St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

# Standard Operating Procedure (SOP)
# Issuing Sponsorship in Principle for CTIMPs

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| **SOP ID number:** | JREOSOP0003 | **Effective Date:** | 04/01/2018 |
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| **Approved by:** | Subhir Bedi | **Date:** | 21/12/2017 |
| **Signature of Authorisor** | | | |

This is a controlled document.
The master document is posted on the JREO website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JREO website for the most recent version.
They may print off this document for training and reference purposes.

| SOP Chronology | | |
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| **SOP Version Number:** | **Reason for Change:** | **Author:** |
| V1.0 | Original Version | Ailsa Withers |
| V2.0 | Updated to reflect new process adopted by JRO since Jan 2010 and to issue new SOP ID number in line with SOPs designed to outline new JRO processes and procedures | Ira Jakupovic |
| V3.0 | Review of V2.0 | Ira Jakupovic |
| V4.0 | Updated in line with new JREO SOP template and ID issue number and to incorporate new process and procedure | Debbie Rolfe |
| V5.0 | Updated with new Trust Foundation status | Debbie Rolfe |
| V6.0 | Reviewed and updated to include HRA changes | Debbie Rolfe |
| V7.0 | Requirement for deputy PI to cover in absence of CI | Debbie Rolfe |
| V8.0 | Incorporate Portfolio adoption, HTA registration and Data repository | Debbie Rolfe |

## 1. Background

A Sponsor takes responsibility for the initiation, management and/or financing (EU Directive 2001/20/EC) of research and clinical trials. It is a legal requirement that all Clinical Trials of Investigational Products (CTIMPs) have a Sponsor that is willing and able to take on the responsibilities and liabilities under the Medicines for Human Use (Clinical Trial) Regulations 2004 SI 1031 and subsequent amendments (The Regulations).

The Sponsor is usually the company, institution or organisation that is taking responsibility for initiating, financing and/or managing the research or Clinical trial.
The Sponsor has the primary responsibility for ensuring that the design of the study meets appropriate standards and that the arrangements are in place to ensure appropriate conduct and reporting.

A Sponsor is required for all NHS research in the UK, including:

- Research concerned with the protection and promotion of public health
- Research undertaken in or by the Department of Health, its non-departmental public bodies and the NHS
- Research undertaken by or within social care agencies
- Clinical and non-clinical research
- Research undertaken by the NHS or social care staff using the resources of health and social care organisations
- Research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services. (UK Policy Framework for Health and Social Care Research –V3.2 October 2017)

The Sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written standard operating procedures (SOPs) to ensure that trials are conducted, data generated, documented (recorded) and reported in compliance with the protocol, Good Clinical Practice (GCP) and the applicable regulatory requirements.

The Sponsor is responsible for securing agreement from all involved parties to ensure direct access to all research related sites, source data/documents, and reports for the purpose of monitoring and auditing by the Sponsor and inspection by regulatory authorities.

All trials must be adequately funded to ensure that the CTIMP can be set up and conducted in accordance with current legislation.

It is the expectation of St Georges that all Research to be considered for sponsorship by St George's that has received external funding should be submitted for portfolio adoption. It is the responsibility of the Chief Investigator to ensure a portfolio application form (PAF) is completed at the earliest opportunity and submitted via IRAS (prior to the IRAS form completion and submission).

## 2. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JREO acts as the representative of both St George's University of London (SGUL) and St George's University Hospital NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent either institutions acting as Sponsor.

## 3. Scope

This SOP outlines the role of the JREO in the review process for all CTIMP research that is to be considered for Sponsorship by St George's and the subsequent issue of 'Sponsorship in Principle'

## 4. Definitions

For general research management related acronyms used in this SOP refer to "General Research Definitions" working practice document JREOWPD0020

## 5. Responsibilities

This SOP is to be followed by the Chief Investigator, Regulatory Assurance Manager (RAM) and Regulatory Support Officers (RSOs).

It is the responsibility of the HRGD to ensure that the SOP is updated and audited where necessary.

It is the responsibility of the Chief Investigator (CI) to ensure that the completed 'Clinical Trials Risk Assessment questionnaire' (JREODOC0032) and any other requested documentation is submitted to the assigned member of the Research Assurance Team (RAT).

The Chief Investigator is responsible for ensuring engagement with the JREO funding and governance teams prior to submission to the funding body. The JREO funding and governance team will ensure the cost aspects in relation to the delivery of the research study are considered and the Schedule of events is completed to facilitate attribution of costs in accordance with AcoRD.

It is the responsibility of the Chief Investigator (CI) to complete a Portfolio Adoption form (PAF) within IRAS for any externally funded research project considered for sponsorship. A copy of the locked PAF must be provided to the RAM/RSO. Any CI that does not wish to submit a PAF then the RAT should escalate to HRGD.

It is the responsibility of the assigned member of the RAT to ensure review of all relevant documents in accordance with this SOP prior to Sponsorship in Principle being issued.

## 6. Procedure

### 6.1 Investigator Procedure

a) The CI will answer yes to the question 5b in the IRAS project filter questions for the IRAS system to generate a Portfolio adoption form (PAF)

b) The CI or delegate will need to complete the sections on the generated PAF and on the submission tab- select CRN network –London-South and then submit. Bottom RHS of submission tab page- select the PAF PDF save and send to the RAT

c) The CI will submit the completed Clinical Trials Registration and Risk Assessment Questionaire JREODOC0032, a copy of the protocol (template JREODOC001) , the draft IRAS application form and where applicable the Schedule of events and Statement of activities (latest versions available on the Health Research Authority (HRA) website http://www.hra.nhs.uk/resources/hra-approval-guidance-for-sponsorschief-investigators-working-collaboratively-with-nhs-organisations-in-england/ ) to the assigned RAT member. The IRAS website has a training section and question- specific guidance www.myresearchproject.org.uk . If students form part of the study team, they must be added to the Risk Assessment Questionnaire.

d) If the study is multi-site and network supported the Schedule of events should be submitted to the network study support team for assessment and approval. The

CI will be required to complete the Statement of Activities and Schedule of Events latest version found here http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/ Hint- should match QA18 & 19 on IRAS. The network study support service will attribute costs in accordance with AcoRD.

e) No student may act as either the Chief Investigator or the Principal Investigator of a CTIMP study. This includes PhD students.

f) The CI of a study that includes an IMP, medical device or surgical intervention must have a suitably qualified named PI named on the study delegation log as capable through training and experience as deputising for the study CI in his/her absence.

g) The CI will respond to RAT member request for any further documentation or amendments if applicable within 20 working days of email request date.

h) Once completed this Schedule of Events and Statement of Activities should be uploaded on IRAS ready for submission on the Checklist tab.

i) The network Study Support team will also have completed a Milestones and Network Recommendations form to send on to the Network for participating sites to view.

j) Following receipt of the SIP letter and confirmation from the RAT, the CI is then authorised to submit the application to the National Research Ethics Service (NRES) and HRA where applicable.

### 6.2 JREO Procedure

a) Upon notification within the RGT team of a proposed CTIMP for Sponsorship – the RGT team member will inform the RAM who will assign a RAT member within 5 working days

b) The assigned RGT member will email the CI, notifying them of the named JREO point of contact and to request a copy of the PAF.

c) Upon receipt of the locked PAF form via the CI ensure a copy is saved to the study e-file. Print a copy for the physical Sponsor site file.

d) The RAT member will review the completed Clinical Trials Risk Assessment Questionnaire, protocol, the draft IRAS application form, Patient Information Sheet(s), consent forms, Schedule of Events and Statement of Activities (if multi-site) and follow the Risk Assessment working Practice document JREOWPD0002 and Risk Assessment for CTIMPS procedure JREOSOP0005.

e) The RAT member will forward the draft protocol and the draft Participant information sheet and Insurance enquiry questionnaire to the insurance

underwriter for assessment of insurance policy cover. The CI may be required to assist in completion of the questionnaire or to answer generated queries

f) The RAT member shall print and file in the Sponsor site file, any relevant email correspondence with regards to insurance assessment and follow up on any associated advice given by the insurance underwriter.

g) If further documentation is required to complete the Risk Assessment, the RAT member will contact the investigator via email requesting such documentation.

h) If no response has been received within 20 working days, then the RAT member will return any documents held in the JREO to the CI with confirmation that resubmission for SIP will be required.

i) Upon completion of the Risk Assessment the RAT member will enter the new project onto the EDGE database and assign a new sequentially allocated R&D number.

j) The minimum dataset will be entered onto EDGE to include study title; CI and deputy PI contact details as key members of staff, and any other information available including receipt of valid application for Sponsorship on the notes tab.

k) Where relevant, the RAT member will email details of the study to the lead SGHT Research Pharmacist to ensure they are aware of the proposed CTIMP and the requirement to sign off the Risk Assessment completed by the CI prior to return to the RAT.

l) The RAT member will contact the CI to request any further documentation that may be required to complete the HRA/ethics application.

m) The RAT member will cross check the IRAS application form with the protocol, PIS and other supporting documents and feedback comments to the CI

n) The RAM will provide a copy of the Protocol and PIS to the insurance broker together with a completed UMAL webpage assessment application.

o) Issue of a 'Sponsorship in Principle' letter (JREODOC0015) to the CI within 5 working days of receipt of all documentation and completion of a satisfactory review.

p) The RAT member will include a copy of Delegation of Duties Sponsorship Application (DDSA) JREODOC0013 within the communication (usually by email) containing the SIP declaration.

q) Inform the CI to upload the SIP letter to the IRAS study checklist together with study specific SGUL Insurance certificate (upon confirmation of acceptance by UMAL) if study sponsored by SGUL.

r) If the Research study proposes to store tissue samples at SGUL pre-complete a HTA registration form (JREODOC0087) with known fields and email back to the CI and the HTA Designated Individual (DI) with instructions for completion and return

s) If the Research study proposes to store data in SGUL then inform Research Data Support Manager via email sending a copy of the protocol and draft IRAS

t) The RAT member will update the EDGE research database with the EDGE Minimum Dataset (MDS)

u) The RAT member will liaise with the lead Research Pharmacist to progress the MHRA submission

v) Upon confirmation of HRA/REC submission the RAT member will liaise with the Investigator regarding the identified sites for a multi-site study to facilitate sending the submission pack to enable the sites to commence feasibility of capacity and capability assessments- the submission pack could comprise of HRA INITIAL Assessment letter, Statement of Activities, Schedule of Events, Protocol, ICF, PIS and any other documents that would assist the review process.

## 7. References

Integrated Research Application System - www.myresearchproject.org.uk

http://www.hra.nhs.uk/resources/hra-approval-guidance-for-sponsorschief-investigators-working-collaboratively-with-nhs-organisations-in-england/

http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/

https://www.crn.nihr.ac.uk/can-help/study-support-service/

JREODOC0013 Delegation of duties Sponsorship Agreement

JREODOC0015 Sponsorship in Principle letter

JREODOC0087 HTA Registration of Collection Form

## 8. Appendices

None associated with this SOP.