

**UNIVERSITY OF LEICESTER, LOUGHBOROUGH UNIVERSITY
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH SUPPORT OFFICE
STANDARD OPERATING PROCEDURES**

**Research Space SOP 5005
v1.1 November 2017**

**Policy for Use and Maintenance of Research Space Cold
Storage Units**

PGC Registration: C78/2017

OFFICE BASE

**Research Space
Level 0, Balmoral Building
Leicester Royal Infirmary
Infirmary Close
Leicester LE1 5WW**

1. Background

Research Space supports the conduct of a broad range of clinical research studies, including the storage of trial medication and biological samples. To ensure staff safety and the integrity of stored items, it is essential that all Research Space Cold Storage Units (CSUs) are used and maintained correctly and that staff are aware of required actions in the event of CSU failure or malfunction.

2. Purpose

To outline the proper process for use and maintenance of Research Space CSUs.

3. Scope

This policy applies to all staff using Research Space cold storage facilities, the Research Space administration staff, housekeeper and Senior Management Team (SMT) and covers all Research Space cold storage facilities (i.e. refrigerators and freezers), with the exception of the domestic refrigerator in the Research Space kitchen.

4. Responsibilities

All staff using Research Space cold storage equipment are responsible for:

- familiarising themselves with this policy and ensuring they are adequately trained in the use of relevant equipment before storing any items in Research Space CSUs
- following all relevant UHL and local policies/procedures whilst using Research Space equipment and facilities
- ensuring any items stored within Research Space CSUs are adequately packaged, labelled and documented and that the study allocated storage space is not exceeded
- wearing relevant PPE, as per local risk assessment
- visual inspection of Research Space CSUs before/during use and reporting damaged or faulty equipment immediately

The PI (or delegated main contact) is responsible for:

- ensuring that Research Space approval is in place before any items are stored within Research Space CSUs
- ensuring that delegated staff are following study protocols

The Research Space administration team are responsible for:

- monitoring of CSU temperatures and reporting deviations to the SMT
- documenting every time a check of electronic logs has taken place
- producing hard-copies of electronic temperature logs on a monthly basis
- ensuring Research Space CSUs are adequately maintained
- arranging repairs or replacement equipment and notifying research teams in the event of a CSU malfunction or breakdown

The Research Space housekeeping staff and lab supervisor are responsible for:

- ensuring Research Space CSUs are cleaned and defrosted according to local policy and manufacturers' recommendations
- monitoring CSU storage and reporting to the SMT if capacity is being reached
- relocating stored items in the event of a CSU malfunction or breakdown

The SMT (or delegated staff) are responsible for:

- ensuring adequate cold storage facilities are available for research use
- approving use of Research Space facilities and allocating space in CSUs
- quarterly inspection of temperature logs to ensure each CSU and its contents are being properly maintained
- approval of maintenance/repair/replacement of CSUs as required
- monitoring compliance with this policy

5. Equipment Use

- Use of Research Space cold storage equipment is by prior agreement only (see RS-SOP 5000 – Research Space Application Process). Cold storage space is allocated to research teams on a 'per study' basis; if additional space is required

a new application must be made. In the event that space is limited, priority will be given to existing studies

- No food or beverages are to be stored in any of the clinical refrigerators or freezers. A dedicated refrigerator is provided for staff use in the kitchen area of Research Space
- Prior to storage, all substances - including biological samples - must be placed in an appropriate container to prevent the possibility of spills, leakage, odours or spoilage
- All samples must be appropriately labelled. At a minimum this should include the study number, unique subject identifier and date
- Bottles, tubes, and containers with a cap or top must be stored in an upright position wherever possible and in such a way as to ensure their stability
- An up-to-date log of contents should be maintained for each CSU to allow easy retrieval of all stored substances/samples
- Where possible, all CSUs should be powered via a protected electrical circuit with generator backup

6. Health and Safety

- The doors of all CSUs should be labelled with appropriate hazard warning signs to indicate the nature of their contents
- Hazardous substances must not be kept in any of the Research Space CSUs
- PPE must be worn as per PPE Risk Assessment for Use of Research Space Cold Storage
- Any spillages should be dealt with in accordance with the UHL Cleaning and Decontamination policy

7. Equipment Monitoring

- All CSUs must be regularly monitored to ensure they are functioning correctly. This is the responsibility of all staff members. Faults or damage must be reported immediately to Research Space administration or the SMT stating the CSU number and location

- Most Research Space CSUs are fitted with external temperature monitoring devices to allow remote monitoring. For devices where these are not fitted (or faulty) the CSU must be fitted with an external digital thermometer (this includes units with a built-in temperature display). The external thermometer must be calibrated and a calibration certificate must be available
- Refrigerator/freezer temperatures must be checked daily*, to include the highest and lowest temperatures reached since last recorded. A separate temperature log must be maintained for each CSU; this should clearly identify the unit being monitored as well as the acceptable temperature range for that unit. For paper logs, each entry must be dated and initialled by the person completing the monitoring
- Where temperatures are remotely monitored, online logs will automatically be generated. The administration team will check these daily for deviations, reporting any problems to the SMT. Daily* checks will be documented and a monthly printouts of logs produced, to be made available on request
- The SMT (or designee) must inspect all temperature logs quarterly to ensure each CSU and its contents are being properly maintained and document this. Routine inspections will also be carried out by the Clinical Trials Pharmacy of equipment where IMP is stored

**There is currently no requirement to check temperatures out-of-hours, at weekends and during public holidays*

8. Temperature Out-of-Range Action Plan

- When items are being moved in and out of cold storage a temperature fluctuation can be expected. If a temperature alarm is sounding, this should be cancelled and the temperature allowed to stabilise. Temperatures are only deemed to be out of range if they do not stabilise within 60 minutes

- If a temperature reading is found to be outside the designated range without an obvious explanation staff must undertake the following actions:
 - immediately report the temperature deviation to an administrator, SMT member or designee
 - avoid opening the door of the affected unit to maintain the internal temperature for as long as possible
 - label the affected unit with a sign stating that the fault has been reported and that the unit must not be opened.
- If the temperature has not stabilised within 4 hours, or has continued to fall:
 - relocate all stored items to a backup unit or another unit with spare capacity
 - notify study teams who are storing samples or holding an Investigational Medical Product (IMP) in the affected unit of the temporary location of their items
 - if the faulty unit contains an IMP, the Clinical Trials Pharmacy must also be notified. Move all IMP to an alternative unit and quarantine until further instructions received from pharmacy (as per 'Clinical Trials Involving Medicines Stored on Wards or in Clinics' SOP)

9. Maintenance

- All CSUs should be cleaned externally as per manufacturer's recommendations following the schedule in the Standard Operating Procedure for Housekeeping within Research Space (SOP 5001)
- To maintain airflow and minimise external temperatures, windows in rooms containing CSUs must be kept open at all times
- Frost build-up in freezers must be avoided to ensure efficiency of cooling and to ensure good access to contents. Where possible, freezer units should be defrosted every 6 months. When removing ice build-up, care must be taken to avoid damaging the insulation or cooling elements
- Ultra-low temperature freezers (-60°C or below) should have their filters cleaned monthly by the lab supervisor as per manufacturer's instructions

- All equipment should be regularly inspected for faults - including a visual inspection of the electrical cord/plug - to ensure safe operation. All CSUs must be formally tested for electrical safety on an annual basis (PAT testing)
- Equipment determined to be unsafe must be removed from service and immediately reported to the administration team, who will arrange for service, repair or replacement
- Servicing of equipment must only be performed by authorised personnel

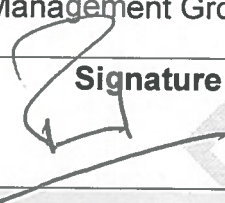
10. Related documents

- RS-SOP 5001 - Housekeeping within Research Space, LRI
- Pharmacy SOP 406 - Clinical Trials Involving Medicines Stored on Wards or in Clinics
- UHL B5/2006 - Cleaning and Decontamination for infection prevention
- UHL B10/2002 - Control of Substances Hazardous to Health (COSHH) Policy
- Relevant PPE risk assessments
- Manufacturer's Operations Manuals

11. List of Appendices:

None

12. Approval and sign off

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT			
Author:	Adam Lewszuk	Job Title:	Senior Research Nurse
Reviewed by:	Research and Innovation Management Group		
Approved by:	Prof. Nigel Brunskill	Signature 	Date Approved 13/11/17
REVIEW RECORD			
Date	Issue No.	Reviewed by	Description of Changes (If Any)
Nov 2017	1.1	Sally Batham, Christina Daines, Aidan Dunphy & Adam Lewszuk	Update /clarification of procedures, corrections and reformatting.
DISTRIBUTION RECORD			
Date	Name	Department	Received