St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

# Standard Operating Procedure (SOP)
# Issuing Final Sponsorship for CTIMPs

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| **Author:** | Debbie Rolfe | **Title:** | Acting Head of Research Governance |
| **Approved by:** | Mark Cranmer | **Date:** | 27.1.17 |
| **Signature of Authorisor** | | | |

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They may print off this document for training and reference purposes.


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| SOP Chronology | | |
|---|---|---|
| **SOP Version Number:** | **Reason for Change:** | **Author:** |
| V1.0 | Original Version | Ailsa Withers |
| V2.0 | Updated to reflect the new process adopted by the JRO since January 2010 and to issue a new ID number in line with SOPs designed to outline new JRO processes and procedures. | Ira Jakupovic |
| V3.0 | Review of V2 | Ira Jakupovic |
| V4.0 | Updated in line with new JREO SOP template and ID issue number and to incorporate new process and procedure | Lisa Clutterbuck and Debbie Rolfe |
| V5.0 | Updated with new St Georges Trust Foundation status | Debbie Rolfe |
| V6.0 | Updated with incorporation of new HRA process in England | Debs Rolfe |
| V7.0 | Updated RGT roles | Debbie Rolfe |


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| Table of Contents | Page |
|---|---|
| 1. Background | 4 |
| 2. Joint Research and Enterprise Office (JREO) Policy | 5 |
| 3. Scope | 5 |
| 4. Definitions<br>4.1 Sponsorship in principle<br>4.2 Clinical Trial<br>4.3 Investigational Medicinal Product (IMP)<br>4.4 Final Sponsorship | 5<br><br>6 |
| 5. Responsibilities | 6 |
| 6. Procedures<br>6.1 Investigator procedure<br>6.2 JREO procedure | 7 |
| 7. References | 9 |
| 8. Appendices<br>Appendix 8.1 Final Sponsorship letter template JREODOC0016 | 9<br>10 |


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## 1. Background

A Sponsor takes responsibility of the initiation, management and/or financing of research and clinical trials as stated in the EU Directive 2001/20/EC. For Clinical Investigations of Investigational Medicinal Products, it is a legal requirement that a Sponsor is in place to take on the responsibilities and liabilities under the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031) and subsequent amendments (The Regulations).
The Sponsor is usually the company, institution or organisation that takes responsibility for initiation, financing and/or managing the 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's responsibilities include (but are not necessarily limited to):

- Confirming that everything is ready for the research to begin.
- for putting and keeping in place arrangements to initiate, manage and there are sufficient funds to cover the study costs;
- satisfying itself the research protocol, research team and research environment have passed appropriate scientific quality assessment in the form of 'peer review' (JREOSOP0021)
- satisfying itself the study has ethical, regulatory and Research Governance approval before it begins;
- Satisfying itself that arrangements and sufficient oversight will be in place to ensure good clinical practice in conducting the study, for monitoring and pharmacovigilance activities.

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.


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(Research Governance Framework for Health and Social Care 2nd edition 2005, section 1.2)

The Sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written standard operating procedures (SOPs) to ensure that studies 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 research must be adequately funded to ensure that the research can be set up and conducted in accordance with current legislation.

## 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 Hospitals NHS Foundation Trust (SGHT). St George's will be the official name used on all SOPs to represent either institution 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 Georges and the subsequent process of issuing 'Final Sponsorship'.

## 4. Definitions

### 4.1 Sponsorship in principle

St George's is prepared, in principle, to act as Sponsor based on the information presented by the applicant. It is recognised that Sponsors cannot give a final confirmation of their


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ability to Sponsor a study until all arrangements for the study have been confirmed as satisfactory. Once a Sponsor has declared that they agree in principle to act as a Sponsor, the Sponsor is expected to make clear in writing to all parties if it no longer agrees to Sponsor a study at any stage. It is therefore reasonable for all parties to assume that an organisation that has agreed in principle to 'act as Sponsor' is the final Sponsor unless the organisation clarifies in writing that it is no longer the Sponsor.

### 4.2 Clinical Trial

Any investigation in human subjects intended to discover or verify the clinical pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or identify any adverse reaction(s) to that Investigational product(s) and to study absorption, distribution, metabolism and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

### 4.3 Investigational Medicinal Product (IMP)

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when to gain further information about an approved use.

### 4.4 Final Sponsorship

Following the initial agreement to act as 'Sponsor in principle' on behalf of St George's the JREO will also issue Declaration of Final Sponsorship once the process described in this SOP is completed

## 5. Responsibilities

This SOP is to be followed by the JREO Governance and Approvals team: Head of Research Governance (HRG), Regulatory Assurance Manager (RAM), Clinical Trial Monitors (CTMs), Research Governance Officers (RGOs) and JREO Legal team

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


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It is the responsibility of the Chief Investigator (CI) to ensure that the completed requested documentation is submitted to the assigned member of the Research Governance Team (RGT)

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

## 6. Procedure

### 6.1 Investigator Procedure

a) The CI or delegated research team member will respond to the RAM's and/or HRG's request for any further documentation or amendments if applicable within 20 working days of email request date.

b) The CI or delegated research team member must maintain appropriate version control of all documents.

c) The CI must file the fully executed DDSA and Final Sponsorship letter in the Trial Master File.

### 6.2 JREO Procedure

a) Prior to 'Final Sponsorship' being issued, the RAM and/or HRG will ensure that the following documentation is in place:

- For adopted multi-site studies The Health Research Authority (HRA) Schedule of events needs to have been approved by the network and returned to the JREO prior to IRAS upload. For non-adopted multi-site studies the HRA schedule of events needs to have been completed by the CI (RGT member may need to assist)
- Issue of HRA approval – where the HRA issued an opinion subject to conditions being met, the RAM/HRG must ensure those conditions have been met and a final HRA approval letter has been issued.
- Favourable Ethical Opinion – where the REC has issued a Provisional Opinion or Favourable Opinion subject to conditions according to JREOSOP0040 Applying to NHS Ethics, the RAM and/or HRG must ensure that any responses to the REC's request for further information have been made and a final approval letter has been issued
- MHRA Acceptance Letter for a Clinical Trial Authorisation – the RAM and/or HRG will liaise with the CI in order for the RAM and/or the HRG to respond to the MHRA's request for further information if a 'Grounds for non-acceptance' letter or


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'Acceptance of the request for a clinical trial authorisation subject to conditions' letter has been received according to the JREOSOP0045 (Applying to the MHRA for a CTA)

- Evidence of funding agreement and confirmation of sufficiency of funds
- Evidence of Insurance/indemnity cover
- Risk Assessment
- Completed Monitoring Plan as per the JREO Monitoring Working Practice Document JREOWPD0008
- Delegation of Duties Sponsorship Agreement (DDSA) JREODOC0013 signed by the Chief Investigator

b) Please note that pharmacy may also need to approve any subcontracting arrangements prior to final Sponsorship being issued.

- Agreements with Sub-Contractors e.g. Technical Agreements –NB you may need to liaise with the Lead Research Pharmacist to check on the progress as the absence of a final version should not prevent Final Sponsorship being issued
- Pharmacy 'Green Light' correspondence from the Lead Research Pharmacist
- Final 'approved' versions of Protocol, GP letters, Patient Information and Informed Consent forms and any IMP related documents such as Investigator Brochure or IMP dossier etc.

c) If any issues arise or the documentation above is not complete the RAM/HRG will email the CI within 5 working days for clarification.

d) On receipt of the REC Favourable Opinion and the MHRA Acceptance Letter, the RAM and/or HRG will inform the Lead Research Pharmacist to start finalising the Research Pharmacy Green light procedure (CTPSOPB8).

e) The RAM and/or HRG will inform the following officers of the approvals so that the following processes can be initiated:

| Person/Officer | Process/Action Required | SOP Reference |
|---|---|---|
| Clinical Trial Monitor | Prepare for the Clinical Trial Initiation | JREOSOP0013 |
| Lead Research Governance Officer | Confirmation of Host Site capacity and capability Process | JREOSOP0017 |
| Legal team | Contracts/Agreements | JREOSOP0030 |

f) The RAM will sign and date the CI signed DDSA.


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g) The RAM and/or HRG will prepare a Declaration of Sponsorship Letter (JREODOC0016) and email the signed letter together with the completed DDSA to the CI and other relevant study team members along with the JREO Zip File for CTIMP studies. This folder contains all the JREO CTIMP related SOPS and Logs.

h) The RAM and/or CTM will inform the CI of the Site Initiation procedure (JREOSOP0013) and that patient recruitment must not commence until the Site Initiation Procedure has been conducted and the Open to Recruitment letter (JREODOC0043) has been issued by the CTM or RAM.

i) The RAM and/or CTM will update ReDA and EDGE with the relevant information and upload any study related documents e.g. MHRA Clinical Trial Authorisation (CTA), Ethics approval

j) The CTM and/or RAM will set up the email alerts/reminders in ReDA for Annual Progress Report according to anniversary date of Ethics approval and DSUR according to approval date of MHRA CTA. The RAM and/or CTM will ensure all relevant documentation and correspondence is filed in the paper and electronic Sponsor File in accordance with the JREO CTIMP file index (JREODOC0066).

k) The RAM and/or CTM will move the electronic Sponsor file from pending/in set up folder to Investigator/ XX.Xxxx_Trial Acronym_Agresso code once the first site has been activated. This may or may not be SGHT.

l) The RAM and/or CTM will update the Sponsored Clinical Trials tracking systems with the new status and required details

m) The RAM/CTM will update EDGE Minimum Dataset (MDS) with study details and status.

## 7. References

ReDA – www.reda.org.uk

Research Governance Framework (2nd Edition, 2005) - www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf

ICH Good Clinical Practice - http://ichgcp.net/

## 8. Appendices

Appendix 8.1: JREODOC0016 Final Sponsorship

**Appendix 8.1: JREODOC0016 Final Sponsorship Template Letter ( to be on headed paper)**

**Direct Line:** 020 8


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**Direct Fax:** 020 8725 0794

**Email:** xxxx@sgul.ac.uk

Insert Date FS issued

Dear Insert CI's name

**PROJECT TITLE:** Insert full study title

**Protocol version and date:** Insert protocol version number and date

**REC Reference:** Insert REC reference **IRAS ID:**

**JREO Reference:** Insert JREO project reference number

**EudraCT number:** Insert EudraCT number

**Chief Investigator (CI):** Insert CI's name

**Declaration of St George's University Hospitals NHS Foundation Trust / St George's, University of London *(delete appropriate)* Sponsorship**

The Trust/University *(delete appropriate)* has reviewed the application, supporting documentation and applicable approvals for the above project, and I am pleased to inform you that the Trust/University *(delete appropriate)* is willing to act as the trial Sponsor.

Trust/University *(delete appropriate)* Sponsorship is provided on the condition that all research will be conducted in accordance with the Research Governance Framework for Health and Social Care, 2nd Edition, April 2005 and The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) and its subsequent amendments, SI 2006/2984 and SI 2008/941 and Sponsor's Standard Operating Procedures (SOPs).

The Sponsor will undertake the responsibility to implement all applicable regulatory requirements and to ensure that the outlined responsibilities of the ***Delegation of Duties Sponsorship Agreement (DDSA)*** are adhered to at all times.

I can confirm that necessary indemnity and/or insurance arrangements are in place and that insurance and/or indemnity policies will be renewed for the duration of the study where necessary.

***Please be aware that this letter does NOT constitute confirmation of capacity and capability (R&D) approval. Host site (R&D) approval must be obtained for each site hosting the trial before research commences at that site, including St George's.***

Please contact the Joint Research & Enterprise Office (JREO) if you require any further guidance or information on any matter mentioned above.


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Yours sincerely

Regulatory Assurance Manager/Head of Research Governance

**On behalf of Sponsor**


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