Production, Approval and Review of SOPs

Standard Operating Procedure Details	
Document Type	Standard Operating Procedure
Document name	KHP-CTO/CT/SOP1.0 Production, Approval and Review of SOPs
Version	Final v 4.2 - 03/04/2024
Effective from	8th April 2024
Review date	10th January 2027
Owner	King's Health Partners Clinical Trials Office
Originally Prepared by	Sarah Ruiz Senior Clinical Trials Training Executive
Reviewed by	Amy Holton KHP-CTO Quality Manager
Approved by	Ann-Marie Murtagh, Interim Director KHP CTO
Superseded documents	Final v 4.1 - 05/01/2021
Relevant regulations/legislation/guidelines	Statutory Instrument 2004 no 1031 Statutory Instrument 2006 no 1928

Change History			
Date	Version Number	Change details	Approved by
26th April 2010	1.1	Transferred to King's Health Partners Livery and inclusion of King's Health Partners into the Glossary.	Jackie Powell
1st April 2014	2.0	Inclusion of file notes #1 and #2. Inclusion of Delegate of KHP-CTO as authorised signatory for SOP approval.	Jackie Powell
12th August 2014	3.0	SOP review date extended to no more than 3 years from the effective date.	Jackie Pullen
12th December 2017	4.0	Change in Authorised signatory job title and addition of a reviewer on page 1 in line with current KHP-CTO SOP template	Jackie Pullen

5th Jan 2021	4.1	Minor amendment to include trials managed by KHP-CTO and glossary update	Jackie Pullen
3rd Jan 2024	4.2	Update to location of hard copy of SOPs	Ann-Marie Murtagh

Table of Contents

1.0 GLOSSARY

The Regulations - The Medicines for Human Use (Clinical Trial) Regulations 2004, which transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031, is applicable for all Clinical trials of investigational medicinal products, this became effective on the 1st May 2004**.** An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928, which includes the Conditions and Principles of GCP. As amended from time to time.

The Medicines & Healthcare products Regulatory Agency (MHRA) - UK Competent Authority responsible for regulation of clinical trials.

The King's Health Partners Clinical Trials Office (KHP-CTO) - Established in 2006 by Kings College London, Guy's & St Thomas' NHS Foundation Trust and King's College Hospital NHS Foundation Trust to provide a streamlined approach for all aspects of trial administration.

Clinical Trial of an Investigational Medicinal Product (CTIMPs) - Any investigation in human participants, other than a non-interventional trial intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal product or to identify any adverse reactions to one or more such products and to study absorption, distribution metabolism and excretion in one of more such products with the object of ascertaining the safety or efficacy of those products.
.

KHP-CTO Standard Operating Procedure (SOP) - "detailed, written instructions to achieve uniformity of the performance of a specific function," SOPs are the base on which Quality Systems and Processes are conducted and monitored against.

Good Clinical Practice (GCP) - As defined in Statutory Instrument 2006/1928.

JCTO Quality Policy - Policy signed by the Medical Directors of King's College Hospital NHS Foundation Trust, Guy's & St Thomas' NHS Foundation Trust and the Vice Principal of the Health Schools of King's College London, the Quality Policy binds all relevant clinical research activity conducted or managed by the Partner Organisations to the KHP-CTO Clinical Trial SOPs.

King's Health Partners - King's Health Partners Academic Health Science Center is a pioneering collaboration between one of the King's College London (University) and three of London's most successful NHS Foundation Trusts – Guy's & St Thomas', King's College Hospital and the South London & Maudsley.

2.0 BACKGROUND AND PURPOSE

Statutory Instrument 2004/1031 – the Medicines for Human Use (Clinical Trials) Regulations 2004 transposed the European Union Directive 2001/20/EC for Clinical Trials into UK law effective from the 1st May 2004. The original UK regulations were amended in August 2006 to incorporate the EU Good Clinical Practice Directive (2005/28/EC) as Statutory Instrument 2006/1928.

The Regulations state that Clinical Trials involving medicinal products MUST be authorised by the MHRA and conducted according to the Principles of GCP as defined in the Amended Regulations and any subsequent amendments.

MHRA GCP Inspectors assess compliance with the requirements of GCP by conducting inspections at the sites of pharmaceutical sponsor companies, contract research organisations, academic research organisations, investigational trial sites, clinical laboratories, GCP archives and other facilities involved in clinical trial research. Mandatory GCP inspections will be conducted in both commercial and non-commercial organisations within the UK.

SOPs covering all key aspects of Clinical Trial function are a key component for adherence to the principles of GCP and are monitored against for quality assurance and compliance with the Regulations.

The JCTO was re-branded as King's Health Partners Clinical Trials Office (KHP-CTO) in 2012. As each individual SOP is reviewed it will be re-branded as KHP-CTO and hence the suite of current SOPs collectively referred to as the KHP-CTO SOPs will include a number with the JCTO nomenclature..

This Standard Operating Procedure (SOP) describes the process for writing, implementing and reviewing KHP-CTO SOPs.

3.0 SCOPE

All clinical trials sponsored, co-sponsored, managed or hosted by KCL, GSTFT, KCH and SLaM as bound by the JCTO Quality Policy. All Clinical trials sponsored by one or more of the Partner Organisations will be monitored for GCP compliance and adherence to the KHP-CTO SOPs using a risk based approach.

Trials sponsored by organisations other than the Partner Organisations may be conducted according to individual trial SOPs or policies as described in the trial protocol if available;

however, if no Sponsor SOPs are available the trial will be conducted according to KHP-CTO SOPs.

4.0 PROCEDURE

4.1 Writing SOPs

The KHP-CTO Quality Manager will ensure that core Clinical Trial activities are supported by appropriate SOPs and where relevant, SOPs will be supported by working documents and/or process maps.

Prior to an SOP being produced for a clinical trial activity the process will be mapped, tested and finally the SOP written. This will ensure that all SOPs produced are both robust and accurate.

SOP authors will be allocated by the Quality Manager and typically will be members of staff concerned with the relevant clinical trial activity. The SOP process will be overseen by the author's manager and/or Quality Manager as appropriate.

On completion of a draft SOP, internal review by relevant members of staff, (relevance according to SOP purpose) will be conducted. This review should look at compliance with the Regulations, readability, conciseness and accuracy of information.

4.2 Authorising SOPs

This SOP (KHP-CTO/CT/ SOP/1.0) was originally approved by the incumbent Chair of the KHP-CTO Board. All subsequent SOPs will be reviewed by the R&D Directors of each Trust and College Vice-Principal (Health Schools) and once review is completed will be approved by the Director of the KHP-CTO or Delegate.

Prior to implementation of a new or amended SOP, the Quality Team Clinical Trial Training Executives will ensure that all staff involved in the clinical trial activity affected by the new or amended SOP are aware of the changes and provide training where appropriate.

All SOPs will have an effective date following authorisation by KHP-CTO Director or Delegate and the implementation of any required training.

4.3 SOP Review

Each SOP will have a review date which should be no more than three years from the effective date. SOPs will also be reviewed on an ad hoc basis as a result of amendments to legislation, process or organisational change. The KHP-CTO Quality Manager will coordinate the review of SOPs.

When an SOP is reviewed and no changes are required, this will be recorded in the *Change History* section on page 1 of the SOP and this will be approved by the Authorised SOP

Signatory. The date of review will be recorded, however the version number of the SOP and the version control details within the footer of the SOP will remain unchanged.

4.4 SOP Referencing

Each new KHP-CTO SOP will be issued with a unique SOP number using the same format as this SOP – KHPCTO/CT/SOP1.0.

4.5 Version Control

The table on the front cover documents the SOPs version history which should be amended with each change to the SOP. Once finalised, the document will be called “final” version 1.0. Updates to the SOP will result in an increase in version number.

4.6 Distribution of SOPs

All authorised SOPs will be available electronically via the KHP-CTO website. A signed hard copy will kept in a designated SOP central file in the KHP-CTO.

5.0 RELATED TEMPLATES

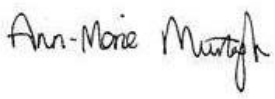
5.1 KHP-CTO SOP Template

5.2 KHP-CTO SOP Review Form

6.0 RELATED DOCUMENTS

Not applicable

7.0 APPROVAL and SIGNATURE



_____ _____03/04/2024_____

Ann-Marie Murtagh Date
Interim Director
King’s Health Partners Clinical Trials Office