NIHR | King's Clinical Research Facility

The Application and Approval Process for Studies in the King's Clinical Research Facility

Document Detail	
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Authorised by	Professor Peter Goadsby, CRF Director
Related documents	CRF-QA-SOP-1: Local Induction Procedure for King's CRF Users CRF-QA-SOP-2: Risk Assessment of Clinical Trials/Studies Conducted in the King's CRF CRF-ADMG-SOP-4: Room Booking and the Registration of Study Subjects in the King's CRF CRF-ADMG-FRM-6: CRF Approval Letters CRF-ADMG-FRM-7: Guidance for Investigators
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Supporting references	See Section 6.0

Change History		
Date	Change details, since approval	Approved by
January 2014	1. Amended text in SOP title from "Clinical Research Facilities" to "King's Clinical Research Facility" 2. Amended name of Director to reflect new Director 3. Amended logos to update to current CRF letterhead template 4. Amended document number from CRF SOP022 to CRF-ADMG-SOP-1 to comply with QPulse document numbering	E Giemza

	5. Amended numbers of documents referred to throughout the text to reflect revised QPulse/CRF numbers 6. Removed appendix as document available in QPulse 7. Section 5.6.12: Added requirement for study medical cover needs to be discussed at study feasibility meeting 8. Section 4.3: Corrected name of CRF database to actual title -CRF Manager® 9. Section 5.7 and "Related Documents" section: Added reference to CRF-QA-SOP-2: Study Risk Assessment 10. Section 5.19: Amended to reflect implementation of paperless filing of CRF study documentation on CRFManager 11. Removed reference to "Study Documentation and Archiving SOP- document still in draft	
January 2015	1. Update to the study review /approval process and the responsible personnel 2. Clarification of the information which is sent for review 3. Addition of the online CRF Application Form in Section 5.1 4. Minor administrative changes to text	E. Giemza
October 2015	1. Change to SOP title 2. Incorporation of *CRF-ADMG-SOP-2: King's CRF Study Application Process – Internal* (this SOP is now obsolete) 3. Addition of the CRF's Research Information & Data Manager's role and responsibilities relating to the study application and approval process 4. Section 5.0: updated to reflect current CRF practice 5. Minor administrative amendments to text	E. Giemza
October 2017	1. Minor administrative amendments to the text 2. Updated names of the related documents 3. No changes to the actual procedure is required	E. Giemza
August 2020	1. Change to NIHIR logo 2. Addition to related documents 3. Section 1.2: Further clarification of study 4. Removal of Section 1.3, 1.4 and 1.5 5. Section 4.2 & 4.3: Addition and change to order of text 6. Section 4.4.5: Additional clarification of approval requirements 7. Section 5.4: addition of cross check task 8. Section 5.7: Removal of text 9. Section 5.8 & 5.9: Clarification for Risk Assessments for Phase 1 studies & Approval clarification 10. Section 5.11: Change to text, approval clarification 11. Section 5.12: addition of text 'core' 12. Addition to Section 6.0	E. Giemza

August 2023	1. Section 5.1: Weblink for study application updated 2. Section 5.8: Phase 1 replaced by First in human 3. Section 5.11: Reference for KHPCTO added 4. Role of Data Analyst changed to Research Information & Data Manager 5. Minor administrative changes	E. Giemza B.Chakraborty

Review History		
Date	Review details	Approved by
January 2014	Review of v1.0 conducted by Lara Edwards, CRF QA Manager, superseded by v2.0 (effective date 28th January 2014)	E Giemza
January 2015	Review of v2.0 conducted by Georgia Bullock, CRF QA Manager, and Professor Peter Goadsby, CRF Director, superseded by v3.0	E. Giemza
October 2015	Review of v3.0 conducted by Georgia Bullock, CRF QA Manager and Stewart Lee Loong, CRF Research Information & Data Manager. Changes made as per 'Change History' and re-issued as v4.0	E. Giemza
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August 2020	Review of v5.0 conducted by Angelina Twumasi, CRF QA Manager, Elka Giemza CRF Manager and Stewart Lee Loong, CRF Research Information & Data Manager. Changes made as per 'Change History' and re-issued as v6.0	E. Giemza
August 2023	Review of v6.0 conducted by Elka Giemza, CRF Manager, Bidisha Chakraborty, CRF QA Manager and Stewart Lee Loong, CRF Research Information & Data Manager. Changes made as per 'Change History' and re-issued as v7.0	E. Giemza

1.0 Background

1.1 The King's Clinical Research Facility (CRF) is a specialist unit for experimental and translational medicine and provides facilities for researchers wishing to conduct clinical research. Both commercial and non-commercial studies can be conducted in the CRF. Commercially-sponsored studies will mainly be conducted within the Clinical Trials Facility (CTF) and non-commercial studies will mainly be conducted within the Experimental Medicine Facility (EMF).

1.2 All applications to conduct a study within the CRF are submitted by the Principal Investigator or other study contact online via the CRF's website. This includes studies which:

- utilise CRF support for staff and space

- Clinical space only
- Sample processing/storage only

2.0 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to describe how applications for the use of the CRF are processed from the initial enquiry to the actual commencement of a study within the CRF, including the CRF approval process for these studies.

2.2 As the number of studies rise and competition for CRF space usage becomes a consideration, the Director will consider the strategic fit of a study within the KHP (King's Health Partners) research agenda.

2.3 No study can commence at the CRF until all the required documentation and approvals are in place and the study has been approved and made 'Active' on CRFManager®.

3.0 Scope

3.1 This SOP applies to Principal Investigators and the members of their research teams.

3.2 This SOP also applies to core CRF team members who are involved in the approval process.

3.3 The CRF is comprised of the Clinical Trials Facility (CTF), the Experimental Medicine Facility (EMF) and the Cell Therapy Unit (CTU). CRF SOPs apply to the CTF and EMF only and staff working in these areas should work to all relevant CRF SOPs. The CTU will continue to control and use its own policies and SOPs to ensure compliance with Good Manufacturing Practice (GMP). Separate documentation to apply to use the CTU can be obtained from the CRF Manager and/or CTU Director.

4.0 Responsibilities

4.1 The Principal Investigator or main study contact is responsible for ensuring that the CRF application form is completed accurately and that all relevant sections are completed.

4.2 The Principal Investigator is responsible for ensuring that the relevant approvals for the study have been applied for at the time of submitting an application to the CRF

4.3 All CRF staff members who enter data and information onto the CRF's study management and scheduling system, CRFManager®, must ensure that the information is accurate and entered onto the system in an appropriate and timely manner.

4.4 The CRF Research Information & Data Manager is responsible for the following:

- 4.4.1 Assisting the study contacts to complete the application form as required
- 4.4.2 Dealing with any queries relating to the application process
- 4.4.3 Ensuring that all required documents relating to the application and approval process are available on CRFManager®
- 4.4.4 Submitting the applications for approval once all documents are available
- 4.4.5 For studies being conducted in the CRF, there are different governance and approval requirements, depending on whether the study involves patients or healthy volunteers/non-NHS subjects (see section 'Governance Arrangement for King's CRF Studies' in *CRF-ADMG-FRM-7: Guidance for Investigators*)'. The Research Information & Data Manager will assist in liaising with the appropriate KHP institution or organisation involved with the study (KCH R&I, SLaM R&D, KHP Clinical Trials Office or KCL research group) where necessary in parallel with CRF application, particularly for the provision of confirmation and capacity to support the study
- 4.4.6 Informing the study contact of the approval decision

5.0 Procedure

5.1 The CRF study application form is an online form and can be accessed on the CRF's website here CRFManager | Login

5.2 Study team contacts will need to 'Request Access' if they do not have a username and password. Once provided, they can log-in to the website.

5.3 Principal Investigators (or other appropriate member of the study team) should complete the application form and submit it.

5.4 Once submitted, the CRF's Research Information & Data Manager, or appropriate delegate, will contact the person who submitted the form if any of the required information is missing and will complete these sections. The CRF Research Information & Data Manager should also cross-reference the appropriate research database for the study if applicable (e.g. EDGE) to ensure the information is accurate and available.

5.5 The Research Information & Data Manager, or delegate, will ensure that all documentation is uploaded to CRFManager® for that study (eg: Protocol, any available approvals, Patient Information Leaflet and Consent Form).

5.6 The CRF Manager will meet with the Principal Investigator or other study contact at some stage before or during the study application process, to discuss the feasibility and conduct of the study (for example: costs, staffing and resource requirements, any out-of-hours access, sample storage, medication management, equipment requirements, medical cover and medical emergency management).

5.7 The Research Information & Data Manager will request that a risk assessment of the submitted study is completed (see *CRF-QA-SOP-2: Risk Assessment of Clinical Trials/Studies Conducted in the King's CRF)* and a review of the intensity of the study (using the Intensity Tool) is completed by CRF Manager or appropriate delegate. These two documents must be uploaded to CRFManager® under the relevant study.

5.8 For First in human studies, a separate Phase 1/FIH Study Risk Assessment (see *CRF-QA-FRM-24 Phase 1 FIH Risk Assessment v3.0*) will also be sent to

the research team to be completed. This will be stored on CRFManager® and will be reviewed by the CRF QA Manager and CRF Manager upon its return.

5.9 For a study to be conducted in the CRF, this study must have approval from the CRF Director and or CRF Manager.

5.10 A decision regarding the CRF application will be provided within thirty days.

5.11 The Principal Investigator and/or the main study contact, along with the appropriate contact as required from KCH R&D or KHP Clinical Trials Office, will be informed of the decision in writing by the Research Information & Data Manager, or delegate, using one of the templates in *CRF-ADMG-FRM-6: CRF Approval Letters* (non-commercial or commercial depending on the study).

5.12 Until the CRF has received all of the required approvals and visit types created for the study, it cannot be made 'Active' in its study status on CRFManager®. Once all required documentation has been received and all approvals are in place, the CRF Manager, or an appropriate delegate, can authorise the use of the CRF for the study. Approval of the study on CRFManager® generates a 'K' number for that study and confirms that the study has been authorised to take place in the CRF. Appointment bookings can then be made for the use of the CRF facilities (*see CRF-ADMG-SOP-4: Room Booking and the Registration of Study Subjects in the King's CRF*).

5.13 Arrangements must also be made for a member of the core CRF staff to conduct an induction for all study team members who will be working within the CRF (See *CRF-QA-SOP-1: Local Induction Procedure for King's CRF Users*).

5.14 All study documentation and approvals will be filed electronically on CRFManager® for at least 5 years.

6.0 Related documents & References

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

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

6.3 CRF-ADMG-SOP-4: Room Booking and the Registration of Study Subjects in the King's CRF

6.4 CRF-ADMG-FRM-6: CRF Approval Letters

6.5 CRF-ADMG-FRM-7: Guidance for Investigators

7.0 List of Appendices

N/A

8.0 Approval and sign off

Approval and sign off are performed via Q-Pulse as described in *CRF-QA-SOP-3: Preparation, Review, Approval and Release of Standard Operating Procedures in the King's CRF*, version 7.0 dated 10 August 2023. All approval record are captured in the Document module section of the relevant SOP on Q-Pulse.

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