St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

Issuing Final Sponsorship for Competent Authority (Regulated) Research & Confirmation of Capacity & Capability

SOP ID number:	JREOSOP0004	**Effective Date:**	04/01/2018
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Approved by:	Subhir Bedi	**Date:**	22/12/2017
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

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 team roles	Debbie Rolfe
V8.0	Reflect new harmonised process to incorporate both NIHR portfolio adoption and R&D/ Site permissions	Debs Rolfe

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 to ensure 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 the appropriate ethical and regulatory approvals in place and that relevant host site permissions are evident before study activities begin;
- 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 research worldwide. Within the UK, a Sponsor is required for:

- 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 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 (SGHFT). 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/ regulated Device research that is to be considered for Sponsorship by St Georges and the subsequent process of issuing 'Final Sponsorship' and where applicable confirm St George's open to recruitment or where St George's is not participating as a site to communicate to all participating sites that Sponsor green light will be issued upon receipt of Signed contracts/ Statement of Activities and local R&D Confirmation of Capacity and Capability.

4. Definitions

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

5. Responsibilities

This SOP is to be followed by the Regulatory Assurance Manager (RAM), Regulatory Support Officers (RSOs), and Research Contracts Manager

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 requested documentation is submitted to the assigned member of the Regulatory Assurance Team (RAT)

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 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 RSO's request for any further documentation or amendments if applicable within 20 working days of email request date.
b) For the purposes of Tissue collection and sample storage on St Georges University premises the HTA Registration form JREODOC0087 must be completed and returned to the JREO via the RAT
c) The CI or delegated research team member must maintain appropriate version control of all approved documents within the Trial Master File
d) The CI must file the fully executed Delegation of duties Sponsorship Agreement (DDSA) JREODOC0013 and Final Sponsorship letter in the Trial Master File.

6.2 JREO Procedure

a) Prior to 'Final Sponsorship' being issued, the RAM and/or RSO will ensure that the following documentation is in place and saved electronically: W drive / Investigator/ XX.Xxxx_Trial Acronym_Agresso code.

- 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 (RAT member may need to assist). NB this process should have been completed at Grant application stage to ensure correct attribution of study specific tasks is appropriately recompensed.
- Issue of HRA approval – where the HRA issued an opinion subject to conditions being met, the RAT 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 RAT 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 RSO will liaise with the CI in order for the RAM and/or the RSO to respond to the MHRA's request for further information if a 'Grounds for non-acceptance' letter or '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 or progress of Pharmacy Green light from the Lead Research Pharmacist. N.B. Absence of Pharmacy Green light will not prevent Final Sponsorship issue.

- Final 'approved' versions of Protocol, GP letters, Patient Information and Informed Consent forms; any IMP related documents such as Investigator Brochure or IMP dossier etc. or in the case of a regulated Device study a copy of the finalised documents submitted to the MHRA such as Instructions for use and Technical Data sheet.

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

d) For the retention and storage of Human Tissue or samples request the CI complete the HTA Registration/collection form JREODOC0087 and ensure the SGUL Designated Individual is cc'd into the email request.

e) On receipt of the REC Favourable Opinion, the MHRA Acceptance Letter and the HRA approval, the RAM and/or RSO will ensure the Pharmacy Site File (for CTIMP studies) is furnished with all approved documents and approvals and will inform the Lead Research Pharmacist to start finalising the Research Pharmacy Green light procedure (CTPSOPB08).

f) The Sponsor site file (electronic and physical) must be updated and maintained throughout the process.

g) The RAM/RSO must circulate the approved protocol and PIS to the Care Group Lead and Business Manager to facilitate departmental approval. Ensure the CI is included in the email to field any queries.

h) The returned HTA Registration and collection form must be checked for completeness and can be filed by HRGD or RAM on shared Z drive

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

Person/Officer	Process/Action Required	SOP Reference
Regulatory Support Officer	Prepare for the Clinical Trial Initiation	JREOSOP0013
Research Contracts Manager	Contracts/Agreements	JREOSOP0030

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

k) The RAM and/or RSO 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.

l) The RAM and/or RSO will need to ensure portfolio adoption status is confirmed. Related correspondence must be filed. Delays or issues must be escalated to the HRGD

m) Upon receipt of evidence of Care Group Lead and Business Manager Approval and where relevant evidence of support department approvals and confirmation of Portfolio Adoption status the RAT can issue confirmation of Capacity and Capability.

n) The RAM and/or RSO 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 RSO or RAM.

o) The RAM and/or RSO will update EDGE with the relevant minimum data set information, study status and update Key Staff on the Project site details page

p) The RSO and/or RAM will set up the email alerts/reminders in their Outlook email accounts for Annual Progress Report according to anniversary date of Ethics approval and DSUR according to approval date of MHRA CTA. The RAM and/or RSO 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) or JREO JREODOC0082 file index in the case of Device studies.

q) The RAM and/or RSO will update the Sponsored Clinical Trials xls with the new status and required details.

6.3 Sponsored multi-site studies

a. Ensure participating organisations are added on EDGE against the study entry

b. Any organisational involvement requests on EDGE should be confirmed or rejected promptly

c. The CI or delegate will circulate the approved study document pack to all participating PI's and their respective R&D teams – the RAT should be cc'd to facilitate fielding of any queries

d. If a site contract is to be utilised in addition to the Statement of Activities inform the Contracts Officer in the JREO where non-standard text or conditions apply.

e. Sponsor green light will be requested from participating R&D departments

f. Upon receipt of completed Statement of Activities (additional contract where appropriate) and R&D confirmation of Capacity and Capability the RAT will issue Sponsor green light – see Appendix 8.3 for example for non-CTIMP studies

g. Upon receipt of Statement of Activities (additional site agreement where applicable); R&D confirmation of Capacity and Capability and confirmation that SIV has taken place the RAT will issue Open to Recruitment- see Appendix 8.4 for example for CTIMP studies

h. Ensure corresponding site documents are saved in the ‚sites' e-folder against the study entry on the w drive

7. References

UK Policy Framework for Health and Social Care Research V3.2 October 2017

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 8.2: Confirmation email Template

Appendix 8.3 Sponsor Green light non-CTIMPs

Appendix 8.4 Sponsor Open to Recruitment for CTIMPs

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

Direct Line: 020 8

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:** Insert 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 UK Policy Framework for Health and Social Care Research (v3.3 07/11/17 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.

Yours sincerely

Regulatory Assurance Manager/Regulatory Support Officer

On behalf of Sponsor

Appendix 8.2

Confirmation Email Template

To: Chief Investigator, Principal Investigator or Local Collaborator,

Cc: Clinical Trial Unit/Study Manager/Study Coordinator (where applicable), Lead Research Nurse/Coordinator, Support Departments, LCRN London South (NIHR CRN studies)

Subject: IRAS xxxxxx. Confirmation of Capacity and Capability at **St George's University Hospitals NHS Foundation Trust/ St Georges, University of London**

Attachment: Signed agreement and/or agreed statement of activities, as appropriate

Dear Chief Investigator,

RE: IRAS xxxxxx. Confirmation of Capacity and Capability at St Georges Healthcare NHS Foundation Trust/ St Georges, University of London

Full Study Title:	
Site PI/LC	
Current Protocol version:	
Latest HRA Approval date:	

This email confirms that **St George's University Hospitals NHS Foundation Trust/ St Georges, University of London** has the capacity and capability to deliver the above referenced study. Please find attached the signed agreement [and/or] agreed Statement of Activities as confirmation.

St Georges Healthcare NHS Foundation Trust agrees to start this study on (INSERT DATE), as previously agreed OR on the date the Sponsor issues the green light to begin. Please ensure the R&D office and local CRN contacts are provided with this date.

The local research team must ensure that the participant/patient medical records are clearly marked to indicate their study participation. For electronic medical records you are advised to utilise the system research flags or alerts and for paper records to affix an alert sticker to the front cover. Alert stickers can be obtained from the JREO.

You are required to record all participant recruitment on the Trust's EDGE database. If you are unable to access this please contact the JREO.

If you wish to discuss further, please do not hesitate to contact us and local team (cc above).

Please note, in line with the national HRA approvals process, you will no longer receive a NHS R&D Approval/Permission letter.

Kind regards

INSERT PERSONAL SIGNATURE

Regulatory Assurance Manager/ Regulatory Support Officer On Behalf of the Sponsor

Appendix 8.3

Example Sponsor Green light Activation email Non-CTIMPs

Header – IRAS ID and study title

Dear Investigator team

On behalf of the Chief Investigator and Sponsor I am pleased to confirm that your site is open to recruitment.

You are advised that you must ensure that the participant medical records are clearly marked to indicate their study participation. For electronic medical records you are advised to utilise the system research flags or alerts and for paper records to affix an alert sticker to the front cover.

I would like to wish you every success with recruitment and look forward to hearing when you have identified, consented and enrolled your first patient

Please do not hesitate to contact the study team or I as the lead R&D contact

Warmest Regards

Appendix 8.4 Sponsor Open to recruitment

Direct Line: [Insert number]

Direct Fax: 020 8725 0794

Email: [Insert email address]

[Date]

Dear Insert Investigator name

PROJECT TITLE:

IRAS ID:

Sponsor:

EudraCT #:

RE: Confirmation site 'open to recruitment' and follow up actions and discussions from the initiation visit

I am writing in follow up to the initiation visit held on [Insert date] for the [Insert study] study. Thank you very much for your time and please pass on my thanks to [Insert study team attendees] for their time during the visit. I was also accompanied by my colleagues [Insert any colleagues that attended]

I have summarised our discussions below and actions that are required, with timelines to work to for outstanding actions:

I have also arranged a meeting with [Insert co-ordinator name and date of meeting] to ensure all documentation is up to date in the Sponsor Site File (held in the JREO), Trial Master File and the Investigator Site File.

You are advised that you must ensure that the participant medical records are clearly marked to indicate their study participation. For electronic medical records you are advised to utilise the system research flags or alerts and for paper records to affix an alert sticker to the front cover. Alert stickers can be collected from the JREO

I would like to wish you every success with recruitment and look forward to hearing when you have identified, consented and enrolled your first patient. Once your first patient has been successfully enrolled I will be in contact to organise my first monitoring visit within 2 weeks of this date.

If you have any queries in the meantime please do not hesitate to contact me.

Kind regards

Yours sincerely

[Insert name, job title]