

UNIVERSITY OF LEICESTER, LOUGHBOROUGH UNIVERSITY

&

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

Research Space SOP 5009

v1.1 March 2018

**Standard Operating Procedure for the
Closure of Research Space Hosted Studies**

PGC Registration: C20/2018

OFFICE BASE

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

1. Background

Research Space supports a broad range of clinical research studies and includes the following resources: clinical consultation rooms, laboratory facilities, clinical and other equipment. As studies that have used Research Space facilities close, it is essential that study equipment, samples, and documentation are removed, returned, transferred, or archived appropriately. This is necessary to ensure that there is sufficient room and availability within Research Space for new and on-going studies.

2. Purpose

The purpose of this policy is to outline the required procedures when a study closes that has used Research Space managed facilities in any capacity.

3. Scope

This policy applies to all studies which have used Research Space managed facilities in any capacity, and covers the equipment, samples and/or documentation that have been used or stored within Research Space.

4. Responsibilities

The Research Space Senior Management Team (SMT) are responsible for:

- ensuring compliance with this Policy
- raising non-compliance to the respective PI to ensure that samples and equipment are returned, removed or disposed of (as appropriate).

The lead Research Nurse/Research Officer/Research Assistant for each study is responsible for:

- notifying the Research Space Admin Team of study closure via clinical.research@uhl-tr.nhs.uk
- returning, transferring or disposing of all study related equipment, samples and documentation in a timely manner following study closure, as outlined in the Policy Statement below.

The Principal Investigator (PI) is responsible for:

- ensuring all necessary actions outlined in the Policy Statement have been completed.

The Research Space Admin Team are responsible for:

- flagging any closed studies to the SMT, following email receipt.

5. Policy Statement

General

- When a study closes, please notify the Research Space Administration Team via email at: clinical.research@uhl-tr.nhs.uk
- If, for some reason, study samples or equipment need to remain in Research Space after study closure, contact the SMT for advice via email at: clinical.research@uhl-tr.nhs.uk

Equipment

- All study specific equipment that is no longer required should be returned to the study team or destroyed, as per the study team's instructions.
 - Please ensure adequate precautions are taken when disposing of sharps to prevent injury, as per the UHL Sharps Management Policy
- Any study specific settings that have been programmed into centrifuges or other Research Space equipment should be deleted.
- If authorisation has been given from the study team to keep any clinical equipment, consumables or packaging, please notify the SMT. If agreement is given for this to be kept, take the following actions:
 - **Clinical equipment** will become a Research Space asset. Please notify the Research Space Admin Team, so equipment details can be added to the asset register.
 - **Consumables/lab kits and unused packaging for sample transportation** should be transferred to an appropriate place within Research Space to allow for general use (e.g. store room, clinical trolley).

Stored Biological Samples

- All stored samples should be transferred to the designated study-specific central laboratory, as per individual study procedures.
- Any stored samples which are no longer required should be disposed of in a clinical waste bag as per UHL Waste Management Policy and Guidance. It is imperative that this has been agreed with the study team and appropriately documented prior to sample destruction.

- Please ensure adequate precautions are taken when handling or disposing of samples to prevent spillage, as per UHL Policy for Cleaning and Decontamination for Infection Prevention.
- Study specific logs must be removed from laboratory folders and filed appropriately.

Study Documentation

- Research Space does not provide any archiving facilities for study teams. All study documentation must be archived either with the study team, off-site, or in an alternative, appropriate location.
- Research Space does not provide any pre-archiving facilities for staff not based within Research Space. Please ensure all study documentation (site files, CRFs, etc.) are removed from Research Space when a study closes, even if the end of study documentation is still pending.
- All study documents should be archived as outlined in the protocol, or as per R&I SOP S-1029: SOP for Archiving of Essential Documents.
- To prevent the risk of injury, please ensure adequate precautions are taken when moving and handling boxes and heavy files, as per the UHL Safer Handling Risk Assessment Policy.

6. Related Documents and References

- UHL A15/2002 Waste Management Policy and Guidance
- UHL B5/2006 Cleaning and Decontamination for Infection Prevention policy
- UHL B65/2011 Safer Handling - Risk Assessment Policy.
- R&I SOP S-1029: SOP for Archiving of Essential Documents

7. Approval and sign off

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT			
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Reviewed by:	Research and Innovation Management Group		
Approved by:	Prof. Nigel Brunskill	Signature	Date Approved
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