Management Team (RSMT), administration staff, laboratory supervisor and all staff members intending to use medical or laboratory equipment within Research Space managed facilities. It covers all laboratory equipment and medical devices owned by and permanently based within Research Space managed facilities, plus all loan equipment brought in temporarily for specific clinical trials.

4. Procedure

4.1. Approvals

- Access to Research Space equipment is by prior agreement only (see RS-5000: Research Space Application Process for details)
- It is the responsibility of the PI (or delegated main contact) to ensure that any medical devices or laboratory equipment required by the study protocol are available within Research Space - or arrangements have been made to purchase or loan this equipment - before agreeing to undertake a study
- In the event that a trial sponsor has agreed to donate, or temporarily loan research equipment to a study team for the purposes of research, this must not be stored or used within Research Space managed facilities without prior authorisation by the RSMT.

4.2. General Use

- Research Space equipment is available on a 'first-come, first served' basis and cannot be pre-booked.
- Prior to using any equipment for the first time, users must ensure they:
    - are authorised to operate the equipment
    - are aware of all relevant policies, procedures and manufacturer operating instructions
    - have received adequate training and are competent in the use of the equipment (as per section 5)
- Prior to every use, users must visually inspect the equipment to assess:
    - damage
    - cleanliness
    - within service and calibration dates (where necessary)
    - approved for use (i.e. does not have a 'DO NOT USE' sticker attached)
- Any issues must be reported immediately (as per section 4.5)
- After each use (and before, if required) equipment should be cleaned according to the UHL Decontamination of Medical Equipment Policy (B5/2006) and RS-SOP 5001: Housekeeping within Research Space, LRI.

4.3. Scheduled Preventative Maintenance

- Before first use, all relevant equipment must be registered with the appropriate UHL in-house technical support service and, where necessary, undergo acceptance testing.
- All Research Space medical devices and high risk laboratory equipment must be regularly serviced (and calibrated where necessary) according to the UHL Medical Devices Policy (B26/2005) and manufacturer's recommendations.
- If service / maintenance cannot be done in-house, this must be contracted to an external service company and their details retained.
- Relevant electronic equipment must undergo safety testing, as per UHL Medical Devices Policy.
- A record of all service/ calibration dates will be maintained by the RSA and made available on request. In most cases, stickers showing 'last service' and 'due by' dates will also be placed

by the engineer on individual pieces of equipment at the time of service; photographic evidence of this will be made available on request.

- On a monthly basis, the administration team will check if any equipment is due for maintenance and, where necessary, organise for this to be carried out as per UHL policy and manufacturer's recommendations.
- The RSMT and / or Laboratory Supervisor should be notified once a service date has been arranged.
    - For laboratory equipment, the Laboratory Supervisor (or delegate) must ensure that the equipment is decontaminated and taken out of use prior to service (see section 4.6).
    - Any equipment with a display unit that does not require calibration, will be labelled to notify the user that the display data is for indication only.

4.4. Out-of-Service Maintenance

- Any equipment found to be out of service/ calibration must be reported to the RSA immediately, so a service visit can be booked as soon as possible.
- The RSA must immediately notify the RSMT and/ or Laboratory Supervisor, who will decide whether the equipment needs to be removed from service (preferable action).
- Any equipment taken out of service must be decontaminated and clearly labelled with a 'DO NOT USE' sticker (see Appendix 1 Research Space Decontamination Certificate / Safety Declaration).
- If the equipment is unique and must remain in use until a service / recalibration can take place - and the RSMT or Laboratory Supervisor has deemed it safe to do so - a warning must be placed on the equipment stating that it is outside of its calibration / certification date, which could result in the generation of inaccurate data (see Appendix 2).

4.5. Equipment failure or malfunction

- Faulty medical devices/ laboratory equipment must be taken out of service immediately; the user must place a 'DO NOT USE' notice on the device and notify the RSA (see Appendix 1 Research Space Decontamination Certificate / Safety Declaration). If stickers are not available, hand written notices can be used.
- In the event of equipment failure or malfunction, the RSA should liaise with the relevant party to organise repair. For medical devices and equipment supported internally, this will be the UHL Medical Equipment Service team.
- For loan equipment this should be organised with the relevant party.
- For all other equipment, the RSA should obtain a quote for repair from a licensed subcontractor. All repairs must be authorised by the RSMT.
- For laboratory equipment, the Laboratory Supervisor (or delegate) must ensure the item has been decontaminated (as per section 4.6) and labelled with a 'Decontamination Certificate / Safety Declaration' sticker prior to repair (see Appendix 1 Research Space Decontamination Certificate / Safety Declaration).
- A record of the repair should be retained

4.6. Decontamination

- All clinical and laboratory equipment must be decontaminated after each use according to UHL and local policies, unless otherwise stated in the manufacturer operating instructions. For a list of approved chemicals/disinfectants please see the Decontamination of Medical Equipment Policy (B5/2006).
- If the manufacturer decontamination procedure differs from Trust Policy, the RSMT must ensure this has been approved by the UHL Infection Prevention team.

4.7. Records

4.7.1. Asset Register

- Details of all clinical and non-clinical equipment within Research Space managed facilities (including loan equipment) must be recorded on an asset register.
- For laboratory equipment used for sample preparation, or medical devices used for measuring clinical or research data, the asset register should include the following information as a minimum:
    - equipment type
    - manufacturer and model
    - serial number
    - location
    - service / calibration / maintenance frequency and provider
    - date of last service/ calibration completed and date due
    - equipment owner or loan details

4.7.2. Equipment Logs

- Any equipment requiring routine maintenance by Research Space staff will have a log maintained.
- Original documents relating to each piece of equipment (such as warranties, service records and calibration certificates) must also be kept centrally. The RSA will make copies available on request.

4.8. Equipment Procurement, Loan or Donation

- The procurement of any new equipment must be conducted in accordance with the UHL Medical Devices Policy (B26/2005).
- Any equipment donated or temporarily loaned to study teams for use within Research Space managed facilities is by prior agreement with the RSMT.

4.9. Equipment Decommissioning and Disposal

- All clinical equipment should be decommissioned and disposed of according to the Policy for the Management of Medical Devices for Research and Development (B19/2013).
- All other equipment should be disposed of according to the UHL Waste Management SOP (A15/2002).

- Loan equipment must not be disposed of without prior written authorisation from the supplier.
- Documentation of decommissioning / disposal will be recorded on the Study Closure checklist (as per RS-SOP5009: Closure of Research Space Hosted Studies).

5. Education and Training

- Before using any medical devices or laboratory equipment for the first time, staff must:
  - complete any training relevant to each piece of equipment they wish to operate
  - complete the Research Space laboratory orientation programme and online training
  - familiarise themselves with this SOP and all other relevant policies, procedures and manufacturer operating instructions
  - record evidence of training and undertake an assessment of competence where required

6. Supporting Documents and Key References

- Provision and Use of Work Equipment Regulations 1998
- Waste Management Policy (B39/2024)
- Policy for the Donation and Loan of Equipment (B19/2004)
- Medical Devices SOP (B26/2005)
- Cleaning and Decontamination for Infection Prevention (B5/2006)
- Policy for the Management of Medical Devices for Research and Development (B19/2013)
- Work Equipment Policy (B8/2004)
- SOP RS-5000: Research Space Application Process
- SOP RS-5001: Housekeeping within Research Space, LRI
- SOP RS-5009: Closure of Research Space Hosted Studies
- SOP C-2003: PI Responsibilities for Hosted Research in UHL Research & Innovation
- SOP S-1010: Chief Investigator Responsibilities in Sponsored Research in UHL Research & Innovation

7. Key Words

Clinical Research, Equipment, Medical Devices, Maintenance, Cleaning, Procurement

8. Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead

All research Sponsored or Hosted by UHL has appropriate contracts in place	Included in the monitoring/audit programme.	Random audits/monitoring conducted on a risk based approached according to research activity.	R&I QA Manager

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DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT			
Authors / Lead Officers:	Adam Lewszuk Christina Daines	**Job Title:**	Senior Research Nurse Manager Children's Research Manager
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Date	**Name**	**Dept.**	**Received**

Appendix 1 Research Space Decontamination Certificate / Safety Declaration

University Hospitals of Leicester NHS
NHS Trust

Research Space Decontamination Certificate / Safety Declaration

DO NOT USE

EQUIPMENT AWAITING: SERVICE / REPAIR / RELOCATION / DISPOSAL*

SITE	BUILDING	LABORATORY / ROOM
LRI ☐ LGH ☐ GGH ☐		

EQUIPMENT TYPE	MANUFACTURER	MODEL No.	SERIAL No.
CENTRIFUGE ☐ OTHER:			

Laboratory equipment MUST be decontaminated prior to service, repair, disposal or relocation. After decontamination, complete this form and attach to the relevant equipment as proof of decontamination. It is the responsibility of the person performing the decontamination to ensure that equipment is, so far as is reasonably practicable, in a clean and 'safe' condition, i.e. free from microbiological and chemical contamination.

Please complete section A or B below:

A. The equipment described above **has not** been exposed to micro-organisms, clinical material, or hazardous chemicals and is safe to handle.

Name: ..... Signature: .....

Date: …… Extension number: ……

B. The equipment described above **has** been exposed to micro-organisms / clinical material / hazardous chemicals.* Appropriate decontamination procedures have been carried out and the equipment is safe to handle.

Name: ..... Signature: .....

Date: …….. Extension number: ……

(Any queries regarding this equipment should be made to the person named above)

**Delete as appropriate*

Appendix 2 Research Space Equipment Out of Calibration / Service Notice

University Hospitals of Leicester NHS
NHS Trust

Research Space Equipment Out of Calibration / Service Notice

WARNING

EQUIPMENT AWAITING: CALIBRATION / SERVICE*

SITE	BUILDING	LABORATORY / ROOM
LRI ☐ LGH ☐ GGH ☐		

EQUIPMENT TYPE	MANUFACTURER	MODEL No.	SERIAL No.
CENTRIFUGE ☐ OTHER:			

This equipment is overdue for recalibration / service. As there is no alternative available, it will remain in use until a service / recalibration can take place. However, ***the accuracy and / or quality of any generated outputs cannot be guaranteed.***

Users should proceed at their own discretion. If equipment is used, please document this in your Site File and check with the study Sponsor, where required, before submitting results.

**Delete as appropriate*