Standard Operating Procedure (SOP)

Preparation, Review and Management of SOPs for the Clinical Research Facility (CRF) and Vaccine Institute (VI)

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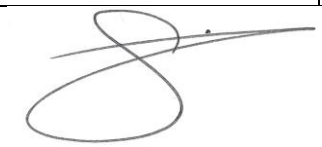
Author:	Georgia Bullock	**Title:**	Research Development and Governance Manager
Approved by:	Subhir Bedi	**Date:**	21/06/2021
Signature of Authorisor:			

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	Lucy H H Parker
V2.0	Removal of CRF from this SOP	Lucy H H Parker
V3.0	New Logo and trust name. Change of title from CRGM to HRG	Lucy H H Parker
V4.0	Update of JREO to JRES. Updated to include CRF SOPs as well as VI SOPs. Updated procedure in line with JRES SOPs. Addition of associated JRES documents.	Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
JRESGOVSOP0001 The Preparation, Approval and Review of JRES SOPs	JRESWPD0023 General Research Definitions	JRESDOC0120 SOP Template for CRF/VI SOPs	

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1. Background

The Joint Research and Enterprise Services (JRES) maintains a set of Standard Operating Procedures (SOPs) which detail the procedures and processes for approving, managing and conducting research studies sponsored or hosted by SGUL or SGHFT. The SOPs ensure that these procedures/processes are standardised across the organisations and are compliant with all relevant legislative and regulatory requirements and local policies. The SOPs describe all processes from study set-up to archiving and are controlled, authorised documents.

The Vaccine Institute (VI) and Clinical Research Facility (CRF) within St George's both maintain their own set of local SOPs for the research activity carried out within these departments. The JRES needs to maintain oversight of these SOPs to ensure that the local SOPs meet with the expectations and requirements of the JRES and to ensure that there is no conflict with, or repetition of, JRES SOPs. The CRF and VI SOPs will form part of the JRES' Quality Management System.

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 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 acting as Sponsor.

3. Scope

This SOP describes the process for the preparation, review and approval of all SOPs for the CRF and the VI.

The SOP applies only to SOPs and not to any other CRF or VI documents.

This SOP does not apply to JRES SOPs (please see JRESGOVSOP0001).

4. Definitions

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

5. Responsibilities

This SOP is to be followed by the JRES Governance team and the staff of the CRF and the VI.

All SOPs produced by the CRF and VI must be used in conjunction with any relevant SGUL/SGHFT policies and procedures and with any relevant JRES SOPs.

The CRF and VI are responsible for ensuring that their SOPs are available for audits and regulatory inspections when requested.

6. Procedure

6.1 Writing SOPs

The assigned CRF/VI staff member must create a new SOP using the JRES SOP Template for CRF/VI SOPs (JRESDOC0120).

The official font for SOPs is Franklin Gothic: 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, but additional sections may be added where necessary:

1. Purpose
2. Definitions
3. Procedure
4. Relevant JRES SOPs / Other Documents
5. References
6. Appendices

All SOPs must:

- Be assigned a unique ID number, according to an agreed format for each department.
- Be version-controlled (V1.0, V2.0 etc).
- Have a date - when the SOP is final and ready for sign-off.

- Have an effective date - when the SOP will be implemented and become the current version. This should usually be after the date of the SOP to allow for sign-off and any training.
- Have a review date - usually 2 years from the effective date.

For generic research procedures (eg: informed consent), the CRF and VI will refer to JRES SOPs, where available, to avoid the repetition of SOPs across the JRES, CRF and VI.

Procedures which are applicable to the VI and to the CRF will be described in one SOP and implemented in both the CRF and the VI.

6.2 Authorising SOPs

Once an SOP has been written, it must be reviewed within the CRF or VI for accuracy and clarity. It can then be approved/authorised by appropriate staff members within the CRF or VI.

The authorised SOP will be sent to the Research Development and Governance Manager (RDGM) or the Head of Research Governance and Delivery (HRGD) in the JRES for review and sign-off.

The RDGM/HRGD will return the signed SOP to the VI/CRF contact if no changes are required or once any requested changes have been made.

6.3 Distribution of SOPs

The VI or CRF will be responsible for distributing their approved SOPs to the relevant personnel and must maintain a record of this and also of any training provided on the content.

Final versions of SOPs should be distributed and stored electronically as PDFs and the Word versions must be stored electronically to enable updates.

6.4 SOP Review

VI and CRF SOPs should be reviewed and updated every 2 years unless an earlier review is necessary (eg: due to a change in legislation or local requirements).

Once reviewed, the SOP should be re-issued as a new version (eg: V1.0 will become V2.0), **even if no changes have been made**. The previous version must not be deleted. The following will need to be updated on the new version:

- The version number and date, including in the footer of the document.
- The effective date and the review date.
- The SOP Chronology table - to reflect the review, any changes made and the new version number.
- The SOP must be authorised and signed-off as for a new SOP.

7. References

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8. Appendices

None associated with this SOP.