St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

The Preparation and Approval of St George's SOPs

SOP ID number:	JREOSOP0001	**Effective Date:**	09/09/2015
Version number and date:	Final Version 4.0 01/05/15	**Review Date:**	01/09/2017
Author:	Debs Rolfe	**Title:**	Regulatory Assurance Manager
Approved by:	Lucy Parker	**Date:**	09/09/15
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	Ira Jakupovic
V2.0	Review of the original version.	Ira Jakupovic
V3.0	Update incorporating changes to official SGUL font and other changes to incorporate changes to the JREO structure.	Lucy Parker
V4.0	Updated with new Trust logo and title and authorised signatories	Debs Rolfe

© St George's

Table of Contents	Page
1. Background	3
2. Joint Research and Enterprise Office (JREO) Policy	3
3. Scope	4
4. Definitions	4
4.1 Standard Operating Procedure (SOP)	4
4.2 Date	4
4.3 Effective Date	4
4.4 Review Date	4
5. Responsibilities	5
6. Procedures	5
6.1 Writing SOPs	5
6.2 Authorising SOPs	6
6.3 SOP review	6
6.4 SOP referencing	6
6.5 Distribution of SOPs	6
6.6 Version Control	6
7. References	7
8. Appendices	7
8.1 SOP template	8

© St George's

1. Background

This standard operating procedure (SOP) has been written to outline the procedure within St George's Joint Research and Enterprise Office (JREO) for the preparation, review, revision and approval of SOPs. SOPs are written to enable the Sponsor to implement systems that assure the quality of every aspect of the trial.

St George's JREO SOPs will be written to outline detailed instructions to achieve uniformity of performance of specific processes and procedures when approving, managing and conducting research at St George's.

An important aspect of a quality system is to work according to unambiguous SOPs. The whole process from set up of research studies to archiving of completed studies should be described by a continuous series of SOPs.

Good Clinical Practice (GCP) clearly rules out the use of SOPs which represent vague statements of intent. It states that SOPs should be detailed and set out in writing. The JREO has implemented GCP by means of SOPs that are written to an agreed format detailed in this SOP.

SOPs are meant to be compulsory instructions. If deviations from this instruction are allowed, the conditions for these should be documented including who can give permission for this and what exactly the complete procedure will be. The original should rest at a secure place while working copies should be authenticated with stamps and/or signatures of authorised persons. For JREO SOPs, only the online versions will be listed as the active controlled document. Any print-off of SOPs will be classed as uncontrolled documents and readers will be referred to the website for up-to-date versions.

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.

© St George's

3. Scope

This SOP will describe the process for the preparation, review and approval of all new SOPs as well as revision of existing SOPs that are produced by St George's JREO for trials sponsored by St George's.

This SOP will cover the numbering of SOPs, but not numbering of other associated JREO documents. Numbering of other documents is covered in the working practice document (WPD) "Document control for important JREO documentation" (JREOWPD0005)

This SOP will not cover training of Investigators or the JREO personnel on SOPs produced by the JREO. Training Records are covered in the JREO SOP "Training Records" (JREOSOP0023)

4. Definitions

4.1 Standard Operating Procedure (SOP)

ICH GCP (1.55) defines SOPs as *'Detailed, written instructions to achieve uniformity of the performance of a specific function.'*
Section 2.13 of ICH GCP goes on to state that 'systems with procedures that assure quality of every aspect of the trial should be implemented.'

4.2 Date

Date of Authorisation defines the date when the SOP is authorised for training and implementation. The authoriser should not be the person writing the SOP. It defines the date when the SOP is finalised and signed off by the person authorised to sign off the SOP. Authorised JREO signatories are the following JREO Director, for Research Governance SOPs the Head of Research Governance and Regulatory Assurance Manager.

4.3 Effective Date

The effective date will be the date the SOP is implemented by the JREO.

4.4 Review Date

This defines the date the SOP is due for review by the author and/or a person designated to review the SOP. The review date will be set by default, 2 year from the effective date. If there is a justification for an earlier review (such as a change in process or regulation), the review date will be brought forward.

© St George's

5. Responsibilities

This SOP is to be followed by the JREO governance section and the Chief Investigator (CI) of the proposed study.

It is the responsibility of the Head of Research Governance (HORG) of the JREO to ensure that this SOP is updated by the review date or as necessary.

Any SOPs produced by the JREO must be used in conjunction with any NHS Trust and other SGUL and SGHT policies and procedures. The SOPs are designed to be used as a template for individual departments and will require amending by researchers and their teams to meet the requirements of their individual projects.

6. Procedure

6.1 Writing SOPs

On completion of a draft JREO SOP by a member of the JREO (using the draft SOP template in appendix one), internal review by members of the JREO will be conducted. The template must be followed. The official font of SGUL is Franklin Gothic and therefore this font should be used. The title of the SOP should be in font size 18, headers in font size 12 and the text font should be size 11. The SOP must always contain the following section titles:

1. Background
2. Joint Research and Enterprise Office (JREO) Policy
3. Scope
4. Definitions
5. Responsibilities
6. Procedures
7. References
8. Appendices

The SOP review performed by the JREO must look at accuracy and readability of the document.

© St George's

6.2 Authorising SOPs

Before a JREO SOP can be implemented, authorisation by the Director of the JREO is required.

6.3 SOP review

All SOPs will have an effective date and a review date. The review date will be set by default, 2 years from the effective date. If there is a justification for an earlier review (such as a change in process or regulation), the review date will be brought forward.

The HORG will always conduct the final review of all SOPs. The HORG will also inform the Director of the JREO and the Research Governance Committee (RGC) members of the new SOPs *via* email.

Providing that no changes are requested within 10 working days of the above email being sent, the HORG will apply the effective date to the SOP and save the final SOP in the SOPs folder of the JREO shared drive. The SOPs will then be uploaded to the JREO website.

6.4 SOP referencing

Each template SOP produced by the JREO will be issued with a unique SOP number. This number identifies that it is a JREO document and whether it is an SOP or Working Practice Document (WPD) and the SOP number (0001), i.e. this SOP is referenced as JREOSOP0001

6.5 Distribution of SOPs

All SOPs will be added to the JREO website once authorised by the Director of the JREO.

6.6 Version Control

An SOP will be called DRAFT until it has been authorised. The table on the front cover documents the SOP's version history which should be amended with each change to the SOP. Once finalised, the document will be called FINAL version 1.0. Updates to the SOP will result in an increase in version number (eg v1.0 will become v2.0)

© St George's

7. References

ICH Good Clinical Practice

8. Appendices

8.1 SOP template

© St George's

Appendix 8.1 Standard Operating Procedure Template

St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

INSERT TITLE OF SOP

SOP ID number:	JREOSOP00xx	Effective Date:	Dd/mm/yy
Version number and date:	Draft Version XXX Dd/mm/yy	Review Date:	Dd/mm/yy
Author:	Insert Name	Title:	Insert Title
Approved by:	Insert Name	Date:	Dd/mm/yy
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 or insert a summary of reasons for change	Insert Name

© St George's

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

© St George's

1. Background

Please insert a short summary derived from any background literature relevant to the purpose of this SOP…

2. Joint Research and Enterprise Office (JREO) Policy

The following text must be added under this section. Any suggestion for changes to be made to this Section can be discussed with the Head of the JREO and the HORG:

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

Please outline the scope of this SOP:

- *i.e. This SOP covers the management of … [insert relevant text] and/or*
- *This SOP does not cover … [insert relevant text].*

4. Definitions

This section must contain any definitions the author or the person reviewing the SOP think may be relevant to the content of the SOP. Please number all the applicable definitions in the following manner (these sub-headers must also be listed in the table of contents):

4.1 Insert relevant text

Insert text to define the above…

4.2 Insert relevant text

Insert text to define the above…

© St George's

5. Responsibilities

Please ensure that this section of the SOP defines the personnel responsible for conducting duties outlined in the SOP (i.e. identify relevant individual by their job title).

6. Procedure

The author must ensure that this section of the SOP details the procedure that should be carried out in accordance with this SOP. All steps of the procedure must also be clearly numbered. It may be necessary to sometimes break the procedure in sections relevant to staff members involved in the conduct of that particular procedure (see examples below). The below are only suggestions and can be changed in accordance with the purpose of the procedure you are detailing in the SOP.

6.1 Investigator Procedure

Please Insert relevant text…

6.2 JREO Procedure

Please Insert relevant text…

7. References

Add any references used (see example given below)

Integrated Research Ethics Application Form - www.myresearchproject.org.uk

8. Appendices

Add any appendices.

© St George's