

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

Document Detail	
Document type	Policy
Document name	CRF-STU-POL-1: Policy for Studies with Paediatric Subjects in the King's CRF
Document location	Q-Pulse \ CRF Documents
Version	2.0
Effective from	25 th September 2017
Review date	25 th September 2019
Author	Georgia Bullock, CRF Quality Assurance Manager
Approved by	Dr Emer Fitzpatrick, Clinical Senior Lecturer Paediatric Hepatology, KCL Elka Giemza, CRF Manager
Authorised by	Professor Peter Goadsby, CRF Director
Related documents	CRF-CL-SOP-6: Management of Medical Emergencies in the King's CRF CRF-QA-SOP-1: Local Induction Procedure for King's CRF Users
Keywords	Paediatric, safeguarding, out-patient, training, emergency
Supporting references	See Section 7.0

Change History		
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

THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR ENSURING IT IS THE CURRENT VERSION
 UNCONTROLLED COPY IF PRINTED

Page 1 of 5

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

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 patient and type of study 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 all ages can participate in studies in the CRF.

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.

THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR ENSURING IT IS THE CURRENT VERSION
UNCONTROLLED COPY IF PRINTED

3.5 CRF Research Nurses and Research Coordinators will be trained to recognise the deteriorating child together with Basic 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.

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 Consideration must also be given to adult 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 are 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 and the exit / entrance should be separate to those used by adults and should be designated for use only by the paediatric subjects and their carers. This is to ensure the safeguarding of children participating in trials.

THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR ENSURING IT IS THE CURRENT VERSION
UNCONTROLLED COPY IF PRINTED

- 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 no piped wall oxygen or suction installed in this ward, however portable oxygen and suction is available on the resuscitation trolley. Specific studies in children requiring oxygen (as opposed to the use of oxygen in an emergency) are not suitable for this area.
- 6.4 A resuscitation trolley is located on the ground floor of the EMF which contains emergency equipment for children of all ages (including neonates). In the CTF, only the resuscitation trolley on the ward (bed) side contains paediatric 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. Paediatric 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

**THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR ENSURING IT IS THE CURRENT VERSION
UNCONTROLLED COPY IF PRINTED**

8.0 List of Appendices

N/A

9.0 Approval and sign off

Author:

Name: Georgia Bullock

Position: CRF Quality Assurance Manager

Signature:

Date:

Approved by:

Name: Dr Emer Fitzpatrick

Position: Clinical Senior Lecturer Paediatric Hepatology, KCL

Signature:

Date:

Name: Elka Giemza

Position: CRF Manager

Signature:

Date:

Authorised by:

Name: Professor Peter Goadsby

Position: CRF Director

Signature:

Date:

Uncontrolled

THE USER OF THIS DOCUMENT IS RESPONSIBLE FOR ENSURING IT IS THE CURRENT VERSION
UNCONTROLLED COPY IF PRINTED