Standard Operating Procedure (SOP)

The Preparation, Approval and Review of JRES SOPs

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Signature of Authorisor			

This is a controlled document.
The master document is posted on the JRES website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JRES 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 JRES 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 Administrative and consistency update	Subhir Bedi
V6.0	Updated JREO's new title and added a new table to the template to incorporate Associated JRES documents	Ali Alshukry
V7.0	Update of JREO to JRES. Update to associated JRES documents table. Removal of SOP Template as Appendix 8.1 as separate Word document available. Minor amendments to text in each section.	Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
JRESGOVSOP0023 Training Requirements for Clinical Research	JRESWPD0005 Version Control JRESWPD0023 General Research Definitions	JRESDOC0108 SOP Template	

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1. Background

Standard Operating Procedures (SOPs) are written to enable an organisation to implement systems that assure the quality of every aspect of research conducted within the organisation.

As the Sponsor and host of clinical studies/trials, St George's must have SOPs which have detailed written instructions on how to achieve uniformity and consistency for specific processes and procedures when approving, managing and conducting research at St George's. The whole process from the set-up of research studies to the archiving of completed studies should be described by a continuous series of SOPs. The Joint Research and Enterprise Services (JRES) has developed a set of SOPs for this purpose and they are written to an agreed format as detailed in this SOP.

SOPs must avoid vague statements of intent or ambiguity. They should be compulsory instructions which must be followed. If deviations from the procedure outlined in the SOP are permitted, the conditions for these should be documented (eg: in an emergency situation), including who can give permission for this and what exactly the procedure will be.

For JRES SOPs, only the online versions will be listed as the active controlled document. Any print-offs of SOPs will be classed as uncontrolled documents and readers will be referred to the website for the up-to-date versions.

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

The JRES acts as the Sponsor 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 Standard Operating Procedure (SOP) outlines the procedure within St George's Joint Research and Enterprise Services (JRES) for the preparation, review, revision and approval of SOPs.

This SOP does not cover other associated JRES documents, templates and forms. The creation of other documents is covered in the Working Practice Document (WPD), JRESWPD0005.

This SOP does not cover the SOPs produced by St George's departments associated with the JRES, such as the Clinical Research Facility and the Vaccine Institute (please see JRESGOVSOP0034).

4. Definitions

For general research-related acronyms used in this SOP, refer to the General Research Definitions Working Practice Document (JRESWPD0023).

5. Responsibilities

This SOP is to be followed by the JRES Research Governance and Delivery Team.

Any SOPs produced by the JRES must be used in conjunction with any relevant SGHFT and SGUL policies and procedures.

6. Procedure

6.1 Writing SOPs

SOPs must be written using the JRES SOP Template (JRESDOC0108) which is available on the JRES website or by request from the JRES. The official font of SGUL is Franklin Gothic and therefore this font should always 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 as a minimum:

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

On completion of a draft JRES SOP by a member of the JRES, an internal review by relevant members of the JRES will be conducted. The SOP review must look at the accuracy and readability of the document.

6.2 Authorising SOPs

JRES SOPs must be signed-off by an appropriate, authorised JRES signatory. Governance and Delivery SOPs will be signed off by the Head of Research Governance and Delivery (HRGD), although this may be delegated to another authorised person where appropriate. JRES SOPs can be signed electronically using DocuSign® for convenience and where appropriate.

6.3 SOP Review

New or updated SOPs will be reviewed by the relevant signatory before being signed off and implemented. The author will add an effective date and review date to the SOP and save the final SOP in the SOPs folder of the JRES shared drive. The Documents tracker spreadsheet should also be updated. A PDF of the SOP should then be uploaded to the relevant page(s) on the SGUL and SGHFT websites.

On occasion, certain SOPs which may influence and/or have significant implications for the function of certain aspects of the Trust and/or University, such as financial implications and/or

functions outside of the JRES oversight, 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 JRES and the HRGD as to which SOPs need to be referred to the next available meeting.

Date of SOP

The date of the SOP defines the date when the SOP is final and ready for review and sign-off by the authoriser. The authoriser should not be the person who has written the SOP.

Effective Date of SOP

The effective date will be the date when the SOP is implemented by the JRES and it becomes the current version. This date will usually be later than the date of the SOP to allow for sign-off, training and implementation.

Review Date of SOP

The review date will be the date that the SOP should be reviewed and updated as required. The review will be done by the author or other appropriate designated person.

The review date will be 2 years from the effective date of the SOP. Some SOPs may need to be reviewed and updated before the set review date, where there are changes to procedures, legislation or local policies.

6.4 SOP Referencing

Each SOP produced by the JRES will be issued with a unique SOP number. This number identifies that it is a JRES document, the type of SOP (eg: 'GOV' for Research Governance and Delivery) and the SOP number (eg: 0001, 0002). For example, this SOP is referenced as JRESGOVSOP0001.

6.5 Distribution of SOPs

Current versions of SOPs are made available on the relevant JRES/research website pages for SGUL and SGHFT. Staff must check that they are accessing and using the current version of an SOP.

6.6 Training on SOPs

Investigators, study teams and JRES staff will be expected to read any SOPs which are relevant to their role and/or their trial. Training on processes described in a JRES SOP can be provided by the JRES where required. All training must be documented (see JRESGOVSOP0023 Training Requirements for Clinical Research).

6.7 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 review of the SOP. Once finalised, the document will be versioned and dated. Each review of the SOP will result in an increase in version number (eg V1.0 will become V2.0).

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

- Version = VX.0 (eg: V6.0).
- Date = DD/MM/YYYY (eg: 09/05/2021).

7. References

ICH Good Clinical Practice.

8. Appendices

None associated with this SOP.