KING'S HEALTH PARTNERS | Clinical Trials Office

Production, Approval and Review of Standard Operating Procedures

DOCUMENT DETAILS	
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Document name	KHP-CTO/CT/SOP1.0 Production, Approval and Review of SOPs
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Table of Contents

1. BACKGROUND AND PURPOSE

International Council for Harmonisation Good Clinical Practice guideline version R3 (ICH GCP R3) defines standard operating procedures as 'Detailed, documented instructions to achieve uniformity of the performance of a specific activity'.

The purpose of Standard Operating Procedures (SOPs) is to provide consistency in clinical trial processes and ensure compliance with the conditions and principles of Good Clinical Practice (GCP) as detailed in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) GCP tripartite Guidelines (E6), the Medicines for Human Use (Clinical Trial Regulations) 2004/1031 as amended, including the Medicines for Human Use (Clinical Trial) (Amendment) Regulations 2025/538, and any other applicable regulations. Breach of SOP requirements noted during trial monitoring or other trial activity should be considered for reporting per **KHP CTO SOP 6: Notification of Serious Breach SOP**.

This SOP describes the process for writing, implementing and reviewing KHP CTO SOPs.

2. SCOPE

All Clinical Trials of Investigational Medicinal Products (CTIMPs), sponsored or co-sponsored by one or more of the Kings Health Partners organisations are within scope of this SOP.

KHP CTO SOPs are freely available on the KHP CTO website.

3. PROCEDURE

3.1 Generating a new draft SOP or policy

Task	Responsibility	Activity
3.1.1	KHP CTO Non-Commercial Trials Manager	Identify the need for a new SOP or policy. This may include situations where: • core clinical trial activities that fall within the remit of KHP-CTO that are not supported by an SOP or policy. • there are updates to the guidance or regulations that govern clinical trials. Note: activities which are only necessary in a small proportion of clinical trials are also not generally documented in KHP CTO SOPs. The intention of the KHP CTO suite of

		SOPs is that all of them apply to all clinical trials overseen by the KHP CTO.
3.1.2	KHP CTO Non-Commercial Trials Manager	Delegate an appropriate member of KHP CTO staff to write the new SOP/ policy: • The author of a new SOP/ policy is typically the member of staff who is most experienced in the relevant clinical trial activity. • Documents to support the SOP may also be necessary. Work instructions, process map, template forms etc should be drafted if appropriate. • Oversight of the SOP writing process should be carried out by the Non-Commercial Trials Manager or delegate.
3.1.3	Author	Draft the new SOP/ policy using **related template 1 - SOP template** including the background, purpose, scope, procedure(s), change log and glossary: • Ensure SOP/ policy is consistent with clinical trial legislation, and all relevant guidance including MHRA, Health Research Authority guidance and KCL policy. • Use active language with timelines and responsibilities specified where appropriate. • KHP CTO SOPs have unique numbers in the format KHPCTO/CT/SOP X.X. • The document should have page footer including version number and page number and document short name. • The first page should detail the effective date and the planned date for review for that version, also see section 3.3. Send the draft to the Non-Commercial Trials Manager and line manager by email
3.1.4	KHP CTO Non-Commercial Trials Manager	Determine appropriate internal KHP-CTO reviewers based on the nature and scope of the SOP. If the SOP was not authored by the Non-Commercial Trials Manager this may be reviewed by the Non-Commercial Trials Manager only. If additional reviewers are required, ensure draft SOP/ policy is circulated for review. Send the draft to reviewers by email.
3.1.5	Reviewers	Review the draft SOP/ policy, considering in particular

		• Compliance with regulations, UK Policy Framework for Health and Social Care Research, HRA guidance, other relevant guidance. • Readability. • Conciseness. • Accuracy. Send comments to author.
3.1.6	Author	Revise the draft to address comments from reviewers Provide updated draft to Non-Commercial Trials Manager
3.1.7	KHP CTO Non-Commercial Trials Manager or delegate	Ensure all comments and revisions have been addressed.

3.2 Approval of new SOPs and updates to SOP or policy

Task	Responsibility	Activity
3.2.1	KHP CTO Non-Commercial Trials Manager	When draft SOP/ policy and supporting documents have been reviewed and any further updates have been made, send to the KHP CTO Director for review.
3.2.2	KHP CTO Director	Review draft SOP/ policy Send comments to KHP CTO Non-Commercial Trials Manager.
3.2.3	KHP CTO Non-Commercial Trials Manager	Ensure any comments are addressed. Send updated draft SOP/ policy for approval.
3.2.4	KHP CTO Director	Confirm approval of updated SOP / policy via email and sign final version of SOP to document approval. Electronic signature should include the date of signature.
3.2.5	KHP CTO Non-Commercial Trials Manager	Save finals signed PDF version in the KHP CTO SharePoint. Ensure final signed version is uploaded to the KHP CTO website per section 3.4.

3.3 Updating a current SOP or policy

In general, KHP-CTO SOPs should be reviewed at a minimum every 3 years, the expected review date for each SOP is documented at the beginning of each document. The Non-Commercial Trials Manager or delegate will maintain a record of the review dates for all SOPs. Review can be triggered before the expected review date if the process described in the SOP or policy needs to be revised e.g. due to the introduction of a new system or in response to changes to relevant regulations or guidance.

Updates to supporting documents such as templates and work instructions can be made at any time at the KHP CTO Non-Commercial Trials Manager's discretion. These changes do not constitute review of the SOP or policy to which the document relates.

Task	Responsibility	Activity
3.3.1	KHP CTO Non-Commercial Trials Manager or delegate	Identify appropriate member of KHP CTO staff to assign as an author for the new version for the SOP or policy: • Within 3 months of the review date of each SOP or policy or • When the need for SOP or Policy update has been identified. Provide any feedback or updated guidance which needs to be addressed in the new version: this can be by email or Teams call or face to face as appropriate.
3.3.2	KHP CTO Non-Commercial Trials Manager	If no changes are necessary to the SOP/ policy on the review date, • Record the review in the change history table. • The date for scheduled review of the SOP should be updated: the usual interval between reviews is 3 years. • The version number and effective date of the SOP will not be changed. Send the SOP/ policy to the KHP CTO Director for review and signature. Signed version of SOP should be filed per procedure below.
3.3.3	Author	Update the SOP/ policy following the same principles in 3.1.3, in addition: • Update footers and amend document section numbers if appropriate. Update the contents list if appropriate. • Update any supporting documents/ templates to maintain consistency with SOP requirements and expectations.
3.3.4	Author	Add details of the main changes made to the change history table.

		Keep the details of previous versions in the change history table as this can include important context for the reason changes were made in the past.
3.3.5	Author	Send draft and any updated supporting documents to KHP CTO Non-Commercial Trials Manager and line manager for review.
3.3.6	KHP CTO Non-Commercial Trials Manager or delegate	Send draft and any updated supporting documents to other reviewers as appropriate.
3.3.7	Reviewers	Send comments or approval of draft (and documents if appropriate) to author.
3.3.8	Author	Update draft (and documents if applicable) to account for reviewer comments. Send updated draft to KHP CTO Non-Commercial Trials Manager.
3.3.9	KHP CTO Non-Commercial Trials Manager	Follow 3.2 to obtain final approval file and distribute the final SOP.

3.4 Distribution new or updated SOP or policy

Task	Responsibility	Activity
3.4.1	KHP CTO Non-Commercial Trials Manager or delegate	Ensure current versions of SOP and supporting documents and templates are available on the KHP CTO website.
3.4.2	KHP CTO Non-Commercial Trials Manager or delegate	Circulate the link from the KHP CTO website for the updated /new SOP or policy to relevant KHP CTO Staff, including details of changes made • Implementation plan e.g. where there changes to existing procedures whether this applies to all trials including ongoing and existing trials or only to new trials. • Timeline for reading the updated SOP. • Instructions for documenting when the SOP has been read and understood in the KHP-CTO staff's training file. Save email to team in KHP CTO SOP folder in SharePoint.
3.4.4	KHP CTO Non-Commercial Trials	Circulate the link from the KHP CTO website for the updated /new SOP or policy to current CIs where relevant copying in the appropriate R&D department. Include a summary of changes and

	Manager or delegate	any actions to be taken by the CI e.g. for ongoing/existing trials or trials in development. Save email to CI's in KHP CTO SOP folder in SharePoint.
3.4.3	KHP CTO Non-Commercial Trials Manager or delegate	Retain superseded versions of SOPs and supporting documents in designated SOP folder in SharePoint.
3.4.4	KHP CTO Non-Commercial Trials Manager or delegate	Provide copies of superseded SOPs and supporting documents in a timely fashion when these are requested for audit, inspection or transparency purposes. Trial Master Files and Investigator Site Files should not contain printed or downloaded copies of KHP CTO SOPs: the contents of the SOP should be viewed 'live' on the KHP CTO website whenever it is needed, to facilitate compliance with the current version of the SOP.

4 RELATED TEMPLATES

1) SOP Template

5 RELATED SOPs

KHP CTO SOP 6: Notification of Serious Breach

6 REFERENCES:

1. The Medicines for Human Use (Clinical Trials) Regulations 2004
https://www.legislation.gov.uk/uksi/2004/1031/contents/made

2. The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025
https://www.legislation.gov.uk/uksi/2025/538/contents/made

3. ICH Topic (E6) guideline for Good Clinical Practice
https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline

4. UK Policy Framework for Health and Social Care Research UK Policy Framework for Health and Social Care Research - Health Research Authority

7 CHANGE HISTORY

CHANGE HISTORY			
Date	Version Number	Change details	Approved by
26 April 2010	1.1	Transferred to King's Health Partners Livery and inclusion of King's Health Partners into the Glossary.	Jackie Powell
01 Apr 2014	2.0	Inclusion of file notes #1 and #2. Inclusion of Delegate of KHP-CTO as authorised signatory for SOP approval.	Jackie Powell
12 Aug 2014	3.0	SOP review date extended to no more than 3 years from the effective date.	Jackie Pullen
12 Dec 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
05 Jan 2021	4.1	Minor amendment to include trials managed by KHP-CTO and glossary update	Jackie Pullen
03 Jan 2024	4.2	Update to location of hard copy of SOPs	Ann-Marie Murtagh
21 Apr 2026	5.0	Add relevant principles from ICH GCP R3 and UK Policy Framework Clarify that superseded versions of SOPs are retained Move SOP to new template	Ann-Marie Murtagh

8 GLOSSARY

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

Co-Sponsors – Two organisations that take responsibility for the initiation, management and financing (or arranging of the financing) in relation to a Clinical Trial. The Co-Sponsors agree how the Sponsor functions for the Clinical Trial are divided between themselves and document this accordingly.

Good Clinical Practice (GCP) - An international ethical and scientific quality standard for designing, conducting, recording, and reporting Clinical Trials that involve human participants. It ensures the safety, well-being, and rights of participants are protected while maintaining the credibility and accuracy of trial data. GCP is crucial for safeguarding participants and ensuring Clinical Trials produce reliable, scientifically valid results.

Health Research Authority (HRA) – The national body in England responsible for protecting and promoting the interests of patients and the public in health and social care research.

ICH GCP E6 (R3) – The International Council for Harmonisation – Good Clinical Practice, Guideline E6 (Revision 3). This is an internationally recognised ethical and scientific quality standard for the design, conduct, oversight, recording, and reporting of Clinical Trials.

KHP-CTO Director – The most senior member of the KHP-CTO.

KHP-CTO Non-Commercial Team - Comprises the Non-Commercial Trials Manager, CRA(s), Clinical Trial Administrator(s), Training Executive(s), Operations Lead and Operations Manager.

KHP-CTO Training Team - The team at the KHP-CTO responsible for determining, and meeting, the mandatory training requirements of KHP staff and students involved in Clinical Trials. The KHP-CTO Training Team are also responsible for delivering elective training courses to KHP staff and students involved in research involving patients (non-Clinical Trials).

King's Health Partners (KHP) - King's College London, Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, and South London and Maudsley NHS Foundation Trust.

King's Health Partners Clinical Trials Office (KHP-CTO) – The department established by King's College London, Guy's and St Thomas' NHS Foundation Trust, King' College Hospital NHS Foundation Trust, and South London and Maudsley NHS Foundation Trust to 1) undertake the set up and financial Management of commercial research hosted by one or more of the KHP Partners, and 2) undertake the regulatory submissions and oversight, as well as monitoring activity for non-commercial research studies sponsored by one of the KHP Partners.

Lead Co-Sponsor – Where the Clinical Trial is co-sponsored, the Lead Co-Sponsor is the entity who substantively employs the Chief Investigator.

Medicines & Healthcare products Regulatory Agency (MHRA) – The UK government agency responsible for regulating medicines, medical devices, and Clinical Trials. In the context of Clinical Trials, the MHRA i) acts as the licensing authority for Clinical Trials, ii) reviews the scientific, quality, and safety aspects of a Clinical Trial application, iii) issues CTAs, iv) oversees GCP and GMP inspections, v) monitors pharmacovigilance and safety reporting, and vi) enforces compliance with UK medicines legislation.

Non-Commercial Trials Manager (NCTM) – The most senior member of the KHP-CTO Non-Commercial Team.

Regulations – The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended including the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025).

Sponsor - The person or body who takes on ultimate responsibility for the initiation, management and financing (or arranging of the financing) of a Clinical Trial. The Regulations allow for two or more persons or bodies to take on responsibility for Sponsor functions.

Standard Operating Procedures (SOPs) - Detailed, written instructions to achieve uniformity of the performance of a specific function. SOPs are the basis upon which Quality Systems and Processes are conducted and monitored against.

UK Policy Framework – The UK Policy Framework for Health and Social Care Research.