Out-of-Hours and Weekend Medical Cover for Studies Conducted in the King's Clinical Research Facility

Document Detail	
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Authorised by	Dr Oliver Long Consultant Anaesthetist Site Medical Director, Denmark Hill, King's College Hospital Medical Director, King's Commercial Services
Related documents	CRF-ADMG-SOP-1: The Application and Approval Process for Studies in the King's CRF CRF-ADMG-SOP-3: Lone Working and Personal Security in the King's CRF 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 CRF-QA-SOP-2: Risk Assessment of Clinical Trials/Studies Conducted within the King's CRF
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Supporting references	N/A

Change History		
Date	Change details, since approval	Approved by
February 2015	1. Updated document name to correspond with the numbering system on Q-Pulse 2. Reference numbers for related SOPs updated to correspond with the numbering system on Q-Pulse 3. Updated Section 5.0 which has been reviewed and agreed by Dr Michael Marrinan, Executive Medical Director at KCH	M. Marrinan
February 2017	1. Updated related documents to reflect the current CRF SOPs 2. Minor amendments to the text for accuracy 3. No changes are necessary to the actual process. The procedure is as approved in 2015	N/A
March 2019	4. No change to process 5. Change to logos	N/A
June 2021	1. Section 5.3.2- Addition of text regarding confirmation with Site/ bed Manager Office 2. 5.3.3 Section- Addition of text regarding emailing security by CRF administrator & Receptionist 3. Section- 5.3.2- Reference to Section 6.0 4. Addition to Section 6.0	C. Elston

Review History		
Date	Review details	Approved by
February 2015	CRFSOP027 updated to reflect the current and agreed process. SOP re-named as CRF-CL-CRF-10 and re-issued as V2.0	M. Marrinan
February 2017	V2.0 reviewed by Elka Giemza, CRF Manager, as per the review date. Changes made as per 'Change History' and re-issued as V3.0	N/A
March 2019	V3.1 reviewed by E Giemza. No major changes required	N/A
June 2021	V3.1 reviewed by, as per the review date. Changes made as per 'Change History' and re-issued as V4.0	C. Elston

1.0 Background

1.1 The King's Clinical Research Facility (CRF) is staffed with core research staff during normal office hours (Monday – Friday, 08.30-18.00hrs). It is expected that most visits for research studies will take place within normal office hours, but depending on the nature of the study it may be necessary for study visits to be

conducted within the CRF outside of normal office hours. In these situations, arrangements for appropriate medical cover outside normal office hours must be discussed with the CRF Manager prior to the study commencing and a mutually agreeable arrangement put in place by the Principal Investigator (PI) and CRF Manager.

2.0 Purpose

2.1 The purpose of this SOP is to describe the provision of medical cover for CRF studies, outside of normal working hours.

3.0 Scope

3.1 All core CRF staff and CRF users are bound to adhere to the procedures outlined in this SOP.

3.2 The CRF consists of the Experimental Medicine Facility (EMF), Clinical Trials Facility (CTF) and Cellular Therapy Unit (CTU). CRF SOPs are applicable across both the EMF and CTF; the CTU will maintain and control their own SOPs to ensure compliance with Good Manufacturing Practice (GMP).

4.0 Responsibilities

4.1 The CRF Manager is responsible for ensuring that suitable and proportionate medical cover has been arranged by the PI, prior to any study requiring out-of-hours or weekend study visits commencing within the CRF.

4.2 The PI is responsible for ensuring that adequate medical cover arrangements are put in place for their trial, and that no out-of-hours or weekend study visits are conducted within the CRF until approval of these has been given by the CRF Manager or their delegate.

5.0 Procedure

5.1 All applications to use the CRF must be submitted online to the CRF administration team, and include the necessary documents (such as the study protocol and all relevant approvals). Please refer to *CRF-ADMG-SOP-1: The Application and Approval Process for Studies in the King's CRF.*

5.2 A meeting will be arranged between the CRF Manager and/or suitable CRF delegate and the PI to discuss CRF resources required for the study and an intensity tool assessment will be conducted by the CRF Manager or delegate. The CRF Quality Assurance (QA) Manager, or their delegate, will also conduct a Risk Assessment for the study (see *CRF-QA-SOP-2: Risk Assessment of Clinical Trials/Studies Conducted within the King's CRF*). Any requirements for out-of-hours and weekend study visits to be conducted within the CRF, extra resources required for this and arrangements for medical cover must be discussed with the CRF Manager at this stage.

5.3 For out-of-hours or weekend study visits to be conducted within the CRF, the following must be ensured:

5.3.1 Arrangements must be made for an adequate level of medical cover to be in place. For Clinical Trials of Investigational Medicinal Products (CTIMPs), where administration of an IMP is required on such study visits, a study physician will be expected to be present in the CRF, or available and readily contactable at all times. In addition a research nurse should be present in the CRF and if the physician is not physically present in the CRF, a minimum of two members of staff must be present, one of those being clinical and trained in Immediate Life Support (ILS).

5.3.2 On receipt of a booking confirmation regarding the Research Team to conduct an overnight stay study visit within the CRF/ CTF with the CRF Administrator or CRF Receptionist, It is the responsibility of the PI or delegated Research Team member to immediately contact the Site Managers Office as well as the 'Hospital at Night Service' and confirm this overnight study visit with the Bed Manager. Please refer to Section 6.0.

5.3.3 The CRF Administrator or CRF Receptionist will email security to inform them of this confirmed overnight study visit.

5.3.4 For studies other than CTIMPs, or CTIMPs where no IMP administration is to occur on out-of-hours or weekend visits, at least two members of staff will be required, one of those being clinical and trained in Immediate Life Support (ILS).

5.3.5 For some studies, it may be necessary to arrange for additional clinical staff to be present in the CRF on out-of-hours or weekend study visits. This will be assessed on a case-by-case basis by the CRF Manager, in liaison with the PI/study team and by consulting the CRF study Risk Assessment. This may be relevant for studies with a high volume of subjects being seen at out-of-hours or weekends visits, or studies recruiting subjects with significant co-morbidities or where particularly complex or higher risk interventions are performed at such study visits.

5.3.6 For studies requiring MRI scans to be conducted out-of-hours or at weekends, additional arrangements must be put in place with the Centre for Neuroimaging Sciences (CNS) at King's College London, to ensure radiographers are available (the CNS can be contacted for more information at mri.booking@kcl.ac.uk).

5.3.7 It is envisaged that for most CTIMP studies being conducted in the CRF out-of hours-or at weekends, the study will provide a physician to be present (the PI or Sub-PI for example). However, for the small number of studies where it has been agreed by the CRF Manager and PI that it is not necessary for a study physician to be physically present in the CRF for out-of-hours or weekend study visits, an agreement must be put in place between the King's College Hospital (KCH) on-call medical team (based in the KCH Emergency Department) and the PI/study sponsor at the beginning of the study to allow this service to be accessed by the CRF if a study subject has a non-emergency medical issue that needs attention by a physician. This is also relevant for psychiatry studies, where a study subject has a medical issue that requires assessment by a medical physician, rather than a psychiatrist.

5.3.8 For such studies as described in 5.3.5, it is the responsibility of the sponsor of the study requiring medical cover to submit a study folder to the KCH on-call medical team which includes the current version of the study protocol and 24-hour emergency contact numbers for the PI (or delegate) or the sponsor's medical monitor, as appropriate.

5.3.9 For medical emergencies, the procedure outlined in *CRF-CL-SOP-6: Management of Medical Emergencies in the King's CRF,* must be followed and the KCH resuscitation team must be called and relevant KCH procedures followed.

5.3.10 All CRF users accessing the CRF out-of-hours or at the weekend (including Bank staff contracted to work only at these times) will need to undergo a full CRF induction and receive training in relevant CRF health and safety and emergency procedures, as well as in any relevant CRF Standard Operating Procedures (SOPs). It is the responsibility of the PI to keep the CRF Manager and QA Manager informed of any changes to study staff working out-of-hours or at weekends, as it is vital that all staff are trained in procedures relevant to their study (see *CRF-QA-SOP-1: Local Induction Procedure for King's CRF Users).*

6.0 Related documents & References

6.1 CRF-ADMG-SOP-1: The Application and Approval Process for Studies in the King's CRF

6.2 CRF-ADMG-SOP-3: Lone Working and Personal Security in the King's CRF

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

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

6.5 CRF-QA-SOP-2: Risk Assessment of Clinical Trials/Studies Conducted within the King's CRF

6.6 Clinical Site Manager bleep 333 Wi-Fi Handset EXT 36663

7.0 List of Appendices

N/A

8.0 Approval and sign off

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