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Standard Operating Procedure for Granting UCL Sponsorship for Clinical Trials of Investigational Medicinal Products (CTIMPs)

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Revision Chronology:			
SOP ID Number:	**Effective Date:**	**Reason for Change:**	**Author:**
JBRU/SPON/S07/00	15/10/08	N/A	Joanna Galea-Lauri, Nicky Gower, Sue Kerrison
JBRU/SPON/S07/01	10/01/10	Update SOP to reflect changes in the first contact questionnaire. Clarification of use of risk assessment template to identify trial risk. Format amended in line with revised SOP on SOPs to incorporate a UCL only logo, an Acronyms table, eDocument file path, associated templates/log table, SOP dissemination and training and a signature page. Slight change of title: SOP to be used by Sponsor when assessing risk factors in CTIMPs Sponsorship decision instead of "SOP to be used by Sponsor when assessing risk factors in Sponsorship decision for CTIMPs"	Suzanne Hodgson
JBRU/SPON/S07/02	11/01/12	Due for review. NO CHANGES made as this SOP will be merged with a SOP which is in draft	Same as above, as NO CHANGES
JBRU/SPON/S07/03	16/06/12	SOP Standard Operating Procedure for using the UCL First Contact Questionnaire and CTIMP Protocol Template (JBRU/INV/S01/02) has been superseded by this SOP and is now obsolete. Title of SOP also updated SOP updated to cover all processes involved in UCL sponsorship decision, including costings, protocol review and completion of risk assessment template. Updated to include appointment of UCL as a Legal representative	Alison Evans
JRO/SPON/S07/04	17/06/15	Added JRO peer review procedures Added Initial risk assessment process and template.	Gemma Jones
JRO/SPON/S07/05	29/06/18	Amended insurance confirmation process to align with insurance SOP and inserted flow of information to the JRO Data team.	Nimrita Verma
JRO/SPON/S07/06	22/02/20	Minor clarifications, change of template title from SOC Risk Assessment to Initial Risk Assessment. Reference to additional review committees (e.g. GDPR). Update to clinical trials database from ReDA to EDGE.	Catherine Maidens
JRO/SPON/S07/07	10/12/22	Updated to incorporate the costing process for prospective and retrospective grant applications. Implemented costing review checklist template and CI agreement template. Clarified Stages for Sponsorship review procedure.	Nikkayla Dixon / Samim Patel
JRO/SPON/S07/08	07/01/23	Minor clarifications to the process.	Nikkayla Dixon

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ACRONYMS:	
AcoRd	Attributing the Costs of Health and Social Care Research & Development
ATMP	Advanced Therapy Medicinal Products
BSG	Biostatistics Group (JRO)
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTOM	Clinical Trials Operations Manager
COA	Compliance Oversight Advisor
DIO	Data Information Officer
EEA	European Economic Area
EU	European Union
FCQ	First Contact Questionnaire
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
IMP	Investigational Medicinal Product
JRO	Joint Research Office http://www.ucl.ac.uk/jro/
MHRA	Medicines and Healthcare Products Regulatory Agency
NHS	National Health Service
PIS	Participant Information Sheet
PVG	Pharmacovigilance
QA	Quality Assurance
RA	Risk Assessment
RM	Regulatory Manager
RMP	Regulatory Manager Pharmaceuticals
SOC	Sponsor Oversight Committee
SoECAT	Schedule of Events Cost Attribution Template
SOP	Standard Operating Procedure
SRA	Sponsor Regulatory Advisor
UCL	University College London
UCLH	University College London Hospital NHS Foundation Trust
UK	United Kingdom

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Standard Operating Procedure for Granting UCL Sponsorship for Clinical Trials of Investigational Medicinal Products (CTIMPs)

1. PURPOSE

This standard operating procedure (SOP) describes the activities undertaken by the Joint Research Office (JRO), to grant sponsorship for Clinical Trials of Investigational Medicinal Products (CTIMPs). The sponsorship pathway comprises four defined stages which all CTIMPs must progress through, to obtain sponsorship from University College London (UCL).

2. JOINT UCLH/UCL RESEARCH OFFICE POLICY

All SOPs produced from the JRO must be used in conjunction with local NHS Trust and UCL policies and procedures.

The JRO acts as the representative of the Sponsor and will be the official name used on all SOPs.

3. BACKGROUND

All SOPs are written in accordance with applicable GCP requirements as outlined in SI 2004/1031, SI 2006/1928 and subsequent amendments. Where applicable it incorporates elements of ICH GCP tripartite guidelines (E6). In addition, as UCL sponsors trials with EU and Northern Ireland sites, the SOPs are written to comply with EU Clinical Trials Regulation No. 536/2014.

This SOPs refers to the UCL sponsorship decision process (or agreement to act as EU legal representative) for CTIMPs only.

A **clinical trial** is defined as any investigation in human subjects, other than a non-interventional trial, intended—
(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,
(b) to identify any adverse reactions to one or more such products, or
(c) to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products.
(Ref: Article 2 of Directive 2001/20/EC)

Every clinical trial must have a named Sponsor. A Sponsor is defined in Article 2(e) of Directive 2001/20/EC as “an individual, company, institution or organisation which takes responsibility of the initiation, management and/or financing of a clinical trial”. As per the Clinical Trial Regulations (SI 2006/1928) ‘a person who is a Sponsor of a clinical trial may delegate any or all of his functions under these Regulations to any person, but any such arrangement shall not affect the responsibility of the Sponsor’.

Protocol review
The protocol for a CTIMP must be written in accordance with applicable guidelines and regulations. For UCL sponsored CTIMPs it is a requirement to use the JRO protocol template

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(unless justification is given otherwise and accepted by the Sponsor) which has been written in compliance with these guidelines and regulations.

Risk assessment
A research protocol will always carry an element of risk, which in this case is taken to mean the potential risk to the safety and rights of the research subject, risks to the reliability of the trial results and risks to the Sponsor's institution. A comprehensive risk assessment to identify the inherent risk of a trial is carried out by the JRO prior to UCL sponsorship approval.

Specific factors which are deemed to be risks are outlined in the "**JRO CTIMPs initial and full risk assessment template**" which the JRO uses to assess risk.

Factors that are likely to pose risk in the conduct of a trial include:

- Involving a medicinal product not licensed in the UK or any EU Member State
- Trials that are excluded or restricted in terms of insurance
- Insufficient funding
- Certain groups of patients e.g. pregnant women, children, vulnerable adults.
- CI's lack of trial experience
- Trial complexity in terms of design, size and involvement of multi-centre and/or multinational trials
- Involvement of commercial entities

The risk assessment process is completed to identify potential vulnerabilities in trial design and methodology, including IMP risk, and to identify a management plan to minimise the risks, and facilitate a risk-proportionate approach to the trial activities.

4. SCOPE OF THIS SOP

This SOP describes the JRO process for granting UCL sponsorship for JRO-managed CTIMPs.

The following processes take place, defined as Stages 1 – 4:

Stage 1: Obtain initial study information and determine study categorisation for appropriate regulatory framework and governance processes to be implemented (note this SOP covers CTIMPs only).

Stage 2: Undertake costings to identify the resources and required finances to complete the trial, and confirmation of funding awarded, completion of initial risk assessment.

Stage 3: Review the trial protocol to ensure it meets appropriate standards and corresponds to the UCL protocol template.

Stage 4: Full risk assessment of the trial to identify the risks associated with the trial and appropriate risk mitigation strategies, and, if appropriate, full committee approval of UCL sponsorship, issue of a full sponsorship letter.

For the process and procedure for studies whereby UCL agrees to act as Legal Representative on behalf of a Sponsor based outside of the UK or European Economic Area (EEA), refer to the **Legal Representative Guidance Document**.

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For the process and procedure on taking over sponsorship of a CTIMP from another sponsor organisation, refer to SOP SPON/S27.

5. RESPONSIBLE PERSONNEL

The decision to grant UCL sponsorship, is based on a procedure involving the multidisciplinary team at the JRO.

The roles and responsibilities of individual JRO staff are detailed in the tables found in section 6 of this SOP.

For clinical trials of advanced therapy medicinal products, the duties of the Sponsor Regulatory Advisor (SRA) shall be undertaken by the Regulatory Manager for Advanced Therapy Medicinal Products (RM(ATMP)).

6. PROCEDURE

6.1. Stage 1: Obtain initial study information & Confirm Study Category

	Undertaken by	Activity
1	SRA / RM(ATIMP) / RMP	Receive initial contact from Investigator regarding new trial. Send **First Contact Questionnaire** (FCQ) (associated template) to Investigator.
		Receive completed FCQ and confirm study meets the definition of a CTIMP if this has not already been confirmed. Refer to SOP SPON/S23 for identifying Clinical Trials of Investigational Medicinal Products (CTIMPs). If additional clarification is required, ensure documented evidence is obtained to support the decision. Send Investigator the **Managing Organisation Suitability Questionnaire** (associated template) if the intention is to use a Clinical Research Organisation (CRO) or an external Clinical Trials Unit (CTU) to support the management of this trial.

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6.2.1 Stage 2: Costing Review for prospective grant applications

The aim of this stage is to generate a comprehensive costing of the trial based on the information obtained from stage 1, for the purposes of obtaining a grant for the trial.
If funding has already been obtained for the trial proceed to section 6.2.2. Costing Review for Retrospective grant applications.

	Undertaken by	Activity
1	SRA/RM(ATIMP)	Email Investigator the SoECAT template and request a copy of the draft grant application. https://www.nihr.ac.uk/documents/schedule-of-events-cost-attribution-template-SoECAT-guidance/23214
		If trial statistician is external to JRO Biostatistics Group (BSG) issue **Trial Statistician's Engagement Letter template** (associated template) to Investigator & request statisticians CV. If BSG collaboration is required, advise the Investigator to contact the BSG administrator directly to arrange a meeting. If JRO BSG collaboration has already been negotiated, confirm with BSG.
		Identify if the trial will have peer review as part of the grant application. If not, instruct the investigator to organise the proposal to undergo independent Peer Reviews and provide copies of the Peer Reviews as per the JRO SOP 15: Standard Operating Procedure for Peer Review for Studies Sponsored by UCL and UCLH.
2	SRA/RM(ATIMP)	Receive draft grant application, draft SoECAT and completed statistician engagement letter (if applicable). Review received documents for completeness.
3	SRA/RM(ATIMP) / Data Information Officer (DIO)	Send request to JRO Data Team for trial registration on EDGE. Receive JRO sponsor number (EDGE ID) for the trial and inform Investigator of registration and the trial sponsor number (SRA/RM(ATIMP)). A copy of the following documents should be sent to the JRO Data Team: • FCQ • Draft grant application • Completed statistician engagement letter Create folder on the S drive in the SpF PROPOSED folder once EDGE number received.
4	SRA/RM(ATIMP)	Assess funding requirements for the trial, using the **CTIMP Costing Review Checklist** (associated template).

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	Undertaken by	Activity
5	SRA/RM(ATIMP) / RMP / COA	Send draft grant application / synopsis & FCQ to relevant JRO staff to assess protocol requirements and review impact on cost (e.g. RM (Pharmaceuticals) for review of IMP requirements, and Compliance Oversight Advisor (COA) to assess monitoring requirements).
6	SRA/RM(ATIMP) / BSG	Send signed trial statistician's engagement letter, grant application (including a summary section) & Statistician CV to the BSG clinical trial lead for review. The BSG will review whether the named statistician is adequately qualified and engaged with the study and that they are responsible for the sample size calculation.
7	SRA / RM(ATIMP)/ JRO Finance team	Send completed draft SoECAT and draft grant application form to the JRO Finance Team to initiate Finance Team review.
8	JRO Finance team	Finance team to review and/or arrange meeting with Investigator to develop the SoECAT.
9	SRA/ RM(ATIMP) / JRO CTIMPs team	Complete **Initial Risk Assessment** (associated template) for the trial. Document if escalation is required to the UCL General Data Protection Regulation (GDPR) committee or other committee/departments for specialist review.
10	SRA/ RM(ATIMP) / JRO CTIMPs team	Review Initial Risk Assessment at the Clinical Operations Meeting. For trials requiring input from another committee (e.g. GDPR committee), this should be undertaken before the Clinical Operations meeting. If considered necessary based on anticipated risk, the trial will be referred to the Sponsor Oversight Committee (SOC).
11	CI/delegate / JRO Finance Team	Trial team to update SoECAT based on advice from Finance Team review and send back to Finance Team. Continue with steps 8 and 11 until consensus reached.
12	JRO Finance Team	When the SoECAT has been finalised send to the JRO AcoRd Specialist at UCLH for validation (authorisation). Send authorised SOECAT to Trial Team and SRA.
13	SRA/RM(ATIMP)	Finalise **CTIMP Costing Review Checklist** and have checklist reviewed and counter-signed by another member of the JRO CTIMPs team.
14	SRA/RM(ATIMP)	Send email to Investigator copying in Research Services detailing all the costs (i.e. summary table from CTIMP Costing Review Checklist) that need to be included in the Worktribe and grant application, along with the validated SOECAT. NB. Ensure Worktribe number is included in the email subject line. Issue **"in principle" sponsorship letter** (associated template) (if required for purposes of grant application) signed by authorised JRO signatory.

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	Undertaken by	Activity
15	SRA/ RM(ATIMP)	Request copy of final grant application and pdf of final Worktribe costings from Investigator. File all documents in the Sponsor File.
16	SRA/ RM(ATIMP)	Await outcome of grant award. Follow up with Investigator on an approximate three-monthly basis to track progress of grant application. File correspondence in the Sponsor File.
17	SRA/ RM(ATIMP)	If grant application is not successful, obtain confirmation of Investigator's plan for the trial. If no further applications will be made for funding, file confirmation in Sponsor File, and move the folder on the S drive to the SpF ABANDONED folder. Update the status on EDGE to abandoned. If further applications for funding are to be submitted, repeat steps 4 to 15.
		If application is successful, receive confirmation of grant award from Investigator by receipt of grant award letter and signed funding agreement. If full funding awarded, proceed with Stage 3 and set up Sponsor File in accordance with JRO SPON/SOP S11. If a shortfall in funding is identified (e.g., full award not given), funding will be reviewed internally at JRO and, if required, referred to SOC. Once decision received from JRO or SOC, proceed with Stage 3 or advise Investigator of decision to decline Sponsorship.

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6.2.2 Stage 2: Costing Review for Retrospective Grant Applications

The aim of this stage is to generate a comprehensive costing of the trial based on the information obtained from stage 1 and to confirm the funding awarded is sufficient for the trial.

Costing will be generated based on information provided from the Investigator. Any subsequent changes to the study design, management etc. may impact on the overall costs and sponsorship decision and further adjustments may be required.

	Undertaken by	Activity
1	SRA/RM(ATIMP)	Request copy of the submitted grant application, completed SoECAT (if submitted as part of grant application), funding award letter, signed funding contract and approved Worktribe costings.
		If trial statistician is external to BSG issue **Trial Statistician's Engagement Letter template** (associated template) to Investigator & request statisticians CV. If SoECAT was not completed as part of grant application, issue SoECAT template for investigator to complete. https://www.nihr.ac.uk/documents/schedule-of-events-cost-attribution-template-SoECAT-guidance/23214 Send appropriate protocol template (CTIMP or ATIMP) to Investigator.
		Identify if the trial has had peer review as part of the grant application. If not, instruct the investigator to organise the proposal to undergo 2 independent Peer Reviews and provide copies of the Peer Reviews as per the Standard Operating Procedure for Peer Review for Studies Sponsored by UCL and UCLH.
2	SRA/ RM(ATIMP)	Receive copy of submitted grant application, funding award letter, signed funding contract , approved Worktribe costings, Trial Statistician Engagement & Statistician CV and SOECAT.
3	SRA/RM(ATIMP) / Data Information Officer (DIO)	Send request to JRO Data Team for trial registration on EDGE. Receive JRO sponsor number (EDGE ID) for the trial and inform Investigator of registration and the trial sponsor number. A copy of the following documents should be sent to the JRO Data Team: • FCQ • Submitted grant application • Completed statistician engagement letter • Funding award letter Create folder on the S drive in the SpF INSETUP folder once EDGE number received.

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	Undertaken by	Activity
4	SRA/RM(ATIMP)	Assess funding requirements for the trial, using the **CTIMP Costing Review Checklist** (associated template).
5	SRA/RM(ATIMP) / RMP / COA	Send grant application / synopsis & FCQ to relevant JRO staff to assess protocol requirements and review impact on cost (e.g. RM (Pharmaceuticals) for review of IMP requirements, and Compliance Oversight Advisor (COA) to assess monitoring requirements).
6	SRA/RM(ATIMP) / BSG	Send signed trial statistician's engagement letter, grant application (including summary section) & Statistician CV to the BSG clinical trial lead for review. The BSG will review whether the named statistician is adequately qualified and engaged with the study and that they are responsible for the sample size calculation.
7	SRA/RM(ATIMP)	If SoECAT was submitted as part of grant application, confirm it has been authorised by an AcoRd specialist. If not send to JRO Finance Team to review along with grant application.
8	SRA/RM(ATIMP) / JRO Finance Team	If SoECAT was not submitted as part of grant application send completed draft SoECAT and grant application form to the JRO Finance Team to initiate Finance review.
9	CI/delegate / JRO Finance Team	Finance team to review and/or arrange meeting with Investigator to develop the SoECAT.
10	CI/delegate / JRO Finance Team	Trial team to update SoECAT based on advice from Finance Team review and send back to Finance Team. Continue with steps 9 and 10 until consensus reached.
11	JRO Finance Team	When the SoECAT has been finalised send to JRO AcoRd Specialist at UCLH for validation (authorisation). Send authorised SoECAT to Trial Team and SRA.
12	SRA/RM(ATIMP)	Finalise **CTIMP Costing Review Checklist** and have checklist reviewed and counter-signed by another member of the JRO CTIMPs team.
13	SRA/RM(ATIMP)	Review the approved Worktribe costings against **the CTIMP Costing Review Checklist**, to confirm there is sufficient funding for the trial. If a shortfall in funding is identified, inform Investigator and confirm their plan to make up the shortfall. If there is no plan, funding will be reviewed internally at JRO and, if required, referred to SOC. If trial remains underfunded and an adequate plan is not identified, Sponsorship will be declined.
14	SRA/RM(ATIMP)	Complete **Initial Risk Assessment** (associated template) for the trial. Document if escalation is required to UCL GDPR committee or other committee/departments for specialist review.

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	Undertaken by	Activity
15	SRA/RM(ATIMP) / JRO CTIMPs Team	Review Initial Risk Assessment at the Clinical Operations Meeting. For trials requiring input from another committee (e.g. GDPR committee), this should be undertaken before the Clinical Trial Operations meeting. If considered necessary based on anticipated risk, the trial will be referred to Sponsor Oversight Committee (SOC).
16	SRA/RM(ATIMP)	Set up sponsor file in accordance with JRO SPON/SOP S11.

6.3 Stage 3: Protocol Review

Wait for funding to be obtained, and/or confirm sufficient funding in place prior to starting this step.

	Undertaken by	Activity
1	SRA/RM(ATIMP)	Request draft protocol (completed using the JRO Protocol Template (associated template) and applicable supporting documents from Investigator.
2	SRA/ RM(ATIMP) / RMP / COA / Pharmacovigilance manager (PVG) / Clinical Trials Operations Manager (CTOM) / BSG	Upon receipt of completed protocol template send protocol and the following supporting documents to the BSG for review: • Signed trial statistician's engagement letter • Statistician CV • Funder details (i.e., Award letter if funding section not completed in protocol) **and in parallel** undertake protocol review across JRO CTIMPs team.
3	SRA/RM(ATIMP)	Return consolidated protocol comments to Investigator. BSG may correspond with Investigator directly.
4	SRA/RM(ATIMP)	Receive amended draft protocol, confirm standard of protocol is compliant with the regulations and sufficient (including approval of the BSG) to complete the **Full Risk Assessment** (associated template). Continue with steps 2 and 3 until consensus reached and final draft of protocol is approved.
5	SRA/ RM(ATIMP) / CI	Ensure final protocol is signed by the Chief Investigator and JRO authorised signatory (refer to JRO Authorised Signatories List).
6	SRA/RM(ATIMP) / CI	Prepare supporting trial documents (e.g Participant Information Sheet (PIS), Informed Consent Form (ICF), GP Letter etc). (Refer to JRO/SPON/SOP29)

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6.4 Stage 4: Sponsorship Review and Approval

	Undertaken by	Activity
1	SRA/RM(ATIMP)	- Send or complete the **Insurance Registration Form** (if not already done) (refer to JRO/SPON/SOP28). - Inform the CI or delegate of the requirement to register trial with the UCL Data Protection Office. https://www.ucl.ac.uk/data-protection/guidance-staff-students-and-researchers/research/research-registration-guidance - Draft **CI Agreement** (associated template), send for review and obtain signatures.
2	SRA/RM(ATIMP) / CTOM	Undertake **Full Risk Assessment** (associated template) and review in Clinical Operations Meeting. Finalise Full Risk Assessment and sign off.
3	SRA/RM(ATIMP)	Issue **Full Sponsorship Letter** (associated template) (signed by JRO authorised signatory) and fully executed CI agreement, or notify Investigator of decision to decline sponsorship, as applicable. Ensure Investigator is informed of any conditions attached to sponsorship approval. Note: Following issue of the full sponsorship letter, if a change is made which significantly affects the trial design, patient safety, or management of the trial it may be necessary to repeat applicable stages of this SOP.
4	SRA/RM(ATIMP)	File all relevant information in the Sponsor File. Update EDGE with the status 'project in set-up' and complete 'CTIMP milestones' on the workflow tab.
5	SRA/RM(ATIMP)	Send a copy of the following document to JRO Data Team for uploading onto EDGE: • Completed FCQ • Signed Sponsorship in Principle letter (if applicable) • Signed Full Sponsorship Letter • Signed CI agreement • Confirmation of Funding letter
6	SRA/ RM(ATIMP)	Proceed with obtaining REC/MHRA approvals. (Refer to JRO/SPON/SOP29)

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7. REFERENCES

MHRA website:
https://www.gov.uk/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk

Joint Research Office website:
https://www.ucl.ac.uk/joint-research-office/

ICH Harmonised Tripartite Guideline for Good Clinical Practice E6(R2) (2016)

Directive 2001/20/EC OF the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

The Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004 No 1031) as amended.

COMMISSION DIRECTIVE 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products.

EU Regulations 536/2014

8. TEMPLATES/LOGS ASSOCIATED TO THIS SOP

JRO Templates	
1	First Contact Questionnaire
2	CTIMP Protocol Template
3	ATIMP Protocol Template
4	Statistician's Engagement Letter Template
5	CTIMP Costings Review Checklist
6	Full Sponsorship Letter Template
7	Sponsorship In Principle Letter Template
8	Legal Representative Letter Template
9	Legal Representative Guidance Document
10	Chief Investigator Agreement Template
11	Managing Organisation Suitability Questionnaire
12	Initial Risk Assessment Template
13	Full Risk Assessment Template

UCL SOPs/ Policies / Guidance Documents	
1	SPON/S27: Standard Operating Procedure for Transfer of CTIMP Sponsorship to UCL
2	SPON/S28: Standard Operating Procedure for Ensuring Appropriate Insurance Provision for UCL Sponsored Clinical Trials and Clinical Research Studies Managed by the JRO or UCL CTUs

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3	SPON/S23: Standard Operating Procedure for identifying Clinical Trials of Investigational Medicinal Products.
4	SPON/S11: Standard Operating Procedure for the Preparation of the JRO Sponsor File
5	JRO SOP 15: Standard Operating Procedure for Peer Review for Studies Sponsored by UCL and UCLH
6	SPON/S29: Standard Operating Procedure for Preparing and Obtaining Approvals for Clinical Trials of Investigational Medicinal Products

9. SOP DISSEMINATION AND TRAINING

SOPs will be distributed to the relevant staff, by the named author on the front page of the SOP. Staff will sign the SOP training log (12. SOP TRAINING LOG) which is part of each SOP.
The training will constitute of the person reading the SOP and being provided with the opportunity to ask specific questions to the author of the SOP.

10. SIGNATURE PAGE

Author and Job Title:	Nikkayla Dixon, Sponsor Regulatory Advisor
Signature and Date:	DocuSigned by: Nikkayla Dixon EF2DE1E12340484... 07/12/22

Authorised by: Name and Job Title	Helen Cadiou, Head of QA
Signature and Date:	DocuSigned by: Helen Cadiou 9FE319AE9B744D5... 07/12/22

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12. SOP TRAINING LOG

	Name of Staff (Capital letters)	**Job Title:** **Department:**	**Training Date**	*I confirm that I understand & agree to work to this SOP* **SIGNATURE**	**Name of Trainer** (if training required)	**Signature**	**Date**
1							
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	Name of Staff (Capital letters)	**Job Title:** **Department:**	**Training Date**	*I confirm that I understand & agree to work to this SOP* **SIGNATURE**	**Name of Trainer** (if training required)	**Signature**	**Date**
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	Name of Staff (Capital letters)	**Job Title:** **Department:**	**Training Date**	*I confirm that I understand & agree to work to this SOP* **SIGNATURE**	**Name of Trainer** (if training required)	**Signature**	**Date**
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