1. Introduction

Research Space supports a broad range of clinical research studies and provides a range of resources for research staff, including clinical consultation rooms, laboratory facilities for processing and storing samples, clinical and other equipment, and training.

The purpose of this Standard Operating Procedure (SOP) is to outline how the application process is managed from initial enquiry to study start-up. It applies to:

- Principal Investigators (PI) and relevant members of their research teams applying to use Research Space facilities and resources
- Research Space administrators, members of the Senior Management Team (SMT) and any other staff receiving or reviewing enquiries and applications

2. Responsibilities

The **Study PI** (or delegate) is responsible for:

- Ensuring that a Research Space application form is accurately completed and submitted for approval, along with required supporting documents, as early as possible in the study set up process
- Ensuring that any required Research Space resources are available and approved before confirming study feasibility
- Agreeing for storage of loan equipment within Research Space with the SMT, where applicable
- Ensuring that any loan equipment is serviced and maintained in accordance with the protocol and UHL policy, and provide evidence where requested
- Ensuring that any staff using Research Space resources are appropriately delegated and adequately trained to do so
- Signing the PI declaration on the application form once approval is given
- Providing appropriate oversight of studies taking place in Research Space in order to ensure participant and staff safety.

The Research Space **Administration Team** are responsible for:

- Receiving the initial enquiry
- Acknowledging the request by email
- Entering the details of the application onto a spreadsheet
- Filing a copy of the application form and supporting documents
- Passing the application to the SMT for review
- Notifying the appropriate research team of the decision
- Recharging agreed costs

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

- Reviewing applications and considering resource implications
- Carrying out a review of applications in a timely manner
- Considering if a charge is applicable

- Updating the spreadsheet when the outcome is known
- Feeding back decisions via the Research Space administration team

3. Procedure

3.1. Initial application

Any research team wanting to use Research Space facilities or equipment will need to complete an application form (see Appendix A) and submit this by email to the Research Space administration mailbox: uhl-tr.clinicalresearchmailbox@nhs.net

Each application should include the following supporting documentation:

- Current study protocol (or protocol summary / visit schedule if full version not available)
- Details of any amendments in progress, if relevant
- Laboratory manual
- Risk assessment, for higher risk studies (e.g. GMO, ATIMP, Novel, Complex, Early Phase, Infection)

If necessary, supporting documentation can be submitted at a later date if not immediately available, but this may delay approval.

Once an application is received, the administration team will:

- Acknowledge receipt of the application (see Appendix C)
- File a copy of the application and accompanying documentation
- Update application details on local spreadsheet

3.2. Review and Approval Process

The SMT will meet every 1-2 weeks to review the feasibility of all applications, consider costs, update the spreadsheet with the outcome, and feedback the decision to the Research Space administration team.

The spreadsheet will be updated and applicants notified of the outcome by email as follows:

- **Full approval**
  - If access to Research Space resources is **fully approved**, a copy of the original application will be emailed to the PI to sign
  - The PI must sign the 'declaration' section of the application and return to the Research Space administration team
  - Use of Research Space resources will be permitted once the signed form has been received, however all other regulatory approvals must also be in place before any research activity can commence
  - The administration team will file a copy of the approval with the application supporting documents.

- **Conditional approval**
  - Where 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 at the next review meeting.

- **Approval declined**
  - On occasion, use of Research Space resources may be declined. In this case the reasons for this will be provided to the study team.

4. Education and Training

It is the responsibility of individual staff members, their line managers and study PIs to ensure that all research staff using Research Space facilities or resources are adequately trained, familiar with Trust and local policies/ guidelines and have completed a Research Space orientation before commencing any work within the facility.

5. Supporting Documents and Key References

SOP RS-5006 - Research Space Orientation

6. Key Words

Research Space, Facility, Application, Laboratory, Clinical Trials, Equipment

7. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Training requirements and staff folders	Random selection for audit	Juliette Verheyden	As and when	A report will be produced

This line signifies the end of the document

CONTACT AND REVIEW DETAILS	
Guideline Lead: Christina Daines - Children's Research Manager Juliette Verheyden - CRF Operations Director	**Executive Lead:** Professor Nigel Brunskill Director of Research and Innovation

REVIEW RECORD			
Date	Issue Number	Reviewed By	Description Of Changes (If Any)
September 2017	1.1	Sally Bathan Christina Daines Aidan Dunphy Adam Lewszuk	Original SOP
7th January 2026	2	Christina Daines and Juliette Verheyden	• Transferred to new template • Clarified responsibilities for staff training • Revised flowchart to better reflect current process • Added risk assessment to documents for submission • Clarified responsibility for arranging storage and maintenance of loan equipment

			Updated application form

APPENDIX A: APPLICATION FORM

APPLICATION FOR USE OF RESEARCH SPACE FACILITIES

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

Please Note: Charges may apply – tariffs available on request

Study Short Title:	EDGE ID: IRAS no.

Office Use Only

APPLICANT

Research Team: UHL Cost Centre:

Principal Investigator:

Research team main contact — Name : _____ Job title: Contact number:

STUDY DETAILS

Sponsor:

Start date: End date: Local recruitment target:

Funding type: Commercial ☐ Non-Commercial ☐ Non-funded ☐

Higher risk study? No ☐ Yes ☐ *If **Yes**, please select study type and submit a copy of relevant risk assessment for review (e.g. GMO committee, phase 1 risk assessment, local health & safety risk assessment)*	GMO ☐ ATIMP ☐ Novel ☐ Complex ☐ Early Phase ☐ Infection ☐ Other (please specify):

RESOURCES REQUIRED

Clinical room ☐

Consumables (*blood bottles etc.)* Supply own ☐ Not required ☐

- Phlebotomy chair ☐
- BP monitor ☐
- IV infusion pump ☐
- ECG machine ☐
- Weighing scales ☐
- Height measure ☐
- Urine dipsticks ☐
- Pain distraction* ☐ **Children's studies only*
- UHL desktop PC ☐

Other (please specify):

Approximate uses per month:

Approximate length of each study visit (hours):

Study stock ☐	Limited storage is available for study consumables *(charges may apply)*
Loan Equipment ☐	The study team are responsible for ensuring loan equipment is serviced and maintained in accordance with the protocol and UHL policy

Office Use Only

LABORATORY EQUIPMENT REQUIREMENTS

Centrifuge ☐	Sample type* Whole blood ☐ Urine ☐ Other:_____ Rotor speed: _____ g *or* _____RPM Refrigerated centrifuge required? Yes ☐ No ☐ **Purchase of additional centrifuge adapters may be required if using non-standard sample bottles. Costs will be charged to the study team.*	*RPM conversion:*
Sample storage ☐	Fridge: Yes ☐ No ☐ Sample type: Length of storage:	*Capacity?* *Yes* ☐ *No* ☐
	Freezer -20°c: Yes ☐ No ☐ Sample type: Container size (LxWxH): _____ cm Total containers: Length of storage:	
	Freezer-80°c: Yes ☐ No ☐ Sample type: Container size (LxWxH): _____ cm Total containers: Length of storage:	
CTIMP storage ☐	Cupboard: ☐ Fridge: ☐ Dedicated Fridge*: ☐ ** e.g. for GMO or blinded studies*	Container size (LxWxH): _____ cm Total containers: Length of storage:

Capacity?

Yes ☐ *No* ☐

Out-of-hours laboratory access required (before 08:00 or after 17:00)? Yes ☐ No ☐

☐ *If yes, please ensure arrangements are in place to avoid lone working in the lab*

If lab equipment/storage requested, please provide emergency contact details	Emergency contact name : Job title:
	Contact numbers Daytime:

in case of equipment malfunction.	Out-of-hours:

PERSONAL PROTECTIVE EQUIPMENT (PPE)

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

Any additional PPE will need to be provided by the study team

SUPPORTING DOCUMENTATION

Please provide any available supporting documentation:	Protocol or Study Outline ☐ Laboratory manual ☐ Risk Assessment ☐

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

- I understand that the use of Research Space facilities and equipment has been approved for the study outlined in this application, and the use of Research Space for any other studies need to follow the same process.
- I understand that storage of loan equipment within Research Space is by prior arrangement only.
- I will ensure any loan equipment is serviced and maintained in accordance with the protocol and UHL policy, and provide evidence where requested.
- I accept that any applicable charges will be invoiced as outlined below.
- I will ensure that staff working on this study:
  - are familiar with all relevant policies and procedures
  - have completed all required training before commencing any work within the facility.
- I understand that persistent breaches of policy will require additional training and review of facility use.
- I agree to provide appropriate oversight of the study to ensure participant and staff safety.

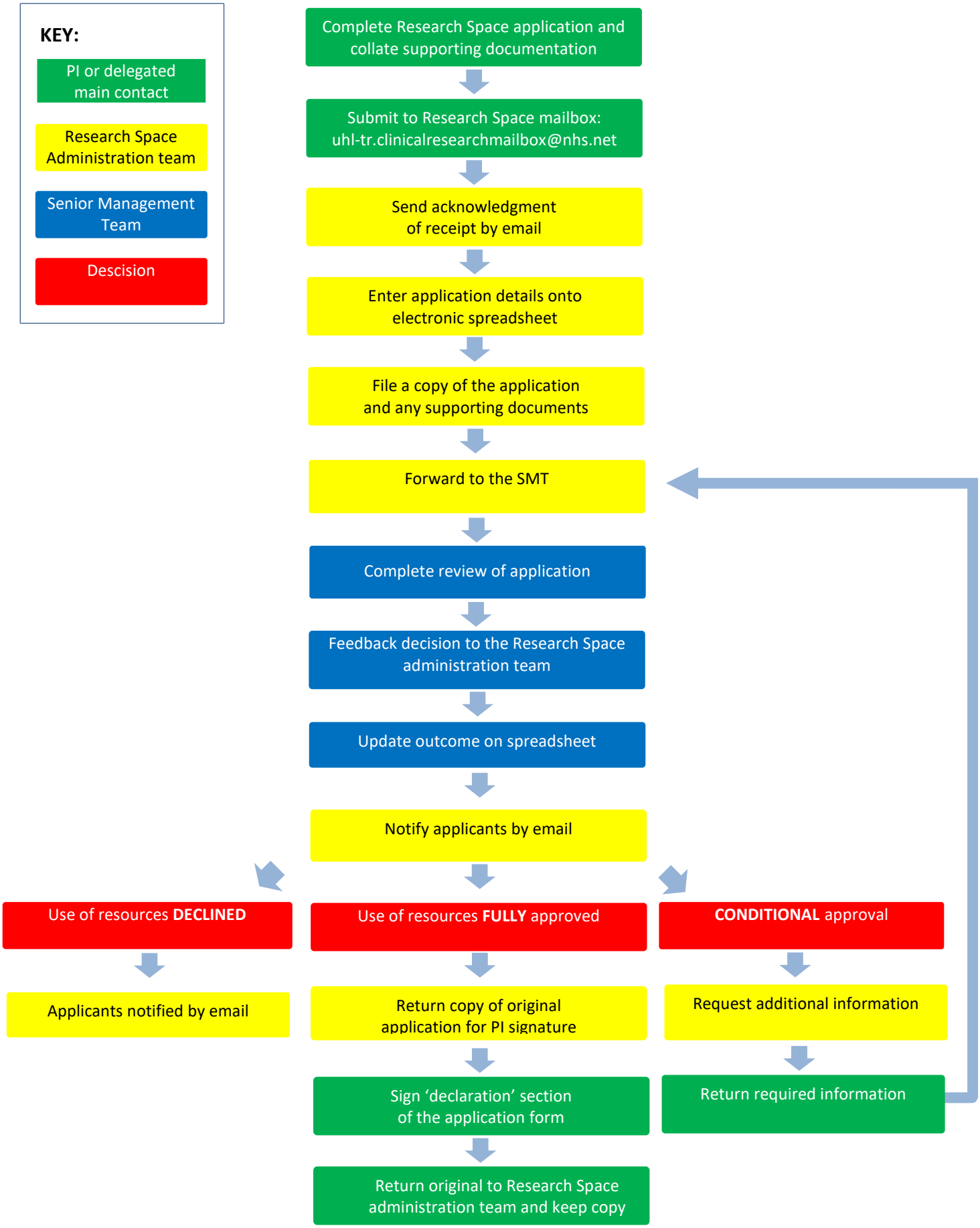
Name: _____ Signature: ☐

Date: _____

Please email completed application form and documents to: uhl-tr.clinicalresearchmailbox@nhs.net

OFFICE USE ONLY			
Date of review:			
Reviewed by:			
Decision:	*Fully Approved*	*Fully Approved*	*Fully Approved*
	Conditionally Approved	*Conditionally Approved*	*Conditionally Approved*
	Declined	*Declined*	*Declined*
Charges agreed :			

APPENDIX B: APPLICATION PROCESS FLOWCHART



APPENDIX C: 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)

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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 ask the PI to sign the attached declaration form to confirm they accept these charges and our conditions of use, then return to:
uhl-tr.clinicalresearchmailbox@nhs.net
Use of Research Space resources will be permitted once the form has been received.

Note: clinic rooms are available for booking within our core hours of Mon-Fri 08:00 to 17:00. Any use outside of these hours is by prior arrangement only. Access is given on the understanding that all regulatory approvals/training are in place before any research activity commences.

Good luck with your trial and 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)

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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: uhl-tr.clinicalresearchmailbox@nhs.net

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)

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4. <u>STUDY DECLINED</u>

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)
