St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

The Confirmation of capacity and capability for St George's hosted research

SOP ID number:	JREOSOP0017	**Effective Date:**	11/12/17
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Approved by:	Mr Mark Cranmer, Director of the JREO	**Date:**	01/12/17
Signature of Authorisor			

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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:**
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	Complete re-write of Version 7.0. Update to approach and processes reflective of HRA approval pathway for local organisations	Subhir Bedi

1. Background

The Health Research Authority (HRA) was established in December 2011 under the UK Government's Plan for Growth, to streamline the regulation of research in healthcare whilst promoting and protecting the interests of patients. In line with the Health and Care act 2014, the HRA was been established as statutory Non Departmental Public Body (NDPB) as of the 1st January 2015. .

HRA Approval is the current 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' National Research Ethics Service (NRES). 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 (AAC) their Capacity and Capability (C&C) to deliver the study. _The decision to formally confirm an organisations C&C to deliver a specific study is normally issued by

the organisations Research and Development (R&D) function[1]. For St Georges University Hospitals NHS Foundation Trust (SGHFT) patients and or site(s), confirmation can only be issued by the Joint Research and Enterprise Office (JREO).

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 both institutions.

3. Scope

This SOP provides the procedure for confirming capacity and capability (NHS R&D "Approval") of healthcare research being hosted at St George's. Research undertaken at St George's University Hospitals NHS Foundation Trust and/or involving Trust patients as participants will require confirmation of capacity and capability (when directed by the HRA). This is subsequent to HRA and REC approval (and any other necessary approvals e.g. MHRA approval) and before the project can commence.

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).

For clinical research studies being conducted in or on St Georges University of London (non-NHS) premises, the NRES REC has the responsibility of providing Site-Specific Assessment (SSA)[2].

[1] http://www.hra.nhs.uk/research-community/hra-approval-the-new-process-for-the-nhs-in-england/
[2] http://www.hra.nhs.uk/resources/applying-for-reviews/site-specific-assessment-ssa/

4. Definitions

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

5. Responsibilities

In respect to the process outlined in this SOP the following responsibilities are applicable:

- *Sponsor/ CI:*

It is the responsibility of the Sponsor (or CI if delegated to him/her) to ensure the formal steps of HRA approval are followed.

It is the responsibility of the Sponsor (or CI if delegated to him/her) to ensure that an HRA local document package is simultaneously submitted to the study delivery team (PI) and the JREO (and to the Local Clinical Research Network, where applicable) once they have received the HRA Initial Assessment letter (or HRA Approval Letter where no Initial Assessment letter is issued). The HRA local document package is outlined in section 6.1.

- *JREO*

It is the responsibility of the assigned JREO Governance and Facilitation Officer (RGF) to operationally manage the local process for studies being proposed within SGHFT.

Only the Director of the JREO, Head of Research Governance and Delivery (HRGD) and / or Head of Funding for the JREO may authorise any formal clinical research site agreements/contracts on behalf of St George's (as Sponsor and / or participating centre).

The HRGD, Regulatory Assurance Team (RAT), Research Development and Delivery Manager (RDDM) and Research Governance and Facilitation Officers (RGF) are authorised to give written (email) confirmation of C&C on behalf of St George's for research to commence, once all requirements are met.

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

In accordance with the UK policy framework for health and social care research (v2.5) **it is not** the role of the JREO to repeat compliance checks carried out and confirmed by the HRA as part of HRA Approval for hosted sites.

- *Principle Investigator (PI)*

It is the responsibility of PI to actively contribute to the set up process locally to ensure the studies s/he take on can ultimately deliver. This will include participating in feasibility meetings and discussions among other activities.

Please note, SGHFT acts as "one site" overall and there can only be **one** named PI per study proposed and undertaken within the Trust. Additional investigators can and should be added to the study team and delegation logs as sub/deputy-PI, however the main named PI has overall responsibility of onsite study conduct. .

6. Procedure

The HRA has defined the 4 stages that sponsors and participating sites must go through to support and review local C&C to deliver a study (study set up). Some of these stages are used to identify time points which the Trust must measure in order to examine where barriers to study set up and delivery occur (see flowchart Appendix 7.2).

The 4 stages are:

1. **Identify:** Identification of potential study (of interest) by PI to then initiate discussions with sponsor or identification of potential site by sponsor. Start of site level feasibility which can be supported by NIHR CRN Expression of Interest (EOI) and or Site Intelligence (SI) processes if applicable. Supported by final/draft protocol and or protocol synopsis.
2. **Assessing:** Assessing the feasibility of a study and whether or not the Trust has the capacity and capability to participate in the study. Supported by final/draft protocol and or protocol synopsis.

Please note: Stage 1 and 2 may:

- Occur simultaneously (to avoid duplication)
- May not be required/ be minimal in certain types of studies where it is expected that the site will participate for example urgent public health research and or studies involving

minimal local activity such as distributing questionnaires, on line. In these instances the HRA assessment/approval letter(s) will detail the status and nature of the local review requirement.

3. **Arrange**: Putting and approving (internal) all practical arrangements required to support effective and timely study delivery. This is based upon the nature of the study, its timelines and target population and will require interactions with internal service support departments such as imaging, pharmacy, pathology and the Clinical Research Facility (CRF). This stage is initiated formally by the submission of the local submission package/addition of site, marking the start of the 40 day formal set up timeline.
4. **Confirming:** Final confirmation notification marking that the Trust has the capacity and capability in place to deliver the study and that all practical arrangements are in place. This confirmation is given through the agreement of the contents of the statement of activities (for non-commercial studies) and sign-off on relevant site agreement where applicable.

It is the role of the RGF to coordinate, oversee and deliver this process for their portfolio of studies within established timelines.

5. 1 Local HRA Information Package

- IRAS application form, PDF (signed) version.
- Protocol (final HRA/REC submitted version).
- Patient information sheet and consent form (final HRA/REC submitted version).
- Relevant template contract/model agreement (if needed in addition to Statement of Activity)
- Statement of Activity relevant to the participating NHS organisation (non-commercially sponsored only)
- Costing template (commercially sponsored only) or Schedule of Events (non-commercially sponsored only)
- Any amendments
- Copy of HRA Initial Assessment letter (if one is issued) and (when issued) HRA Approval letter and final document versions
- Relevant documents to support site set up e.g. pathology manual, Investigator Boucher etc.

Additional documentation may be required to support study review within specific departments i.e. imaging review form(s). **These are Trust internal documents not to be sent to the sponsor/CI for completion.** The RGF should collectively work with the PI/research team and relevant department to ensure the relevant form/information is conveyed in a timely and proportionate manner.

5.2 R&D Database Registration:

To ensure effective oversight any newly proposed study should be registered on the JREO R&D database:- EDGE, at the earliest opportunity (during the Identify and/ or Assess phase). At the very latest the study has to be registered at the point of HRA Local Package submission to the PI and JREO (and LCRN if applicable). For details of EDGE database registration and management please refer to working practice document JREOWPD0019

In addition, whilst the ReDA database is still active, at the same time as EDGE registration, the study should be registered within ReDA to create a JREO reference number. Minimum study information should be added to ReDA.

5.3 Metrics

Please note, only once the (initial) HRA local information pack (all relevant documents marked within 5.1) has been received, does the formal 40 day set up clock commence. The JREO aims to confirm C&C within this timeline. Please see Appendix 7.3 outlining study set up metrics.

Study feasibility and assessment discussions should continue regardless of formal submission (and where a protocol/protocol synopsis has been provided) to avoid unnecessary delays and duplication (this should include interactions with internal support departments).

5.4 Confirmation notification

Once the local assessment and arrangement of study requirements have been completed (and a site target agreed with the PI and sponsor agreed based on these), the relevant member of the JREO will be able to formally confirm capacity and capability on behalf of St George's.

Final JREO sign-off is dependent on the following reviews/approvals being in place internally:

- ✓ Feasibility review detailing study requirements and relevant arrangements to support study target and timelines

- ✓ Relevant site agreement(s) signed off by the JREO and Sponsor organisation (if applicable) in line with section 4 Responsibilities. **Fully signed contracts need to be in place before Trust confirmation can be issued.**
- ✓ Approved site Statement of Activities (non-commercial only)- completed with confirmed site target
- ✓ Registration or Authorisation of support from applicable support department's e.g. imaging, pathology, pharmacy & CRF.
- ✓ Care Group Lead (and where relevant Business manager) (email) agreement.
- ✓ Confirmation of NIHR Clinical Research Network (CRN) eligibility status

When everything is in place, template email in Appendix 7.1 confirming capacity and capability should be issued for the study addressed to the Sponsor/CI , copying in the PI, study team, support department(s) and LCRN (if applicable). The study can now open (providing relevant sponsor green light has been given).

A copy of the approval email (PDF) along with all attachments should be placed in the electronic R&D file.

EDGE and ReDA data points and status should be updated to reflect study status.

6. References

- www.hra.nhs.uk
- JREOSOP0040 Applying for NHS ethics
- JREOSOP0003 Sponsorship in principle (CTIMPS/Regulated device studies only)
- JREOSOP0004 Issuing Final Sponsorship approval
- JREOWPD0020 General Research Definitions
- NIHR CRN Study Support Services- CRN Principles for assessing, arranging and confirming local capacity and capability (17/09/2015)
- UK policy framework for health and social care research (v3.2 10/10/17)

7. Appendix

7.1 Confirmation of Capacity and Capability notification email template:

From: St Georges JREO

To: Sponsor representative/ 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 Sponsor Representative,

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 a date to be agreed when you as sponsor give 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.

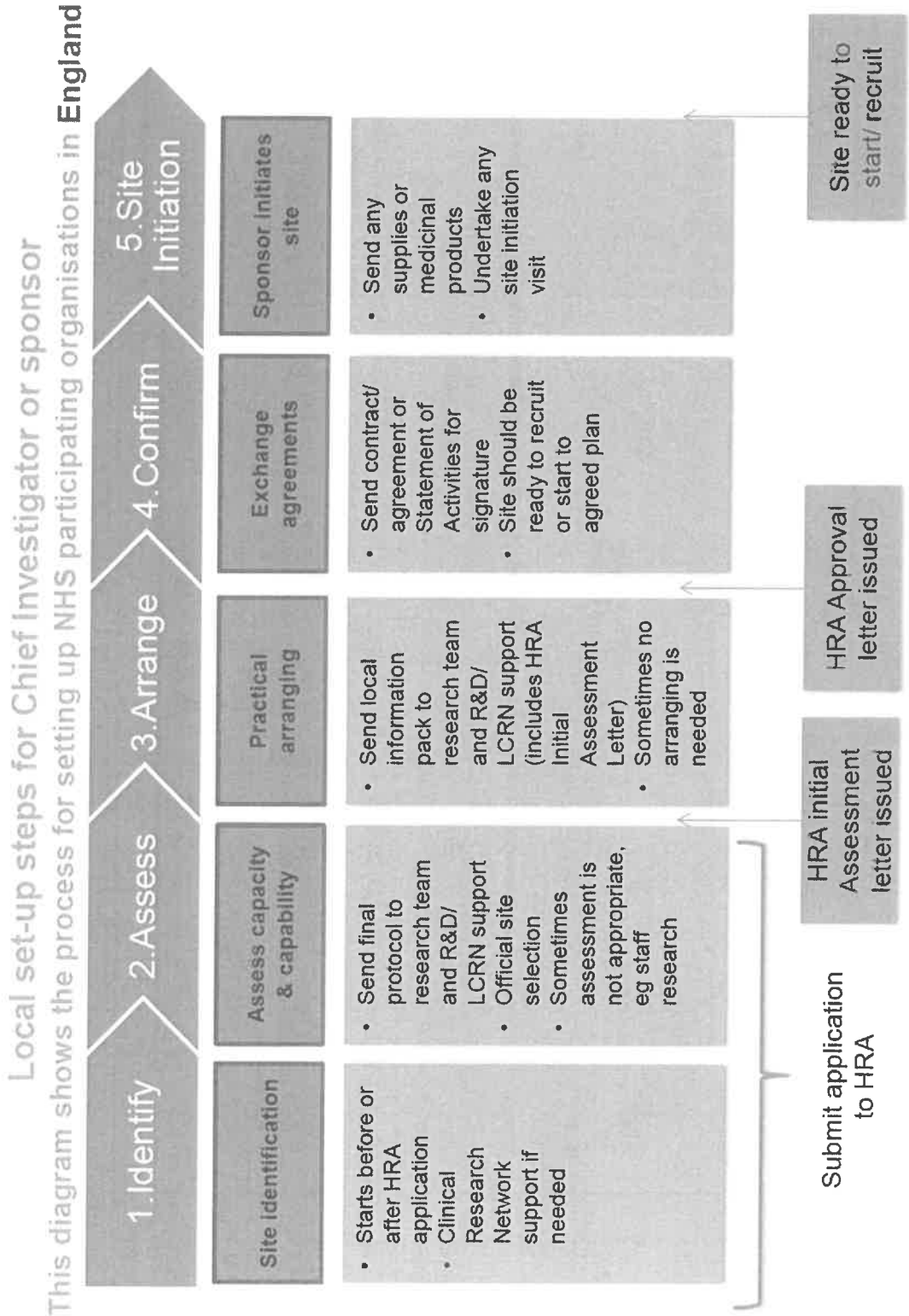
If you wish to discuss further, please do not hesitate to contact us and local team (cc above).

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

7.2 Phases of local Study Set up (1-4) as per HRA Approval guidance



7.3 Set Up and Delivery Metrics