King's Health Partners Clinical Trials Office
Obtaining Clinical Trial Insurance
(KCL Employed Investigators)

Standard Operating Procedure Details	
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Superseded documents	Final v4.0 24 February 2016
Relevant regulations/legislation/guidelines	Statutory Instrument 2004 no 1031 Statutory Instrument 2006 no 1928

Change History			
Date	Version Number	Change details	Approved by
01 Dec 2010	2.0	Policy now supplied by Newline Insurance rather than Zurich Municipal. SOP amended accordingly.	Jackie Powell
04 Feb 2013	3.0	Change to reflect rebranding of JCTO to KHP-CTO	Jackie Powell

25 Feb 2016	4.0	Scheduled review including consistency check of Glossary terms.	Jackie Pullen
15 Mar 2019	4.0	Scheduled review no change required	Jackie Pullen
07 Apr 2021	4.0	Scheduled review no change required	Jackie Pullen
02 May 2023	4.1	Scheduled review, minor terminology updates	Jackie Pullen

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1.0 GLOSSARY

Clinical Trial of an Investigational Medicinal Product (CTIMPs) - Any investigation in human subjects, 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.

Good Clinical Practice (GCP) - as defined in the Regulations.

Informed Consent Form (ICF) – The document which is signed by the participant/legal representative as well as the person who conducted the informed consent discussion confirming the volunteers willingness to participate in the particular trial, having been informed of all aspects of the trial that are relevant to their decision.

KCL – King's College London *(University).*

King's Health Partners (KHP) - 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.

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

KHP-CTO Quality Team – Comprises the Clinical Quality Manager, Clinical Research Associate(s), Clinical Trial Administrator(s), Systems Executive, Training Executive(s) and Training Assistant.

KHP-CTO Standard Operating Procedures (SOPs) - "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.

Quality Policy - Policy signed by the Medical Directors of the Partner Organisations 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.

The Regulations - Medicines for Human Use (Clinical Trial) Regulations 2004 transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. 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.

2.0 BACKGROUND AND PURPOSE

The Regulations state that provision must be made for insurance or indemnity to cover the liability of the Investigator and Sponsor which may arise in relation to the clinical trial.

Where the Chief Investigator is employed by an NHS Trust, clinical negligence is provided via the NHS Indemnity Scheme, once Trust R&D approval has been received.

Trials where the Chief Investigator is substantively employed by KCL will be sponsored or co-sponsored by the College and will require additional indemnity cover, trials where the Chief Investigator holds an adjunct or honorary contract with KCL **may** be co-sponsored by KCL and will also require additional indemnity cover if this is the case. This is provided by the College Insurance Policy.

This SOP describes the process to be followed to obtain insurance and indemnity for clinical trials sponsored or co-sponsored by KCL.

3.0 SCOPE

All CTIMPs **sponsored** or **co-sponsored** by KCL (ie Chief Investigator is substantively employed by KCL).

4.0 PROCEDURE

4.1 Policy

Newline Insurance provides indemnity for KCL sponsored or co-sponsored clinical trials. This is a no-fault compensation policy and covers any person participating in a clinical trial including their dependants, heirs, executors, administrators and legal representatives.

Cover applies automatically to general clinical research and Clinical Trials within wide parameters without the need for referral although there are exclusions (section 4.2).

4.2 Policy Exclusions

Although Cover applies automatically to general clinical research and Clinical Trials within wide parameters without the need for referral, there are exclusions to the Policy – these are detailed in the KCL Insurance Investigator Guidance for Clinical Trials document (see section 5.1). (Ownership of this document lies with the College Treasury Department).

When a trial falls within one of the policy exclusions, it is the responsibility of the Chief Investigator to ensure that the following are sent to the College Treasury Dept:-

a) Copy of the trial protocol.
b) Copy of the Informed Consent form
c) Confirmation of the country where the trial is taking place.

The Treasury Department will liaise with Newline Insurance and receive one of the following*:* -

- Confirmation of trial inclusion on the policy
- Confirmation of trial inclusion on the policy after payment of an additional premium
- Confirmation of trial exclusion on the policy.

Confirmation of cover will be provided by email to the Chief Investigator from the College Treasury Dept.

If the trial is excluded from the policy, cover will have to be sought from elsewhere and any costs covered by the trial budget. If insurance and indemnity is **not** obtained, the trial cannot progress and KCL cannot provide sponsorship.

This process is detailed in full in the related document - KCL Insurance Investigator Guidance for Clinical Trials (section 5.1)

5.0 RELATED DOCUMENTS

5.1 KCL Insurance Investigator Guidance for Clinical Trials

https://internal.kcl.ac.uk/about/ps/finance/treasry/insure

6.0 APPROVAL and SIGNATURE

3rd May 2023

Jackie Pullen
Director
King's Health Partners Clinical Trials Office

Date