St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

SOP ID number:	JREOSOP0017	**Effective Date:**	30/01/2017
Version number and date:	Version 8.0 27/12/2016	**Review Date:**	31/05/2018
Author:	Debbie Rolfe	**Title:**	Acting Head of Research Governance
Approved by:	Mark Cranmer	**Date:**	27.1.17
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.

Standard Operating Procedure (SOP)
Confirmation of St George's capacity and capability

© St George's

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
Version 1.0	Original Version	Ailsa Withers
Version 2.0	The above SOP was amended to the recent changes made to the process and to implement the new numbering system for SOPs.	Ira Jakupovic
Version 3.0	Review of Version 2.0	Ira Jakupovic
Version 4.0	Re-write to incorporate new JREO process, change to new numbering	Nadia Azzouzi
Version 5.0	Updated to reflect use of JREODOC0100 for CGL & BM approvals	Debs Rolfe
Version 6.0	Review of version 5.0. Updated Logo and Trust Name	Anika Kadchha
Version 7.0	Review of version 6.0. Updated with information relating to HRA approval process	Nadia Azzouzi
Version 8.0	Requirement for deputy PI to undertake clinical responsibilities in named PI absence and update of national study approval-recruitment time-lines.	Debbie Rolfe

© St George's

Table of Contents	Page
1. Background	4
2. Joint Research and Enterprise Office (JREO) Policy	4
3. Scope	4
4. Definitions	5
5. Responsibilities	5
6. Procedures	5
7. References	8
8. Appendices HTA Registration & Collection form	9

© St George's

1. Background

The Health Research Authority (HRA) was established in December 2011 to promote and protect the interests of patients in health research and to streamline the regulation of research.

HRA Approval is the new process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent Research Ethics Committee (REC) opinion provided through the UK Health Departments' Research Ethics Service. The HRA has taken over the responsibility for ensuring that each new study complies with all applicable regulatory requirements in England. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study. www.hra.nhs.uk

As of 1st April 2016, all research must obtain HRA, REC (and where applicable MHRA) approval. NHS RECs will continue to review all research conducted within the NHS through the National Research Ethics Service (NRES). As well as obtaining REC and HRA approval, St George's R&D office must also confirm capacity and capability where research is being undertaken at St George's University Hospitals NHS Foundation Trust (SGHT) and/or St George's University of London and/or involving SGHT participants before it commences. Confirmation of capacity and capability must be issued by each R&D office, at each NHS organisation, where the study is due to start. This approval is **in addition** to the approval from the MHRA approval (where applicable), HRA and the NHS REC who approved the study.

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 both institutions acting as Sponsor.

3. Scope

This SOP describes the procedure for confirming capacity and capability of healthcare research being conducted under the auspices of St George's. Specifically, if the research is being

© St George's

undertaken at St George's University Hospitals NHS Foundation Trust and/or St George's University of London and/or involving SGHT participants, confirmation of capacity and capability is **mandatory.** This is required in addition to HRA approval, REC approval (and any other necessary approvals e.g. MHRA approval) before the project can commence. This SOP is concerned with confirmation of capacity and capability at St George's for research that has been, or is being, submitted for ethical approval and should be used in conjunction with JREOSOP0040 Applying for NHS Ethics.

This SOP will not cover obtaining Sponsor approval, which is required before the project can be booked in to ethics. Please refer to JREOSOP0003 'Sponsorship in principle' (applicable only to studies that qualify for inspection by the MHRA) or JREOSOP0004 'Issuing Final Sponsorship approval' (applicable to all studies).

If your study has already been adopted onto the NIHR portfolio or maybe eligible for adoption, please refer to JREOPSOP0044 'Applying for NIHR adoption' instead.

4. Definitions

None applicable to this SOP.

5. Responsibilities

It is the responsibility of the principal investigator (PI) to ensure that all documentation as detailed below in section 6.1 are submitted to the JREO in a timely manner.

It is the responsibility of the assigned JREO Governance contact to determine that all the documents detailed in section 6.1 are submitted by the PI.

The Head of Research Governance (HRG), Regulatory Assurance Manager (RAM) and Research Governance Officers (RGO) are authorised to give written permission on behalf of St George's for research to commence, once all requirements are met.

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

6. Procedure

Please note that we will accept **one** investigator for St George's University Hospitals NHS Foundation Trust as the main PI. So if the Chief Investigator is based at SGHT, they must also be named as the Principal Investigator. Other researchers can be named as co-investigators. However

© St George's

a deputy PI MUST be named to facilitate appropriate clinical cover for the clinical management of the study participants in the absence of the lead PI/study CI.

In order for St George's governance team to assess, arrange and confirm capacity and capability at St George's, all of the following applicable documents are required:

6.1 Required Documents

1. *IRAS form, PDF format. **Must be the final signed version.** We will accept hard copy of the final submitted document (no watermark).
2. Signed and dated summary CVs (no more than 2 years old) of the PI and anyone else listed as part of the research team.
3. GCP certificate of the PI, (deputy PI where applicable) and anyone else listed as part of the research team (no more than 2 years old) if study is CTIMP or Device. For non-CTIMPs, it is still preferable that the PI has completed GCP training (or is booked onto a GCP course).
4. *Protocol (final HRA/REC approved date and version).
5. *Patient information sheet and consent form (final HRA/REC approved version).
6. Study specific documentation approved by the REC and HRA (e.g. patient diary cards).
7. Evidence of insurance (if applicable).
8. Evidence of funding (if applicable).
9. *Evidence of agreement confirming Site and Sponsor Responsibilities and costing template (validated by the network if an adopted study) (if applicable)
10. *Schedule of events and Statement of activities (for non-commercial studies where there is more than one site).
11. Certificate of ARSAC (if applicable).
12. Final HRA approval letter (and *HRA initial assessment letter where provided)
13. REC favourable opinion letter (including provisional opinion and all correspondence).
14. *Confirmation of REC favourable opinion for any substantial amendments (if applicable).
15. MHRA CTA approval or MHRA confirmation of Notification (if applicable).
16. Confirmation of authorisation from MHRA for any substantial amendments (if applicable).
17. Any other approvals documentation that is relevant to the study (CAG approval, GTAC etc.).
18. Approval from the Care Group Lead and Business Manager – an email is sufficient evidence.
19. If planning to store relevant material (as defined by the Human Tissue Act) at St George's University – a tissue collection form (see Appendix 8.1) must be completed and returned to the HTA Designated Individual (DI) and the JREO assigned Governance contact (www.stgeorges.nhs.uk/education-and-research/research/joint-research-and-enterprise-office-jreo/jreo-contact-details.)The Investigator & RGO must receive confirmation from the DI- an email is sufficient.

© St George's

Once the initial HRA local information pack (all the documents marked with an asterisk in list 6.1 required documents) has been received, the study is registered on ReDA and allocated an R&D number. The 70 day clock will start. If any documents are missing from the submission pack the 70 day clock should not commence until these documents have been received. An electronic and paper (where required) study folder is created. Provided a full and valid submission is made, the clocks will be started with a national 70 day target to recruit the 1st participant to the study.

Once everything has been received, the responsible RGO will be able to assess, arrange and confirm capacity and capability at St George's. Final JREO sign-off is also dependent on the following documents/approvals being in place internally:

1. Clinical trial site agreement signed off by the JREO and Sponsor organisation (if applicable). **Fully signed contracts need to be in place before Trust approval can be issued**.
2. Approved and signed Statement of Activities should be signed at point of issue of C of C & C
3. Material Transfer Agreement (may be required if for example, tissue is leaving the Trust). Materials can only be transferred once this is in place.
4. Approval by the support department's e.g. imaging, pathology, pharmacy & CRF approval.
5. Care Group Lead and Business manager sign-off.

When everything is in place, an approval email confirming capacity and capability will be issued by the assigned RGO for the study sent to the PI, study team, the Sponsor and support department e.g. CRF or Pharmacy together with signed Statement of activities if non-commercial Sponsor. The project can commence.

A copy of the approval email should be placed in the electronic Investigator site file and in the paper file (where required). Update the Research Governance database with CRN dates of interest. i.e Date site invited; Date site selected; Date site confirmed by Sponsor; Date site confirmed Capacity and Capability.

6.2 Post Approval

The assigned RGO for the study will supply the researcher with the following documents:

An email confirming capacity and capability to conduct the study to the PI and study coordinator (cc Sponsor and where relevant CRN, CRF and Research Pharmacy) with reminder of due date of the annual progress report.

© St George's

Note to Investigator: For CTIMP studies, not all sponsors will issue an Open to Recruitment letter so ensure that permission to commence the study has been received from the sponsor. Liase with Research Pharmacy

.6.3 Participant Identification Centres (PICs)

If research activity is to occur at an NHS Trust it must be identified as a research site and complete the full site specific assessment process as described in section 6.1 of this SOP

If research participants are being identified at SGHT and all research related activity e,g. consent, medical screening, blood tests, is happening at another organisation, SGHT would be classified as a Participant Identification Centre (PIC).

For non-commercially sponsored studies a Schedule of Events and Statement of Activities for 'Identification centre' must also be submitted for approval and R&D sign off.

In order to approve SGHT as a PIC site, SGHT should be listed in Part C of the original application form as a PIC. All the required relevant documents for the study should be provided as described in section 6.1, including any documentation that may be given out at SGHT, e.g. posters or information sheets. Care Group Lead and Business Manager approval must also be evidenced before approval.

Where SGHFT is to be added as a PIC site to an existing study, an amendment would need to be submitted to REC and HRA. Researchers must wait until they receive approval from the JREO before commencing any PIC activity.

N.B. PIC studies are designated an R&D number differently to research site studies in the format PICXX.XXXX, e.g. PIC13.0001 on ReDA.

7. References

www.hra.nhs.uk

www.mhra.gov.uk

Amendments JREOSOP0011

Applying for NHS ethics JREOSOP0040

Applying for NIHR adoption JREOSOP0044

Sponsorship in principle (CTIMPS/Regulated device studies only) JREOSOP0003

Issuing Final Sponsorship approval JREOSOP0004

8. Appendices

8.1 SGHT Tissue Collection Form

© St George's

HTA Registration of Collection Form

Principle Investigator:

Surname:			
Forename:		Title:	
Work Telephone Number:			
Job Title:			
Division Name:		Division Acronym:	

Responsible Persons:

Surname:			
Forename:		Title:	
Work Telephone Number:			
Job Title:			
Division Name:		Division Acronym:	

Type of tissue obtained:

Sample Description	Maximum Number of samples	Storage Facility : (type/location)	Risk Assessments:
Location and logging (please give specific details):			

Consent obtained:

Consent (written/oral)	Yes/No	Location of consent forms	Risk Assessments
Names of consenting staff			

NRES approval obtained:

NRES Approval		YES	NO

© St George's

Start date and Title:	
Expiry date:	

© St George's