

UNIVERSITY OF LEICESTER, LOUGHBOROUGH UNIVERSITY

&

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

**Research Space SOP 5000
v1.1 September 2017**

**Standard Operating Procedure
for Research Space Application Process**

PGC Registration: C73/2017

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 provides the following resources: clinical consultation rooms, laboratory facilities for processing and storing samples, clinical and other equipment, and staff training.

Researchers who wish to use Research Space must submit an application for consideration by the senior management team (SMT).

The SMT will undertake the feasibility review for the area(s) the PI has applied to use. The feasibility review will include the following considerations:

- comparison of the resources requested with the resources available
- the existing and planned workload
- the cost of any equipment, consumables and staff support required

2. Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the process of how applications to use Research Space are managed from initial enquiry to study start-up.

3. Scope

This SOP applies to:

- PIs and relevant members of their research teams applying to use Research Space facilities and resources
- Research Space administration, SMT, and core staff receiving or reviewing enquiries and applications

4. Responsibilities

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

- Ensuring that the Research Space application form is completed accurately and submitted at an early a stage as possible, along with relevant associated supporting documents (as listed on the application form)
- Signing the 'declaration' section of the application form following approval from the SMT
- Ensuring that the required Research Space resources are approved before taking the study to the next stage.

The Research Space administration team are responsible for:

- Receiving the initial enquiry
- Acknowledging the request via email
- Entering the details of the application onto a database
- Filing an electronic copy of the application form and study protocol and supporting documents
- Passing the application to the SMT for review
- Updating the database when the outcome is known
- Notifying the appropriate research team of the decision

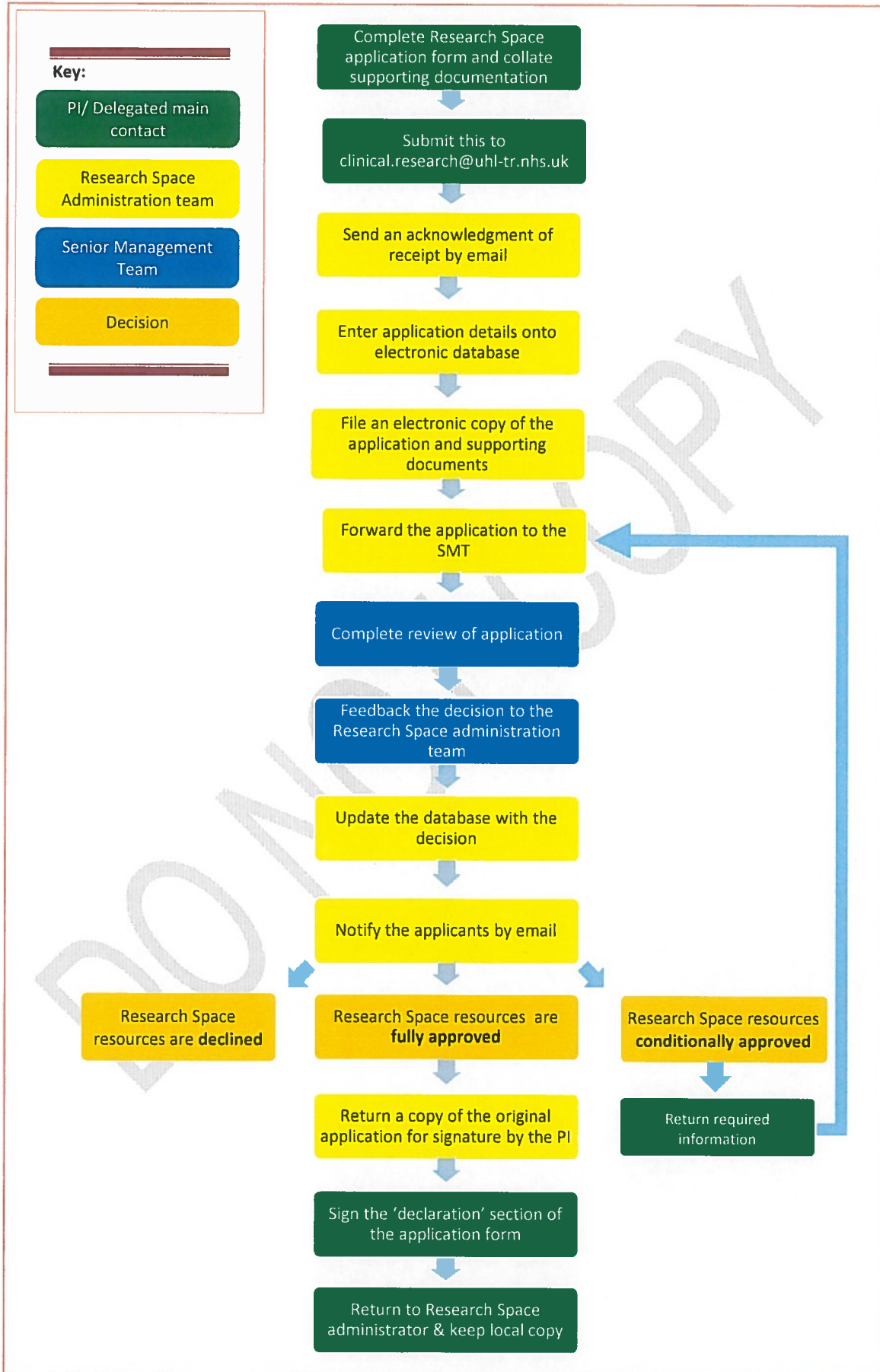
The SMT (or delegated team members) are responsible for:

- Ensuring feasibility reviews are undertaken in a timely manner
- Reviewing applications and considering resource implications
- Carrying out a feasibility review of applications
- Considering if a charge is applicable
- Feeding back decisions to the Research Space administration team.

5. Procedure

- The research team wanting to use the facilities will complete the Research Space application form and submit this by email to the Research Space administration mailbox clinical.research@uhl-tr.nhs.uk
- The following supporting documentation should be included:
 - Research Space Application Form
 - Current protocol, plus any amendments (a protocol summary or schedule will be sufficient)
 - Laboratory manual
 - Where required documentation is not applicable, a short explanation is requested. In some cases, required documentation may be submitted at a later date when available
- Once received, the Research Space administration staff will send an acknowledgment of receipt by email
- The application details will be entered onto the electronic database
- A copy of the application and the study protocol will be filed in the Research Space main office
- The application will then be forwarded to the SMT for feasibility review and consideration of costs
- The SMT will meet on a regular basis to review all applications
- Following feasibility review, the SMT will feedback their decision to the Research Space administration team
- The database will then be updated with the decision and the applicants notified of the outcome by email
- If use of Research Space resources is **fully approved**, a copy of the original application will be returned to the PI for signature
 - If use of Research Space resources is **conditionally approved**, further information will be requested from the PI/ delegated main contact. This should be returned to the Research Space Administration team, who will forward it to the SMT for consideration
 - If use of Research Space resources is **declined**, a reason for this decision will be provided
- The PI must sign the 'declaration' section of the application form and return to the Research Space administrator, keeping a local copy
- Use of Research Space resources will be permitted once this process has been completed (note: all other regulatory approvals must be in place before any research activity can commence).

6. Flowchart

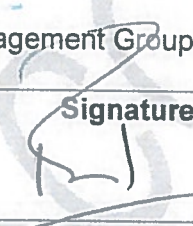


7. Related documents & References
8. List of Appendices

Appendix A: Application for use of Research Space Facilities

Appendix B: Email Response Template

9. Approval and sign off

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT			
Author:	Sally Batham	Job Title:	Research Space Lead 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)
Sept 2017	1.1	Sally Batham, Christina Daines, Aidan Dunphy & Adam Lewszuk	Update of scope and responsibilities, rewording of some procedures, reformatting, addition of flowchart.
DISTRIBUTION RECORD			
Date	Name	Department	Received

APPENDIX A: APPLICATION FOR USE OF RESEARCH SPACE FACILITIES

Study authorisation is required before commencing any procedures within the Research Space, LRI.

Please Note: Charges may apply

Study Title:	EDGE ID:
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Office Use
Only

APPLICANT

Research Team:	UHL Cost Centre:
Principal Investigator:	
Main research team contact	Name : _____ Job title: _____
	Contact number: _____

STUDY DETAILS

Sponsor:		
Start date:	End date:	Local recruitment target:
Funding type:	Commercial <input type="checkbox"/>	Non-Commercial <input type="checkbox"/>
		Non-funded <input type="checkbox"/>
Portfolio adopted?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

RESOURCES REQUIRED

Clinical room <input type="checkbox"/>	Consumables (<i>blood bottles etc.</i>) Supply own <input type="checkbox"/> Not required <input type="checkbox"/>
	Phlebotomy chair <input type="checkbox"/>
	BP monitor <input type="checkbox"/>
	IV infusion pump <input type="checkbox"/>
	ECG machine <input type="checkbox"/> Supplied by study? Yes <input type="checkbox"/> No <input type="checkbox"/>
	Weighing scales <input type="checkbox"/>
	Height measure <input type="checkbox"/>
	Urine dipsticks <input type="checkbox"/>
	Pain distraction* <input type="checkbox"/> <i>*Children's studies only</i>
	UHL desktop PC <input type="checkbox"/>
	Other (please specify): _____
	Approximate uses per month: _____
	Approximate length of each study visit (hours): _____
Study stock <input type="checkbox"/>	Limited storage is available for study consumables (<i>charges may apply</i>)
Meeting room <input type="checkbox"/>	Frequency: _____

LABORATORY EQUIPMENT REQUIREMENTS

 Office Use
Only

 RPM
conversion:

 Capacity?
Yes No

 Capacity?
Yes No

Centrifuge <input type="checkbox"/>	Sample type* Whole blood <input type="checkbox"/> Urine <input type="checkbox"/> Other: _____ Rotor speed: _____ g or _____ RPM Refrigerated centrifuge required? Yes <input type="checkbox"/> No <input type="checkbox"/> <i>*Purchase of additional centrifuge adapters may be required if using non-standard sample bottles. Costs will be charged to the study team.</i>	
Sample storage <input type="checkbox"/>	Fridge: Yes <input type="checkbox"/> No <input type="checkbox"/> Freezer: -20°C <input type="checkbox"/> -80°C <input type="checkbox"/>	Sample type: Container size (LxWxH): _____ cm Total containers: Length of storage (months):
CTIMP storage <input type="checkbox"/>	Fridge: <input type="checkbox"/> Cupboard: <input type="checkbox"/>	Container size (LxWxH): _____ cm Total containers:
Out-of-hours laboratory access required? Yes <input type="checkbox"/> No <input type="checkbox"/>		

If lab equipment/storage is required, please provide emergency contact details in case of equipment malfunction.

Emergency contact name : _____ Job title: _____

Contact numbers _____ Daytime: _____

Out-of-hours: _____

PERSONAL PROTECTIVE EQUIPMENT (PPE)

- The following PPE is available within the facility:
- Disposable Aprons
 - Latex Gloves
 - Eye protection
 - Cryo gloves

Any additional PPE (including latex-free gloves) will need to be provided by the study team

SUPPORTING DOCUMENTATION

Please provide any available supporting documentation

Protocol or Study Outline Attached

Laboratory manual Attached

DECLARATION BY PRINCIPAL INVESTIGATOR (TO BE SIGNED ONLY IF APPROVAL GIVEN)

I understand that the use of Research Space facilities and equipment is at the discretion of the Senior Management Team and that availability cannot be guaranteed. I accept that a charge may be incurred to cover overheads (e.g. training, equipment maintenance). I will ensure that staff working on this study are familiar with all relevant local/Trust policies and procedures and have completed all required training before commencing any work within the facility. I understand that persistent breaches of policy may result in approval being revoked.

Name: _____

Signature:

Date: _____

Please email completed application form and documents to: clinical.research@uhl-tr.nhs.uk or post to:
 Research Space, Balmoral Building Level 0, Leicester Royal Infirmary, Infirmary Close, Leicester LE1 5WW

OFFICE USE ONLY

Date of review:			
Reviewed by:			
Decision:	<i>Fully Approved</i>	<i>Fully Approved</i>	<i>Fully Approved</i>
	<i>Conditionally Approved</i>	<i>Conditionally Approved</i>	<i>Conditionally Approved</i>
	<i>Declined</i>	<i>Declined</i>	<i>Declined</i>
Charges summarised:			
Charges outcome:			

APPENDIX B: EMAIL RESPONSE TEMPLATE

1. ACKNOWLEDGEMENT OF RECEIPT

Dear {PI},

Your application for use of Research Space facilities has been received.

We aim to notify you of our decision within the next two weeks.

Regards,

{NAME, JOB TITLE}

(On behalf of the Research Space Senior Management Team)

2. STUDY FULLY APPROVED

Dear {PI},

I am pleased to inform you that your application for use of Research Space facilities for the {STUDY NAME} has been **fully approved**.

[IF APPLICABLE]: The cost of this service will be {CHARGES SUMMARISED AMOUNT}.

Please sign the attached declaration form if you accept these charges and our conditions of use. Return the completed form to: clinical.research@uhl-tr.nhs.uk or post to:

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

Use of Research Space resources will be permitted once this form has been returned (note: all regulatory approvals/training must be completed before any research activity can commence).

Please do not hesitate to contact me if you have any questions.

Regards,

{NAME, JOB TITLE}

(On behalf of the Research Space Senior Management Team)

3. STUDY CONDITIONALLY APPROVED

Dear {PI},

I am writing to inform you that your application for use of Research Space facilities for the {STUDY NAME} has been **conditionally approved**.

[IF APPLICABLE]: The cost of this service will be {CHARGES SUMMARISED AMOUNT}.

Please could you clarify the following information:

{INSERT QUESTIONS}

Please return the required information to: clinical.research@uhl-tr.nhs.uk or post to:

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

Your application will be reviewed again once this information has been received.

Please do not hesitate to contact me if you have any questions.

Regards,

{NAME, JOB TITLE}

(On behalf of the Research Space Senior Management Team)

4. STUDY DECLINED

Dear {PI},

I am writing to inform you that, unfortunately, your application for use of Research Space facilities for the {STUDY NAME} has been **declined**.

The main reasons for this are:

{INSERT REASONS}

I am sorry we were not able to accommodate your study on this occasion.

Please do not hesitate to contact us if you wish to discuss further.

Regards,

{NAME, JOB TITLE}

(On behalf of the Research Space Senior Management Team)