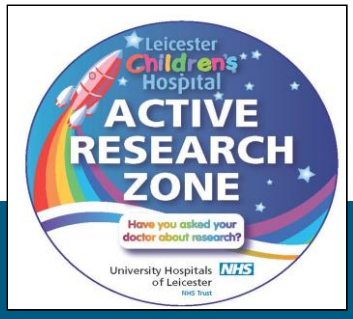
University Hospitals of Leicester NHS
NHS Trust



Clinical Operational Policy

Children's Research Space

March 2018

Version	**Final**
Issue date	**21st March 2018**

Building Caring at its best

Purpose of the Document

This is a live, iterative document which will be refined and developed throughout the lifetime of the project; including OBC development, FBC development and operational commissioning.

The delivery of UHL's capital investment follows a tried and tested route as set out in the NHS Capital Investment Manual and as required by those bodies who will approve business cases (the NTDA and NHS England Project Appraisal Unit (PAU)). Therefore, there are three key processes that projects must pass through in order to achieve business case approval and the flow of funding:

1) The Operational Brief – The function of UHL's activity to illustrate how the Trust want to work in the future
2) The Design Brief – The Operational Brief informs a technical brief and required performance of UHL's built form
3) The Design Solution – The drawn solution which is measured and referenced against the design brief

This Clinical Operational Policy, along with Models of Care and an Activity profile, forms the first process: the Operational Brief. The method above enables a plan, do, check, refine cycle to be followed.

Document Quality Management

Title	Children's Research Space
Date	21st March 2018
Prepared by	Christina Daines, Children's Research Manager
Checked by	Sally Batham, Research Space Manager
Authorised by	Sally Batham, Research Space Manager

Document History

Version	Date Issued	Brief Summary of Change	Author
1.0		Children's Research Manager- Christina Daines updated text from old document	Christina Daines
1.1		Meeting between: Children's Research Manager- Christina Daines Lead Research Nurse/CRU Manager- Sally Batham Deputy Children's Research Manager- Rekha Patel To discuss Trust's organisational structure; service description; hours of service; patient flow; roles and responsibilities	Christina Daines
1.2	17/03/2017	Children's Research Manager- Christina Daines added Management Structure	Christina Daines
1.3	20/03/2017	Meeting between: Children's Research Manager- Christina Daines Service Development Manager- Carmel Angrave To review overall document and add details about clinical and non-clinical support services	Christina Daines
1.4	30/03/2017	Reviewed by Elizabeth Hoyle, Infection Prevention Nurse. Addition of infection prevention information in section 7 and whole trust infection prevention policies in section 4.7.3	Elizabeth Hoyle
1.5	07/04/2017	Reviewed by Donna White, Security and Car Parks Manager. Addition of whole trust security policy to section 4.7.3	Donna White
1.6	25/09/2017	Reviewed by Nick Howlett, Health and Safety Services Manager. Addition of whole Trust Health and Safety Policies to section 4.7.3	Nick Howlett
1.7	02/10/2017	Reviewed by Leila Bahadur, Clinical Trials Pharmacist. Addition of pharmacy procedures to section 6.5	Leila Bahadur
1.8	05/10/2017	Reviewed by Stacey Thrower, Category Specialist, Procurement and Supplies Department. Addition of whole trust Procurement Policies to section 4.7.3	Stacey Thrower
1.9	06/10/2017	Reviewed by David Mitchell, Fire Safety Officer. Addition of fire safety information to section 8.10 and whole trust Fire Safety Policy to section 4.7.3	David Mitchell
1.10	13/10/2017	Reviewed by Helen Knight, Principal Pharmacist Clinical Trials. Addition of Leicestershire Medicines Code to section 4.7.3 and 6.5	Helen Knight
1.11	15/03/2018	Reviewed by Sally Batham, Research Space Manager, on behalf of R&I. Small typos and amendments made throughout the document .	Sally Batham

Non Clinical Sign-off Sheet

Area / Service	Applicable Yes / No	Signature	Name	Date
IT	No			
Infection and prevention	Yes		Elizabeth Hoyle	30/03/2017
Health and Safety	Yes		Nick Howlett	25/09/2017
Emergency Planning	Yes		Aaron Vogel	12/05/2017
Fire Safety Adviser	Yes		David Mitchell	06/10/2017
Security	Yes		Donna White	07/04/2017
Procurement	Yes		Stacey Thrower	05/10/2017
Manual Handling	No			
Partner agencies e.g. LPT, EMAS, Police	No			
CCGs	No			
Training and Education	No			
Research & Development	Yes		Sally Batham	21/03/2018

References & Supporting Documentation

None

Contents

1 | Introduction to 'Research Space'

1.1. Philosophy

'Research Space' is the overarching name for the Adults, Childrens and Genetics Clinical Research Facility (CRF). Research Space houses a shared entrance and waiting area, with separate clinical areas for adults and children.

The development of the Children's Research Space was a stepping stone to the enhancement of two of UHL's Annual Priorities:

- An enhanced reputation in Research, Innovation and Clinical Education
- A clinically sustainable configuration of services, operating from excellent facilities (develop outline business cases for our integrated children's hospital…)

The overarching service objectives of the Children's Research Space are to allow UHL to:

- Improve and optimize patient and family experience of clinical research, their participation and retention to trials, and guarantee studies are conducted according to strict standards of Good Clinical Practice (GCP).
- Significantly support and enhance delivery of the highest quality, smooth, efficient and patient-focused research for children, young people, and their families.
- Considerably augment the capacity of UHL to carry out National Institute for Health Research (NIHR) portfolio commercial and non-commercial studies.
- Conduct an extensive range of research studies. As well as Phase III interventional trials and observational studies, Research Space will strengthen UHL's opportunities for running early paediatric phase (I/II) studies.
- Allow us to pioneer advanced medical treatment for children, and attract patients from further a-field.
- Develop a partnership between Children's and Genetics, which will enable greater income opportunities, and increase recruitment rates.
- Establish UHL as a nationally and internationally recognised centre for Children's and Genetics research excellence.

Our philosophy is "to provide the highest quality research support facilities and service- in conjunction with both commercial and academic partners- for the benefit of all patients within the NHS- from the youngest to the oldest."

1.2. Principles of Care

- High quality care delivered by a highly-trained and educated workforce resourced to meet the projected volume and range of clinical trials
- Flexibility of resources, both physical, human and IM&T to deal with changing workloads and range of studies
- Design for patient safety, privacy & dignity, including age specific facilities for children, young people and their families
- Minimisation of patient, staff and goods moves
- Minimisation of steps in processes
- Integration of assessment processes
- Optimised use of technology, including integrated IT using the skills and expertise of professional staff flexibly
- Access to senior clinical opinion from the earliest point in the patient pathway and onwards
- Provision of high quality family centred care
- Close proximity of functions to support all areas e.g. Childrens Services, labs
- Generic design of facilities to ensure maximum flexibility of use.

It is recognised that the models of service delivery adopted will alter over time. It is therefore essential that the facilities can respond to future changes in the technology surrounding the relevant services within the area but also the changes in clinical and service models within the clinical services to which the area provides support.

2 | Objectives & Scope

2.1. Objectives

This policy is designed to:

- Assist all healthcare professionals involved in the provision of research.
- Outline the purpose and function of the clinical services provided in the Children's area of Research Space and its inter-relationship with Children's services, the Adult area of the facility, and Research and Innovation (R&I)
- Ensure that all staff using the facility understand the philosophy of the service and work as a team, with a comprehensive understanding of patient flow upstream and downstream
- Describe the service flow into, through and out of the department
- Describe the services as they will be delivered for the future
- Inform the design of Research Space
- Describe the purpose and function of the accommodation required
- Identify adjacencies/co-locations required for the service delivery
- Signpost requirements for business continuity
- Outline legislative and mandatory requirements for the delivery of services

2.2. Scope

The scope of this document is to provide an operational policy for the provision of a Children's CRF. This document outlines the operational use of the shared and children's areas of Research Space.

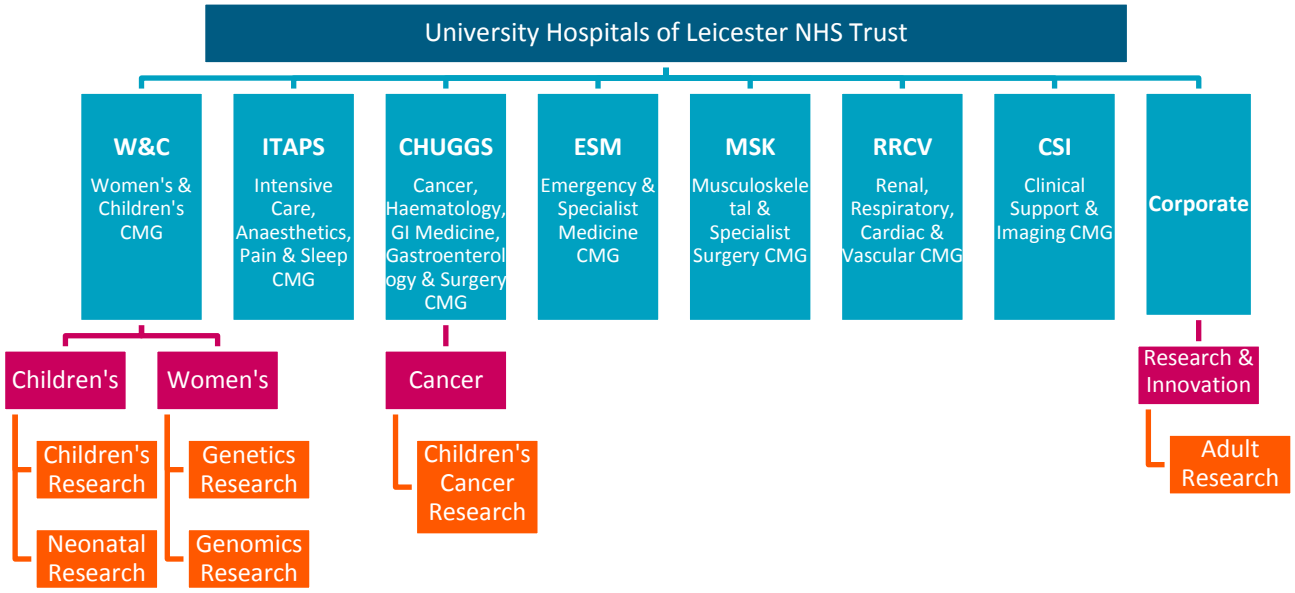
The impact on other services will be positive, as Research Space will remove bottle necks and free up clinical time by conducting research outside of the usual outpatient's clinics.

Having an overarching area to conduct research for adults and children, with a shared entrance, waiting area, and laboratory, will help to:

- Optimise the experience of our patients when they take part in clinical research
- Encourage participants to join and remain on our clinical trials
- Enhance the reputation of the Trust for conducting the full remit of clinical research in specially designed area
- Bring income into the Trust
- Allow research to be branded and sign posted at UHL
- Ensure facilities are shared, as appropriate
- Provide a focus for genetics research, the 100,000 Genome Project and the dawn of personalised medicine

3 | Definitions

This Policy covers the Children's area of Research Space. The following structure chart shows where the service sits in the Trust's organisational structure:



3.1 Abbreviations and Glossary of terms

Term	Definition
100,000 Genome Project	A Government funded project to sequence 100,000 genomes from patients with cancer, rare disorders, and infectious disease, and to link the sequence data to a standardised, extensible account of diagnosis, treatment, and outcomes
CAU- Children's Admissions Unit	A 24-hour unit for children who have been referred by their GP, the Children's Emergency Department or other route
Commercial studies	Research that is funded and sponsored by a commercial organisation e.g. a pharmaceutical company

CRF- Clinical Research Facility	Facility to conduct and support clinical research with consulting rooms, medical equipment, and research staff
Clinical Trials	A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions
ECG- Electrocardiogram	A test to check the heart's rhythm and electrical activity
ED- Emergency Department	A 24 hour unit providing emergency care for adults and children
GCP- Good Clinical Practice	A set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects
ICH-GCP- International Conference on Harmonisation (Europe, USA, Japan)	Defined standards for the terminology, design, conduct, monitoring, recording, analysis and reporting of a study. These standards give assurance that the reported results are accurate and credible and that the rights, integrity and confidentiality of all study participants have been protected throughout the study
IM&T- Information Management and Telecommunications	
Interventional study	A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions
Investigators Brochure	A document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product which are relevant to the study of the product in human subjects

NIHR- National Institute for Health Research	Established by Department of Health for England in 2006 to provide the framework through which DH will position, manage and maintain the research, research staff and infrastructure of the NHS in England as a virtual national research facility
Non-commercial studies	Research that has not been funded or sponsored by a commercial company
Observational studies	A clinical study in which participants identified as belonging to study groups are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to specific interventions
OPD- Out Patients Department	Clinic to see children or adults on an out-patient basis
Phases of a trial	The phases of a clinical trial can generally be categorised in the following terms: • Phase I - Human pharmacology • Phase II - Therapeutic exploratory • Phase III - Therapeutic confirmatory • Phase IV - Therapeutic use
PI- Principal Investigator	The Investigator responsible for the research site where the study involves specified procedures.
PIC sites- Participant Identification Centre	NHS or other organisation which only identifies participants from a database etc., but recruitment/receiving consent and study conduct are managed elsewhere
R&I- Research & Innovation	Department within NHS hospitals giving permission to conduct projects on those facilities with patients/staff
Randomisation	A clinical study in which two (or more) forms of care are compared; the participants are allocated to one of the forms of care in the study, in an unbiased way
Research Governance Framework	Defines the broad principles of good research governance and is key to ensuring that health and social care research is conducted to high scientific and ethical standards

4 | Service Description

4.1. Access

Research Space has a shared main entrance for adults and children, which will be open during office hours. Out of hours the main entrance can be accessed via a secure key pad by research staff.

All visitors will report to the reception desk:

- Patients and families will be booked into the facility via the CRFManager software system and asked to sit in the Waiting Area.
- UHL staff visiting Research Space will be asked to sign in and out via the reception desk. They must wear and clearly display their UHL badge at all times whilst in the facility.
- Non-UHL staff visiting Research Space will be asked to sign in and out and will be issued with a Visitor's Badge, which must be clearly displayed at all times.

The Waiting Area is a shared facility suitable for both adults and children. It is expected that the majority of children will be accompanied by an adult. Any unaccompanied teenagers (below 18 years) will be provided with alternate accommodation in the secure Children's area of Research Space. The CRFManager software system will be used to confirm the patient's age.

Visitors will be collected from the Waiting Area by a member of the appropriate research team and escorted through the secure double doors into the Children's area of Research Space. The Children's area is accessible via a swipe card issued to Research Space staff only or by door release from reception. Swipe cards to new Research Space staff will only be authorised by the Children's Research Manager and Research Space Lead via the standard UHL process.

In the event of an emergency, the secure doors to both the Children's and Adult areas of Research Space can be released by the reception desk.

Research staff who are purely using the lab facilities in the Adult area of Research Space, can access this area via a coded key pad.

Children and families will be seen in the Children's area of Research Space; adults will be seen in the Adult area of Research Space.

4.2. Activity

The Children's Research team recruited over 600 participants in 2015/2016. Research Space would have been suitable for many but not all of these participants. Expected usage is variable depending on the nature of the portfolio of studies actively running at any one time.

The Genomics Project team have recruited over 400 participants so far to the 100,000 Genome project.

4.3. Third Party Providers

Research Space will not be suitable for all studies or all study visits for a particular clinical trial.

Research activity may therefore also take place outside of Research Space in a number of different locations, including but not limited to:

- Children's Admissions Unit
- Children's Development Centre
- Children's Intensive Care Unit
- Children's Out Patients Department
- Children's Wards
- Emergency Department
- Glenfield Hospital
- Leicester General Hospital
- Neonatal Unit

In addition not all procedures, assessments and research related processes will occur in Research Space, for example:

- Imaging
- Labs

4.4. Hours of Service

The service will predominantly operate from Monday to Friday between the hours of 08:30- 17:30. The reception desk will be manned by an Administrator until 16:15. Any visitors who are expected after this time will be greeted by a member of the appropriate research team, who will ensure the appropriate booking-in system is completed, as per section 4.1 above.

There may be weekend or late night usage required, which will be undertaken following standard UHL risk assessments being carried out. Staff working after the Administrator leaves will ensure that the main entrance and any others areas of Research Space are secured before leaving.

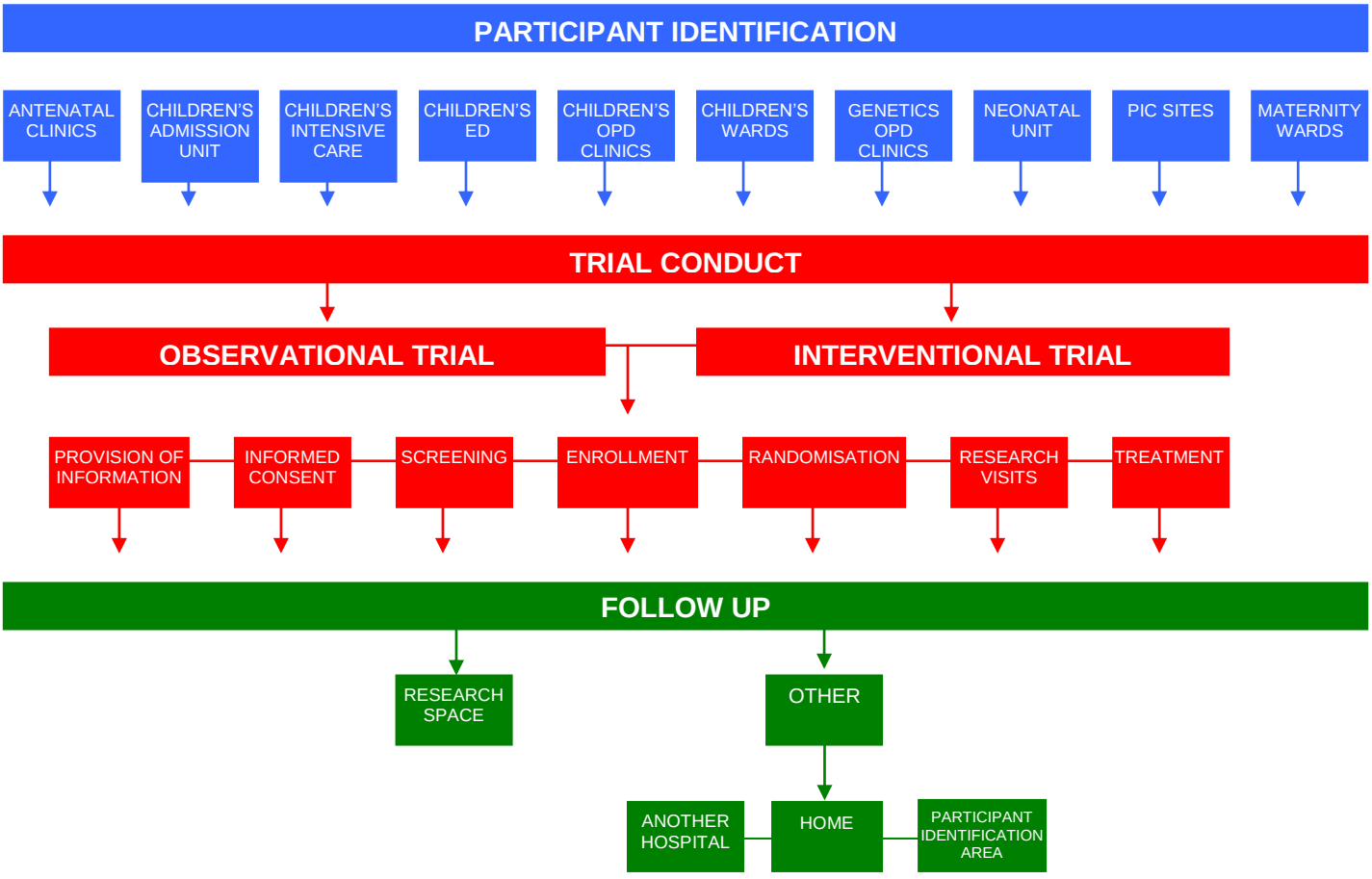
4.5. Patient Flow

Participants are identified through a variety of routes, depending on the nature of the trial. They are usually existing/new patients, but family members and healthy controls may also be recruited to some of the studies.

The nature of contact with the participant will then vary depending on the type of study. Not all of these aspects will apply to every participant or trial, and the amount of work required and number of visits needed will vary considerably.

Most trials require a follow up period, but this may comprise of one visit at the end of study or may involve many years of follow up. Follow up can be conducted in various ways, and once the trial follow up is complete, the participant will return to their usual pathway.

4.5.1 Patient Journey



4.5.2 Patient Placement

All patients/participants attending Research Space will be outpatients. The majority of patients will attend for a short visit, but some patients may have a long or all day visit. This ratio could change in the future as the number of commercial studies being run in Research Space increases, with the impact of longer visits for the research participants.

4.6. Escalation & Business Continuity Plans

In the event of a fire, research patients would be seen in an alternate appropriate area within UHL e.g. Children's Outpatients.

In the event of equipment failure, children may still be seen in Research Space if other equipment is available to use. If not, the equipment could be borrowed from another children's area within UHL, or the procedure could be undertaken elsewhere.

In the event of IT failure, it may still be possible to see the child within Research Space, depending on the nature of the visit. If required, IT equipment would have to be accessed elsewhere within UHL.

In the event of a critical incident, Children's Research Space staff will follow the Policy for Continuity of MCRN East Business.

4.7. Adjacencies

4.7.1 Within the Children's Research Space

Children's Research staff will attend Research Space as scheduled via CRFManager to meet the needs of the allocated clinical trials. They will need to maintain close working relationships with the following personnel to coordinate their attendance within Research Space and the requirements for each individual study:

- Administrator
- Clinicians
- Phlebotomists
- Play Team
- Specialist Nurses
- Adult Research Space Team
- Genetics Research Team
- 100,000 Genome Project Team
- Children's Cancer Research Team
- Neonatal Research Team

Patients/participants and their families will arrive, access and leave Research Space as follows:

- Enter via the main entrance and report to the reception desk
- Asked to sit in the Waiting Area until collected by a member of the research team and escorted through the secure double doors into the Children's area of Research Space.
- Undertake study specific visit in appropriate room(s)
- Once the visit is complete, they will be returned to the main entrance by a member of the research team.

4.7.2 External to the Children's Research Space

Key links are required with the following departments:

- Pharmacy
- Labs
- Children's Wards
- Emergency Department
- CAU
- Imaging
- Theatres
- ECG
- Medical Physics
- Children's Management
- Clinical Research Network

Non-clinical services are also required, including:

- Catering
- Domestic Services
- IM&T
- Portering
- Transport
- Waste management

4.7.3 Whole Hospital Policies

- UHL infection prevention policies
- UHL Healthcare Environment Cleaning Policy and Procedures
- UHL Security Policy
- UHL Health and Safety Policy A17/2002
- UHL Risk Assessment Policy B12/2002
- UHL Procurement Policies
- UHL Fire Safety Policy A7/2002
- Leicestershire Medicines Code

4.8. Service Development

In line with UHL's strategy, it is anticipated that Research Space will help to enhance the development of the new Children's Hospital.

For Children's Research, the development of the children's area of Research Space will strengthen UHL's opportunities to conduct early phase (I/II) clinical trials.

5 | Proposed Accommodation

5.1. Entrance and Waiting Area

The Children's and Adult areas of Research Space share the main entrance and waiting area. It includes a manned reception desk for the booking-in of all visitors. A large open-plan waiting area includes a range of comfortable seating and height adjustable tables for children and adults to play, work, or relax. It is a bright colourful space, equipped with games, toys and entertainment facilities. A water cooler will be provided for research staff and visitors.

5.2. Consultation Rooms

Within the secure Children's area are two consultation rooms. These are multi-functional rooms equipped with a tilting dialysis chair, which can be used for the patient to sit up, recline, or lie down comfortably for the following purposes:

- Cannulation
- Phlebotomy
- Examination
- Setting up intravenous infusions
- Administering Investigational Medicinal Products (IMP)
- Observation

Comfortable seating will provided for consultations, along with a desk, PC, IM&T and office chair.

Clinical equipment will be provided for use in each room:

- Monitor/ dynamap
- Thermometer
- Stethoscope
- Procedure trolley
- Over-bed table

5.3. Treatment Room

Within the secure Children's area is a larger version of the consultation rooms. The Treatment Room is suitable for longer visits, or to accommodate larger family groups. It is equipped as per the consultation rooms, with the addition of the following items which will be stored in the Treatment Room but may be transferred for use to the Consultation Rooms, as required:

- Locked drug fridge
- Mobile examination light
- Ophthalmoscope
- Otoscope
- Urinalysis machine
- Emergency equipment (oxygen)

5.4. Consent Room

Within the secure Children's area is a multi-functional softly furnished room with additional sensory lighting equipment, which can be used for:

- recruitment and consent discussions
- study counselling and consultation
- play specialists to prepare children for protocol procedures to reduce anxiety and increase compliance.

5.5. Office

Within the secure Children's area is a small office suitable for up to 4 members of the research team. This office will house the Children's Research Manager, with additional hot desks for other research staff to undertake administrative duties whilst working in Research Space. It is equipped with benching, PCs, IM&T, office chairs, and secure storage facilities.

5.6. Corridor

The secure children's clinical corridor is a brightly coloured space themed area, which leads the families to their destination. It includes the following equipment for ease of access:

- Weighing scales
- Height measure
- Portable suction

5.7. Toilet

A children's toilet is provided within the secure Children's area, along with a baby changing unit. Adults may use the nearby toilets which are directly opposite Research Space. Disabled toilets are available on the first floor of the Balmoral Building, which can be accessed by the nearby lift outside Research Space.

5.8. Laboratories

The labs in the adult area of Research Space are used for many of the studies, as this comprises centrifuges, fridges and freezers for the processing and storage of samples. The lab can be accessed by Research Space staff via their swipe cards.

For more complex processes, the labs in the Sandringham Building will be utilised.

6 | Clinical Support Services

6.1. Medical Equipment

- A variety of medical equipment is in use within 'Research Space' and therefore there is a need for onsite access to medical physics for maintenance and repair etc.

6.2. Healthcare Records (EPR & EDRM)

- Access to EDRM and other electronic system will available via IM&T.
- Paper healthcare records will be stored in the unit in a secure staff-only area of Research Space.

6.3. Diagnostic Imaging

- The majority of diagnostic imaging required for study purposes will be undertaken within the relevant department.
- There are a small number of diagnostic tests that take place within Research Space, and if this is the case these tests will be conducted by trained members of staff using the appropriate equipment.
- Results of diagnostic tests will be available on the relevant Hospital system.

6.4. Pathology & Near Patient Testing

- Straightforward sample processing is conducted by trained research staff within the laboratories housed in the adult area of Research Space.
- More complex pathology processes are conducted by specialist staff with the Sandringham laboratories.

6.5. Pharmacy

- Nearby pharmacy services for dispensing of trial related and outpatient medication is required.
- Within the children's area of Research Space:
- A centrally-monitored temperature-controlled calibrated drug fridge is available as a short or longer term storage for trial related medicinal products.
- A locked medicines cupboard is also available for investigational medicinal products (IMP) required to be stored at an ambient temperature. This is available for short term IMP storage only, and is temperature assessed by pharmacy prior to approval for each individual trial.
- A small stock of medications e.g. Emla cream, as well as other trial related medications e.g. Cetirizine, or allergens required specifically for each study may also be kept in Research Space.
- A number of security measures are in place:
    - A swipe card is required to enter the children's clinical area
    - The drug fridge and medicine cupboard are located in the treatment room, which can only be accessed via a digital key coded door
    - The drug fridge has a digital lock
    - The medicines cupboard is locked by a key which is kept in a digital key box in the children's clinical corridor
    - IMP and trial related stock levels are checked on a weekly basis by the Research Nurse/Officer supporting the trial
- All products are stored in accordance with the Leicestershire Medicines Code

6.6. Phlebotomy

- Phlebotomy is provided in-house within Research Space, on the wards and in Medical Day care.

6.7. Therapies

- Play Therapy will be provided by the Play Team on a rota basis as part of their research funding.

6.8. Third Party Providers

- Some research related equipment maybe provided by a third party for a short or long term period.

- All relevant equipment are checked by Medical Physics prior to use.

6.9. Sterile Supplies

- The Research Space Administrators order all stock items for Research Space, as required.
- A list of requirements for the children's area are provided for this purpose, along with a contribution towards the costs.

6.10. General Medical Supplies

- The Research Space Administrators order all stock items for Research Space, as required.
- A list of requirements for the children's area are provided for this purpose, along with a contribution towards the costs.

6.11. Manual Handling

- All design solutions must incorporate any legislative requirements for manual handling include where required lifting equipment, adequate circulation space at the bedside/clinical area for the use of manual handling aids.
- All staff are required to do manual handling training specific to their role.

7 | Infection Prevention

- All areas must be approved for use and purpose by the UHL Infections Prevention team and comply with all appropriate HBN Infection control in the built environment. Any change to the rooms must be signed off by the infection prevention lead for the Trust.
- All UHL infection prevention policies are available via the UHL internal website and must be followed. They outline the Trust's policies regarding hygiene and minimising the risk of cross contamination.
- Clinic rooms are cleaned thoroughly between each clinic session. More frequent cleaning may be required depending upon the cohort of patients involved in the trial.
- Cleaning was agreed with the Estates and facilities department prior to opening the facility and the cleaning standards will be monitored by the department and cleaning team as per UHL Healthcare Environment Cleaning Policy and Procedures.
- Patient infection alerts are flagged on patient centre and the research team can contact the UHL infection prevention team for advice on how to manage patients with known or suspected infections within the department.

8 | Non-Clinical Support Services

8.1. IM&T

- All areas will have the appropriate amount of IM&T equipment to perform the task applicable to the area.
- PCs will be available within the hot-desking staff office, consultation rooms, and treatment room.
- A printer/ fax machine/ photocopier will be available in the adult area of Research Space.
- Wi-Fi access is provided by WIFI Spark for children, young people, and parents/carers for entertainment and work purposes.

8.2. Transport

- Children and young people are usually be transported to/from Research Space by their parent or carer.
- If transport is required, this will arranged by the relevant Research Nurse/Officer.

8.3. Portering

- If portering services are required for children or young people, this will be arranged by the relevant Research Nurse/Officer.
- For non-patients, a request will be made to the Children's Hospital caretaker.

8.4. Catering

- In the unlikely event that catering will be required, an order will be placed to the catering team along with the appropriate cost code.

8.5. Linen

- Disposable curtains will be replaced every 6 months, or sooner if they are visibly soiled.

8.6. Domestic Service

- Clinical cleaning will be conducted as per UHL Policy, by Domestic Services.

8.7. Maintenance

- As all equipment will be new, it will be under warranty initially.
- Once the warranty period has ended, any maintenance will be undertaken through facilities.

8.8. Security

- All locations dealing with Children will be compliant with any current or known forthcoming legislation and will need to comply with current safeguarding and UHL security policy.
- The entrance to the Children's area will have access/egress control via swipe card for authorised users only. Swipe card access will be limited to Research Space staff only.
- Visitor access will be via remote lock release from the office, facilitated by visual site from the access/egress point.

8.9. Fire Safety Information

- The Fire Warning and Detection System in the Research Space is linked to the main site system.
- All staff undergo fire safety training as part of their mandatory training.
- Research Space has an up to date Fire Safety Risk Assessment and this will be reviewed periodically by the UHL Fire Safety Advisors.
- The emergency evacuation procedure, covering what to do in the event of discovering a fire, hearing the alarm (Continuous and Intermittent) and the actions to take, is displayed throughout Research Space.
- All staff are made aware of the local emergency evacuation procedures and this is highlighted to new staff during the local induction process.

8.10. Waste Management

- Appropriate waste holding facilities are housed outside of Research Space.

9 | Roles and Responsibilities

Medical

Consultants/Specialists

The role of the Children's and Genetics Consultants/Specialists is to provide specialist and general medical care to adults and children. Within Research Space, they will be responsible as either the Principal Investigator (PI) or co-investigator for the studies which they are involved in.

The PI must be qualified by education, training and experience to assume responsibility for the proper conduct of the clinical trial at the site. They must be thoroughly familiar with the appropriate use of the study drug(s) as described in the protocol and Investigator's Brochure, and are responsible for all trial related medical decisions. They must be aware of and comply with GCP and all regulatory requirements and conduct the trial in compliance with the protocol. They must ensure that all persons assisting with the trial are adequately informed about the protocol, the study drug(s) and their trial related duties**.** They are responsible for obtaining and documenting informed consent in compliance with the regulations and GCP. The PI may delegate some of these duties/responsibilities but retains ultimate responsibility.

Nursing

Research Nurses/ Officers

Children's Research Nurses and Research Officers are each responsible for a defined accountable caseload of studies from study set up (including costings for commercial studies) to archiving of closed studies. They identify and recruit patients into clinical research studies and perform relevant study related procedures which may include:

- providing information
- taking informed consent
- taking bloods
- performing ECG's, basic observations, and other tests in accordance with the corresponding study protocol.

They support the safe conduct of research through compliance with the Research Governance Framework, and for clinical trials in accordance with the International Conference on Harmonisation – Good Clinical Practice (ICH – GCP) guidelines and to provide assurance that the rights, safety and well-being of trial participants are protected. They are accountable for the assessment, planning, organisation and ongoing care of research participants, whilst maximising compliance. They extend their experience to support others involved in research and assist with the training of professional staff and to conform to protocol and practice guidelines.

Specialist Nurses

Specialist Nurses provide support to a number of clinical studies. They help to ensure patients and families are given the right information surrounding their clinical condition and ensure continuity of care throughout and following the trial. They are responsible for providing specialist care/expertise to compliment the research expertise provided by the study team.

Management and Administration

Research Manager

The Children's Research Manager is responsible for developing, maintaining and performance managing a balanced portfolio of Children's clinical trials at UHL. They manage and lead a multi-disciplinary team of Children's research staff. They work closely with the Speciality Research Lead to shape the vision and future development of research within their service. They are responsible for overseeing the operational research performance of their service, including staff allocation following feasibility assessments. They ensure that all financial income is recouped by the appropriate personnel, and plan how generated income should be utilised. They are also responsible for working on corporate research projects to meet the needs of the service.

Research Assistants

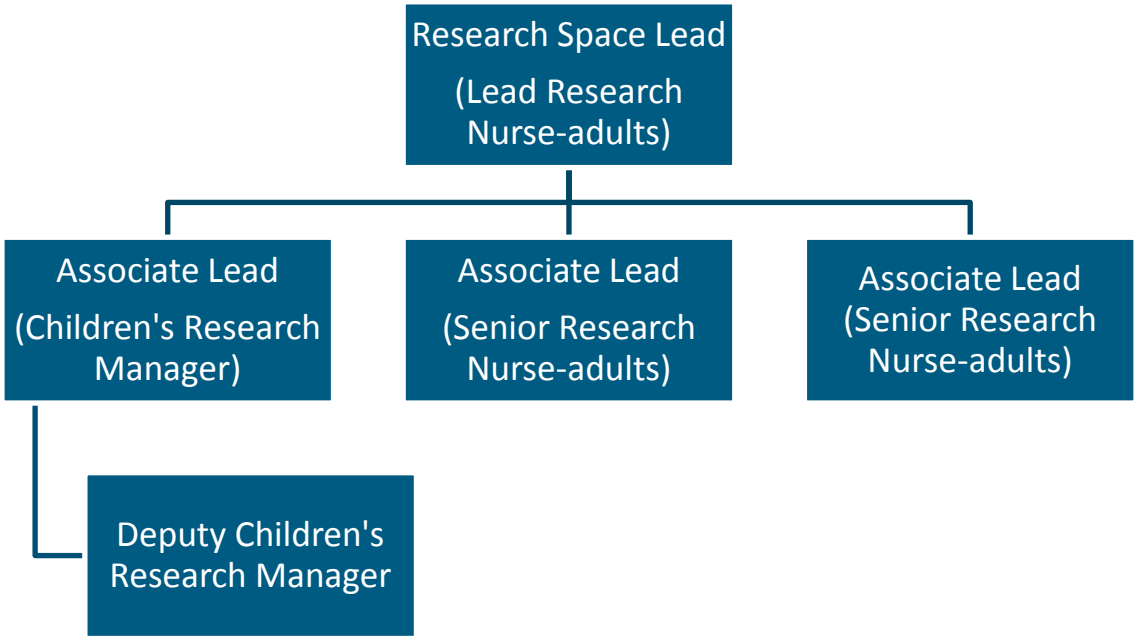
Research Assistants are responsible for supporting a portfolio of clinical trials from study set up to archiving in accordance with the clinical trial protocol and Good Clinical Practice. Their role includes:

- assisting with preparation and submission of documents to obtain Trust authorisation
- collecting, recording and maintaining data for patients on clinical studies
- providing clinical and administrative support to Research Officers/Nurses by organising tests and investigations, preparing and shipping samples, and assisting with recruitment
- other general administrative team related responsibilities

They may also support, and be responsible for, relevant studies in their own right.

Management

The management structure for Research Space is outlined below:



Skill Mix

	Overall head count	**Whole time equivalent (WTE)**	**No. of staff on duty**
Consultants/Specialists	Variable	Variable	3 max
Research Nurses/Officers	9	7.4	0-9
Specialist Nurses	Variable	Variable	3 max
Research Managers	1	0.8	1 max
Research Assistants	2	1.6	2 max

9.1. Equality and Diversity

The Trust recognises the diversity of the local community and those in its employ. Our aim is, therefore, to provide a safe environment free from discrimination and a place where all individuals are treated fairly, with dignity and appropriately to their need. The Trust recognises that equality impacts on all aspects of its day-to-day operations and has produced an Equality Policy Statement to reflect this. All policies are assessed in accordance with the Equality initial screening toolkit, the results for which are monitored centrally.

9.2. Training & Awareness

This Policy will be sent to all members of the research/project teams who will be utilising the children's areas of Research Space.

If specific training is required for any of the aspects contained within this Policy, this will be provided during Team Meetings, Mandatory Training, or bespoke training sessions.

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