


## Standard Operating Procedure (SOP)

### The Preparation , Approval and Review of St George's SOPs

|                                 |   |                        |  |
|---------------------------------|---|------------------------|--|
| <b>SOP ID number:</b>           | JREOSOP0001   | <b>Effective Date:</b> | 01/12/17                                 |
| <b>Version number and date:</b> | 5.0<br>01/11/17   | <b>Review Date:</b>    | 01/12/19                                 |
| <b>Author:</b>                  | Subhir Bedi   | <b>Title:</b>          | Head of Research Governance and Delivery |
| <b>Approved by:</b>             | Mark Cranmer  | <b>Date:</b>           | 01/12/17                                 |
| <b>Signature of Authorisor</b>  |  |                        |  |

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    |
| V5.0                | Update to SOP Title and sign off<br>Administrative and consistency update  | Subhir Bedi   |

| <b>Table of Contents</b>                              | <b>Page</b> |
|---|-------------|
| 1. Background   | 2           |
| 2. Joint Research and Enterprise Office (JREO) Policy | 3           |
| 3. Scope  | 3           |
| 4. Responsibilities                                   | 4           |
| 5. Procedures   | 4           |
| 6. References   | 6           |
| 7. Appendices   | 7           |

## **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 an organisation 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 (SGHFT). St George's will be the official name used on all SOPs to represent either institution acting as Sponsor.

## **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**

For general research management related acronyms refer to "SOP Definitions" working practice document (JREOWPD0020).

## **5. Responsibilities**

This SOP is to be followed by the JREO Research Governance and Delivery Team (RGDT) and the Chief Investigator (CI) of the proposed study.

It is the responsibility of the Head of Research Governance and Delivery (HGD) 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 other relevant SGHFT and SGUL policies and procedures.

## **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 1), 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.

### **6.2 Authorising SOPs**

Authorised JREO signatories for Research Governance and Delivery SOPs are the following

- Associate Medical Director- Research
- JREO Director
- Head of Research Governance and Delivery,

### **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 HGD or Director of the JREO will always conduct the final review of all SOPs. Once reviewed and no amendments are required the SOP can be enacted. The author will apply the effective date to the SOP and save the final SOP in the SOPs folder of the JREO shared drive. The SOP tracker should be updated. The SOPs should then be uploaded to the JREO website.

On occasion, certain SOPs which may influence and or have significant implications to the function of certain aspects of the Trust and or University, i.e. financial and or management outside of the JREO oversight, and may need to be referred to the Research Governance Committee (RGC) and its members for review and or comment. It will be the decision of the Director of the JREO as to which SOPs need to be referred to the next available meeting.

#### **Date of SOP**

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.

#### **Effective Date of SOP**

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

#### **Review Date of SOP**

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.

### **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 and ready for implementation.

### **6.6 Version Control**

An SOP will be watermarked "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 versioned and dated. Updates to the SOP will result in an increase in version number (eg v1.0 will become v2.0)

Version and date reference should be consistent throughout all SOPs using the following format:



- Version = V XX.XX
- Date = DD/MM/YY

## **7. References**

ICH Good Clinical Practice

## 8. Appendices

### Appendix 8.1 Standard Operating Procedure Template

|   |                   |   |              |
|---|-------------------|---|--------------|
|  |                   | <b>St George's University Hospitals</b> <br>NHS Foundation Trust |              |
| <b>Standard Operating Procedure (SOP)</b><br><b>INSERT TITLE OF SOP</b>           |                   |   |              |
| <b>SOP ID number:</b>   | JREOSOP00xx       | <b>Effective Date:</b>  | Dd/mm/yy     |
| <b>Version number and date:</b>   | XX.XX<br>Dd/mm/yy | <b>Review Date:</b>   | Dd/mm/yy     |
| <b>Author:</b>  | Insert Name       | <b>Title:</b>   | Insert Title |
| <b>Approved by:</b>   | Insert Name       | <b>Date:</b>  | Dd/mm/yy     |
| <b>Signature of Authoriser</b>  |                   |   |              |

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.

| <b>SOP Chronology</b>      |  |                |
|----------------------------|--|----------------|
| <b>SOP Version Number:</b> | <b>Reason for Change:</b>                                  | <b>Author:</b> |
| V1.0                       | Original Version or insert a summary of reasons for change | Insert Name    |
|                            |  |                |
|                            |  |                |

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

## **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 HGD:*

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**

*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**

For general research management related acronyms used in this SOP refer to “General Research Definitions” working practice document JREOWPD0020.

#### **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.*

#### **7. References**

*Add any references used (see example given below)*

*Integrated Research Ethics Application Form - [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk)*

#### **8. Appendices**

*Add any appendices.*

