NIHR | King's Clinical Research Facility

Policy for Studies with Paediatric Subjects in the King's Clinical Research Facility

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Author	Danilo Nebres, CRF Lead Research Nurse
Approved by	Elka Giemza, CRF Manager
Authorised by	Professor Peter Goadsby, CRF Director
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Date	Change details, since approval	Approved by
September 2017	1. Change in Author and Approvers for this version as the procedure was approved in version 1.0 and the changes in version 2.0 are minimal 2. Sections 6.2, 6.3, 6.4: updates to the preferred locations for paediatric studies in the CRF and updated information about the resuscitation trolleys 3. Minor administrative changes to the text	E. Fitzpatrick E. Giemza
December 2019	Minor administrative changes to the text	E. Giemza
February 2022	1. Change to 'Author' 2. Section 3.5- Change to responsibility of Paediatric Research Team as well as indication of support by CRF Research Team	E. Giemza

Review History

Date	Review details	Approved by
September 2017	V1.0 reviewed by Georgia Bullock, CRF QA Manager as per the review date. Changes made as per 'Change History' and re-issued as V2.0.	E. Fitzpatrick E. Giemza
December 2019	V2.0 reviewed by Noah Yogo as per the review date. Changes made as per 'Change History and re-issued as v3.0.	E. Giemza
February 2022	V3.0 reviewed by Danilo Nebres as per the review date. Changes made as per 'Change History and re-issued as v4.0.	E. Giemza

1.0 Background

1.1 The department of paediatrics at King's College Hospital (KCH) has a growing portfolio of clinical research studies, which often take place on the wards or in the outpatients department. Use of the Clinical Research Facility (CRF) is likely to improve the conduct of the studies and lessen the burden on the overstretched inpatient and outpatient beds. For the CRF to be used for paediatric studies, a child- friendly environment and the safety of the child must be guaranteed.

1.2 This policy was developed following a meeting between CRF staff and the Department of Paediatrics and a tour of the CRF's facilities. Guidance was sought from the safeguarding team at KCH, Research and Development at KCH, GMC, RCPCH and MRC reports regarding research in children. The MRC's 'Medical Research involving Children' report from 2004 recommends a research environment that is 'friendly' to children of all ages and appropriate for the physical, clinical, psychological and emotional needs of these age groups. In addition if there was a physical or psychological emergency, the research setting needs to be equipped to respond.

2.0 Purpose

2.1 The purpose of this policy is to define the type of paediatric studies which can be managed in the CRF. It also specifies the areas of the CRF where it is appropriate to conduct studies involving paediatric subjects.

3.0 Principles

3.1 Children of 0-18 years of age can participate in studies in the CRF; excluding neonates and including transitioning age prior to 18th birthday.

3.2 The CRF can accommodate children with any underlying condition, including mental health and psychiatric disorders.

3.3 The CRF currently has the capacity to accommodate out-patient paediatric studies only. Studies involving hospital in-patients and overnight stays may be

accommodated in the future, in which case this policy would need to be reviewed and updated.

3.4 The CRF expects that all paediatric out-patient visitors will be accompanied by an appropriate adult or carer.

3.5 The Paediatric Research Team will be trained to recognise the deteriorating child together with Immediate Life Support, and will have attended the KCH Safeguarding Children (Level 3) training. Where indicated, specialist paediatric support will be provided by the Principal Investigator and other members of the study team, for example, a Paediatric Research Nurse, Psychologist or Research Assistant. CRF Research Nurses and Research Coordinators will support this team if required.

3.6 Each study will be individually assessed to ensure that it is feasible to conduct the study in the CRF.

3.7 Examples of acceptable procedures that can be carried out in the CRF include:

- 3.7.1 Venepuncture
- 3.7.2 MRI and ultrasound scanning
- 3.7.3 Administration of medication
- 3.7.4 EEG
- 3.7.5 Questionnaires
- 3.7.6 Interviews

3.8 The CRF supports a wide variety of clinical research from many specialities; therefore consideration must be given to both adult and paediatric studies taking place in the unit at the same time.

4.0 Scope

4.1 This policy applies to procedures conducted within the CRF, which encompasses the Clinical Trials Facility (CTF), the Experimental Medicine Facility (EMF) and the Cell Therapy Unit (CTU). This CRF policy will apply to the CTF and EMF only and staff working in those areas should work to all relevant CRF SOPs.

4.2 This policy is relevant to all Investigators and study teams who wish to use the CRF for paediatric studies. It is also relevant to all CRF clinical and administrative staff who is involved with paediatric studies taking place in the CRF.

5.0 Responsibilities

5.1 The CRF Manager or appropriate delegate will implement this policy and will be responsible for ensuring that all those involved with paediatric studies understand it and are willing to abide by it.

6.0 Procedure

6.1 Where possible, every effort should be made to ensure that paediatric studies are conducted away from areas involving adults participating on trials. Facilities such as toilet facilities should be separate to those used by adults and should be designated for use only by the paediatric subjects and their carers for the period of participation.

6.2 The 4-bed ward on the ground floor of the EMF (with 2 separated bed spaces) is the most suitable area for studies involving paediatric subjects. This ward has piped oxygen and suction and also has en-suite shower/toilet facilities. However its use may sometimes depend on the demand for the MRI suite which is located nearby.

6.3 In the event that the 4-bed ward area is unavailable, or with prior agreement from the CRF Manager (or appropriate delegate), studies may be conducted in the CTF. There is 3-bedded ward with an adjacent room and office, which can be isolated from the main ward. The studies should be separated from areas where adults may be undergoing study procedures. There is piped wall oxygen and suction installed in this ward as well as a resuscitation trolley.

6.4 A resuscitation trolley is located on the ground floor of the EMF which contains combined emergency equipment for both paediatric and adult participants. In the CTF, the resuscitation trolley on the bed side also contains combined paediatric and adult emergency equipment.

6.5 A trolley with paediatric cannulae / butterfly needles and syringes, paediatric blood bottles, paediatric splints etc. should be made available for study visits. Specific weighing scales, stadiometer / measuring tape, stethoscope, and a BP monitor suitable for children (with paediatric cuffs) must also be available.

6.6 Research nurses / investigators within the specific study teams will work in the unit as they currently do on the wards or in outpatients. Phlebotomy / IV cannula insertion will be undertaken by paediatric staff and comply with current regulations and organisational policies.

6.7 All members of the paediatric study team working on studies in the CRF must undertake an induction to the CRF prior to the start of the study (see CRF-QA-SOP-1: Local Induction Procedure for CRF Users).

7.0 Related documents & References

7.1 MRC ‘Medical Research involving Children’ 2004:
http://www.mrc.ac.uk/documents/pdf/medical-research-involving-children/

7.2 KCH Safeguarding Children contacts, training and guidance:
http://kweb/kwiki/Safeguarding_children

7.3 CRF-CL-SOP-6: Management of Medical Emergencies in the King's CRF

7.4 CRF-QA-SOP-1: Local Induction Procedure for King's CRF Users

8.0 List of Appendices

N/A

9.0 Approval and sign off

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