NIHR | King's Clinical Research Facility

Reference to the King's Health Partners Clinical Trial Office (KHP CTO) Standard Operating Procedures (SOPs) for Trial-Related Procedures in the King's Clinical Research Facility

Document Detail	
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Author	Bidisha Chakraborty, CRF Quality Assurance Manager
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Date	Change details, since approval	Approved by
September 2016	1. Minor amendments to text for clarity 2. No change to actual procedure	E. Giemza
September 2018	1. Sections 5.1 and 6.0: updated link to the CTO website 2. No other changes to the procedure are required	E. Giemza
November 2020	1. Update logo 2. Change author	E. Giemza
March 2023	1. Addition of Section 5.3: Completion of SOP training log and uploading onto Q-Pulse 2. CRF-QA-FRM-4: CRF Staff SOP Training Log added in related documents 3. Wellcome Trust logo removed	E. Giemza

Review History		
Date	Review details	Approved by
September 2016	Review of v1.0 conducted by Georgia Bullock, CRF Quality Assurance Manager, as per the review date. Changes made as per 'Change History' and re-issued as v2.0	E. Giemza
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March 2023	Review of v4.0 conducted by Bidisha Chakraborty, CRF Quality Assurance Manager, as per the review date. Changes made as per 'Change History' and re-issued as v5.0	E. Giemza

1.0 Background

1.1 The King's Health Partners Clinical Trials Office (KHP CTO) has produced some Standard Operating Procedures (SOPs) for several generic trial-related procedures. These are available on the KHP CTO website and are updated as required by the KHP CTO.

1.2 The SOPs are particularly relevant to studies which are sponsored, or co-sponsored, by any of the King's Health Partners.

1.3 The King's Clinical Research Facility (CRF) has a set of SOPs available for many of the CRF's procedures and processes. However some generic trial-related procedures are not included in this set as the CRF refers to the KHP CTO SOPs for these procedures.

2.0 Purpose

2.1 The purpose of this SOP is to describe the process for accessing the KHP CTO SOPs.

3.0 Scope

3.1 The CRF consists of the Experimental Medicine Facility (EMF), Clinical Trials Facility (CTF) and Cellular Therapy Unit (CTU). This SOP is applicable to staff working in the EMF and CTF only, as the CTU maintains and controls its own SOPs to ensure compliance with Good Manufacturing Practice (GMP).

3.2 This SOP is applicable to all core CRF staff conducting study-related procedures.

3.3 This SOP refers to the KHP CTO SOPs currently available on the website, including (although not limited to):

- Obtaining Informed Consent for Clinical Trials
- Creation and Maintenance of Trial Master Files
- Archiving of Clinical Trial Data and Essential Documentation
- Notification of a Serious Breach
- Emergency Code Break in Clinical Trials
- Initiation of an Investigator Site
- Investigator Site Close Out Visit

3.4 KHP CTO SOPs are generic and should only be referred to in the absence of a CRF SOP or a study-specific SOP. The requirements of the study protocol must also be adhered to for all study-related procedures.

4.0 Responsibilities

4.1 All core CRF staff involved in conducting study-related procedures are responsible for referring to the KHP CTO SOPs for generic study-related procedures, in the absence of any other SOP or study-specific instructions.

4.2 All CRF staff are responsible for ensuring that the most recent version of the SOP is obtained directly from the KHP CTO website at all times.

5.0 Procedure

5.1 To access the KHP CTO SOPs, CRF staff should go to the CTO website under 'SOPs' https://khpcto.co.uk/SOPs/00_SOPs.php

5.2 The available SOPs are listed on the right-hand side of the page and can be opened by clicking on the required SOP. This will create a page which contains a brief description of the SOP, a link to the SOP and also links to other related documents.

5.3 A record of the training on the KHP CTO SOPs should be documented in CRF-QA-FRM-4 CRF Staff SOP Training Log and filed in the individual training folder. An electronic copy of the completed and signed SOP training log should be sent to the CRF QA Manager for uploading into the training folder on Q-Pulse.

6.0 Related documents & References

6.1 KHP CTO SOPs: https://khpcto.co.uk/SOPs/00_SOPs.php

6.2 CRF-QA-FRM-4 CRF Staff SOP Training Log

7.0 Appendices

N/A

8.0 Approval and sign off

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