St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

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Author:	Debs Rolfe	Title:	Regulatory Assurance Manager
Approved by:	Lucy H H Parker	Date:	30/10/2015
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)
Change Management

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1	New SOP	Sebastian Sethe
V2	Updated Trust status & logo. Concept of JREO chaperone and use of the Internal Memorandum	Debs Rolfe

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1. Background

Changes to plans can occur at all stages of a project lifecycle. Most changes can be planned and implemented by the project team independently, but some changes require that the JREO is informed in order to:

a) update its records

b) review and evaluate the institutional risks of the change

c) inform external stakeholders and approvers.

St. George's Hospital Medical School (also doing business as St. George's, University of London) and St. George's University Hospitals NHS Foundation Trust have agreed a **Memorandum of Understanding for Research**. In this, both institutions have agreed to act jointly in the context of clinical research wherever appropriate and confirmed a framework under which to conduct research activities.

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 covers general aspects of managing change within research projects. It covers expected pre-planned changes, but also unexpected changes and deviations. Compliance with this SOP is required for all research conducted at St.George's.

4. Definitions

4. 1 External Approval

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Approval required from an external agency, e.g. a Research Ethics Committee, the MHRA, the Human Tissue Authority or the Funder.

4.2 Internal Approval

Approvals required by St. George's policies. Given by or coordinated via the JREO including finance-related approvals, NHS R&D approvals, and granting institutional sponsorship

4.3 Documentation

Documents including but not limited to the Protocol, the Application to a Funder (if not evidently superseded as agreed with the Funder), any forms provided to JREO or external Agencies, Contracts, and Standard Operating Procedures.

4.4 Assigned Research Governance Officer (RGO)

The RGO assigned to the study. This will normally be in accordance to the type of study and stage of the project.

4.5 JREO Chaperone

To provide investigators with a single point of contact within the JREO to co-ordinate review and responses.

For governance related issues the chaperone may be the RGO in accordance with the University Institute or Trust clinical division in which the investigator is employed.

For Contractual or Intellectual Property (IP) related issues a chaperone within the Enterprise team (or where deemed appropriate the RGO) will be assigned in accordance with the University institute or Trust clinical division in which the investigator is employed.

If doubt arises the section lead should be consulted e.g. the Head of Research Governance (HRG) for research governance related issues or Head of Enterprise for IP or contractual issues.

5. Responsibilities

The Chief Investigator (CI) for a research project has responsibility for ensuring compliance with this SOP for a particular project. In case of joint CI's all CI's are responsible. The Principal Investigator (PI) is responsible for the project at the local site.

The JREO chaperone has responsibility for co-ordinating a comprehensive but proportionate review of change requests as communicated under this policy in a timely and responsible manner.

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6. Procedures

6.1. Temporary (unplanned) Change:

Temporary, intermittent and unforeseen deviation from agreed practices or existing Documentation, where there is no effect to the safety or well-being of subjects or the integrity of the trial data.

a) **Not** in contravention of the terms of Internal or External Approvals, contractual obligations, regulations, guidelines or essential standards (such as GCP).

The PI should record such deviations but is not required to inform the JREO.

b) **Potentially** in contravention of the terms of Internal or External Approvals, contractual obligations, regulations, guidelines or essential standards (such as GCP).

The PI should record such deviations and inform the JREO chaperone.

6.2. Planned Change

a) Change can be implemented as a modification to working practices **without an amendment** to existing documentation.

- The PI may implement such changes in accordance with relevant SOPs **without notification** to the JREO.

b) Change **requires amendment** to existing documentation e.g. a pharmacy approved prescription that has **no** significant bearing on internal Approval status.

- The PI may implement such changes without approval by the JREO, but must notify the JREO chaperone and ensure appropriate internal approvals are sought e.g. Research Pharmacy for study specific prescriptions.

- A copy of the previous version must be retained within the relevant section in the Trial Master File, clearly dated and marked as superseded, Ensure any new documents approved for use are circulated to the study team(s).

c) Change **requires amendment** to existing documentation (please also refer to the JREO SOP on the management of amendments (JREOSOP0011) and **does affect** Internal Approvals.

- The PI must notify the JREO chaperone at least 28 days in advance of implementing the change wherever possible. The JREO chaperone shall review the change and any

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associated internal approvals and work with the PI to obtain external approvals to the proposed amendment.

6.3. JREO Review

The JREO will review the proposed change against two categories of criteria:

Records management: JREO will update records in electronic and written form to ensure that

a. the proposed changed status is reflected as such in current records
b. reasons for the change are recorded
c. the prior status is archived following evidence of appropriate approvals for reference purposes unless, on a risk-based approach, this is not required
d. if the change requires further post-implementation review, a note is made to alert JREO at such future date

Risk: All factors of assessment commonly conducted by or via the JREO should be considered when assessing the potential consequences of the change.

This includes but is not limited to considerations of

a. finances
b. participant safety
c. operational challenges
d. feasibility of success
e. reputation and relationships
f. academic excellence
g. commercial relevance
h. legal & regulatory compliance.

Specific expertise should be consulted by the JREO chaperone as required on those factors considered potentially relevant.

Where appropriate, the JREO chaperone would summarise the assessment of any changes onto the internal memorandum 'memo', and seek approval by the responsible section manager(s) and final 'sign off' by the appropriate signatoryof the JREO where appropriate.

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7. References

Management of SOPs JREOSOP0011

8. Appendices

Internal memorandum.

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Appendix – Internal Memorandum

St. George's Joint Research & Enterprise Office
internal memorandum – agreement for signature

SIGNATURE BY

PI			SGUL ☐	SGHT ☐		
Ref SGUL	**R(esearch)**		Ref ReDA		Ref Other	
Title						
Other Party						
Suitable partner why?		Risk Assessed ☐	Co-Applicant ☐	Prior Experience ☐	Reputation ☐	
comments						
SUMMARY						

N/A	FINANCE	Approx. amounts		Officer	
we pay ☐/they pay ☐	credit terms(days)		invoicing risk ☐	Equipment ☐	intraStGeorge's ☐
N/A	GOVERNANCE	Sponsor		Officer	
recruitment target		matches SSI? ☐	validated? ☐		

CDA	Period		Retain copy?	Y		N		Mutual?	Y		N	
	Protocol only?	ID:										

N/A	ENTERPRISE			Officer	
N/A	LEGAL	Template		Officer	
N/A	OTHER			Officer	

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