

## STANDARD OPERATING PROCEDURE Paediatric Population Using LCRF

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### RESEARCH AND DEVELOPMENT



### BACKGROUND

Children routinely attend NIHR Lancashire Clinical Research Facility (LCRF) for appointments with Paediatric Research Nurses, Allied Health Professionals or Midwives (referred to hereafter as health care professionals) as part of their participation in paediatric research studies. Sometimes, children with physical and/or learning disabilities will attend LCRF for appointments. The staff who are based in LCRF and Research and Innovation (R&I) Department are predominately adult Nurses, Medics and AHPs. There are many differences between adults and children that health care professionals (HCPs) must be aware of when children are attending LCRF for appointments.

### PURPOSE/OBJECTIVE

The purpose of this SOP is to detail the basic knowledge and training requirements of staff to facilitate paediatric patients to attend LCRF.

### SCOPE

This SOP applies to all research personnel working with children in LCRF.

### PROCEDURE

#### 1. WHO?

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- All research personnel who see children in LCRF for assessment or intervention as part of a research protocol.
- LCRF and R&I staff who provide emergency clinical cover to LCRF.
- LCRF and R&I staff who work in the LCRF or R&I office.
- The Principal Investigator is responsible for ensuring that their own training, knowledge and competencies are up to date as well as those of the LCRF team and any delegated personnel on the study delegation log, before arranging to see a child in the LCRF.

## 2. WHEN?

This SOP must be followed at all times when arranging to see children as research participants in LCRF.

## 3. HOW?

### STAFF TRAINING

- All Principal and Sub Investigators will complete Paediatric Basic Life Support (PBLS) and update on an annual basis.
- All Principal and Sub -investigators will ensure that they adhere to LTHTR's safeguarding supervision policy, attending formal supervision with staff from the safeguarding team on a quarterly basis.
- All Principal and Sub investigators will complete level 3 safeguarding children every 3 years.
- All staff who work in LCRF or R&I office will complete level 2 safeguarding children every 3 years.
- Training on children with learning disabilities e.g. awareness of sensory processing needs, communication, social interactions etc. can be delivered by Paediatric Research Physio if appropriate/required in relation to a specific study.

### MANAGING UNEXPECTED ILLNESS

- The PI is responsible for ensuring medical cover is available for the participants within the study at all times as specified in LCRF-SOP-22. Medical cover must be prearranged by the PI and the name and contact information of the on-call paediatrician must be provided to the nurse /AHP responsible for the study. The Health Care Practitioner (HCP) seeing the paediatric patient in LCRF must inform the on-call paediatrician (via switchboard) of the disabilities/conditions of the patients attending that day.
- If a patient attending LCRF complains of new or worsening symptoms, the treating HCP must signpost to the relevant service e.g. Primary Care, Paediatric Emergency Department.
- If within HCP's scope of practice, a set of clinical observations must be recorded on a PEWS form to guide clinical decision making.
- The HCP must contact the Principal Investigator (PI) or on call Paediatrician to ensure no further action is required and/or it is safe to proceed with the study assessment or treatment. HCPs can use their clinical judgement and escalate to clinical lead within LCRF for advice.
- The Principal Investigator or Sub Investigator will need to make a clinical decision to confirm if the symptoms are related or unrelated to the study drug.
- If the symptoms are felt to be related to the underlying condition or treatment for which they are attending LCRF, this should be documented in the appropriate AE/SAE log,

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as required within Good Clinical Practice and a DATIX completed if appropriate according to RDCL108.

- It is the responsibility of the PI to give advice to the LCRF team on any medical queries.

## MANAGING MEDICAL EMERGENCIES

- On discovering that a patient is unwell, the patient should be returned to a bed if possible and asked about any symptoms they may be experiencing.
- If safe to do so, the PBLs trained HCP or study PI (if present) will assess the child alongside the LCRF doctor and initiate treatment as required.
- If immediate medical support is required e.g. patient has severe shortness of breath, the resuscitation team must be contacted on 2222 stating the specific location of the LCRF and that it is a paediatric emergency
- The assessment should ensure the member of staff's safety. This should follow an airway, breathing, circulation, disability and exposure response (ABCDE) response. The assessment should be done with reference to the patient's past medical history and will involve a review of potential causes of the illness (e.g. known immunosuppression, underlying medical condition, study procedure, drug therapy, etc.) This must be clearly documented in the subject's case notes and/ or case record form.
- The LCRF nurses will assist with the preparation and/ or administration of oxygen, drugs and IV fluids or other treatments required if requested to do so by the doctor/team to who the event is reported. The LCRF nurse must feel competent and trained to deliver these treatments
- If a doctor/emergency team has been called to attend the patient, the HCP responsible for the patient's care must provide a comprehensive handover of all relevant information including full details of the research study in which the patient is participating.
- The HCP will remain with the doctor and/or emergency team until the patient is stabilised and/or transferred to an appropriate hospital department for ongoing care.
- If the event is considered a critical incident, any materials relating to or potentially relating to the situation e.g. drugs, equipment etc must be retained securely for examination and reporting purposes.
- The study HCP will ensure that an Adverse Event or Serious Adverse Event (SAE) report is completed as applicable. The appropriate event report should be submitted as per the relevant CRF SOP.

## SAFEGUARDING

- Children should not wait in the waiting area of LCRF with other adult patients. The HCP should liaise with other HCPs who also have clinic to ensure that patients are brought into the clinic rooms as soon as possible to avoid cross over.
- Children should not be left unattended by their parent/guardian at any time in the communal areas. This includes children attending with other patients (e.g. siblings or children of patients).
- HCPs should not be alone in a clinic room with a child. If parent/guardian need to step out, the door should be left open and where possible, another member of staff should wait in the clinic room until parent/guardian return.
- See staff training for safeguarding training requirements.

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## ENVIRONMENT

- It is no longer recommended that socket covers are used around babies and toddlers as they pose more of a risk than the sockets themselves. Children will be supervised at all times which reduces any environmental risks. This also includes supervision around other potential risks such as (but not limited to) sharp edges and door closures.
- Cleaning procedures in relation to babies, toddlers and young people are the same as for adults as detailed in Infection Prevention Control policies for the Trust.
- If there are any changes to, or new guidance, around managing environmental risks for children and young people, the Women's and Children's Research Team will communicate these to all LCRF, and R&I staff via email.

## 4. OTHER RELATED PROCEDURES;

Neonatal Storage and Administration Policy of expressed breast milk and milk  
LTHTR safeguarding children policy

## CONSULTATION WITH STAFF AND PATIENTS

Name	Role
Dr David Cameron	Senior Research Fellow
Jacqueline Bramley	LCRF Lead
Allan Brown	Senior Research Nurse LCRF
Rebecca Davenhall	R&I Quality Lead
LCRF Operational Group	Review and Approval
Candiss Argent	Paediatric Research Physiotherapist
Dr Christian DeGoede	Paediatric Consultant

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