St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

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Author:	Lucy H H Parker	**Title:**	Head of Research Governance
Approved by:	Debs Rolfe	**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)
for the Preparation and Approval of Vaccine Institute SOPs

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Lucy H H Parker
v.20	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

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1. Background

This SOP has been written to outline the procedure within the Vaccine Institute (VI) and the Joint Research and Enterprise Office (JREO) for the preparation, review, revision and approval of the VI SOPs. SOPs are written to enable the Sponsor to implement systems that assure the quality of every aspect of the trial. The responsibility for writing specific SOPs for Vaccine Institute has been delegated to the unit.

St George's SOPs are written to outline detailed instructions in order to achieve uniformity of the 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 Standard Operating Procedures (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 and the Vaccine Institute are implementing GCP by means of SOPs that will be 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 authorized persons. For JREO SOPs, only the online versions will be listed as the active controlled document. Any print-off of SOP's 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. St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

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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 Vaccine Institute.

This SOP will cover the numbering of SOPs, but not numbering of other associated VI documents.

This SOP will not cover training of Investigators or study personnel on SOPs produced by the VI. The VI should be contacted for their full set of approved SOPs.

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 finalized and signed off by the person authorised to sign off the SOP. It also defines the date when the SOP was reviewed and signed off by the JREO.

4.3 Effective Date

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

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 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.

5 Responsibilities

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This SOP is to be followed by the JREO Governance section and the Vaccine Institute.

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.

It is the responsibility of the person responsible for writing or amending the SOP in the Vaccine Institute to check with the JREO that they have the most current version of this SOP when reviewing an existing SOP or creating a new SOP.

Any SOPs produced by the Joint Research and Enterprise Office (JREO) or the Vaccine Institute must be used in conjunction with any relevant NHS Trust and other SGUL and SGHT policies and procedures.

6 Procedure

6.1 Writing SOPs

On completion of a draft Vaccine Institute SOP by a member of the Vaccine Institute (using the draft SOP template in appendix one), internal review by the Vaccine Institute members should 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. Purpose
2. Definitions
3. Procedures
4. Relevant JREO SOPs or other SOPs
5. References
6. Appendices

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

The final draft review must also be sent to the Head of Research Governance (HORG) in the JREO or their assigned delegate for review.

6.2 Authorising SOPs

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Before a VI SOP can be implemented, authorisation is required. The VI will have a list of authorised personnel.

The HORG or their assigned delegate must also authorise the SOP.

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.

6.4 SOP referencing

Each template SOP produced by the Vaccine Institute will be issued with a unique SOP number. This number identifies that it is a Vaccine Institute document and the SOP number (0001).

The Reference for a Vaccine Institute SOP will be UNI XX , CLIN XX

The reference for a JREO SOP is JREOSOPXXXX

6.5 Distribution of SOPs

The VI will be responsible for distributing their SOPs and will have a recorded process of distribution.

6.6 Version Control

SOPs 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)

7 References

ICH on Good Clinical Practice
JREOSOP0001 SOP on creating SOPs

8. Appendices

8.1 VI SOP template.

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Appendix 8.1 Standard Operating Procedure (SOP) Template

SOP ID number:	XXXXXX	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:			
Approved by JREO:	Insert Name	Date:	Dd/mm/yy
Signature of JREO:			

The Vaccine Institute

Standard Operating Procedure (SOP)

INSERT TITLE OF SOP

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SOP Chronology		
SOP Version Number:	Reason for Change:	Author:
V1.0	Original Version or insert a summary of reasons for change	Insert Name

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1. Purpose	
2. Definitions	
3. Procedures	
4. Relevant JREO SOPs or other SOPs	
5. References	
6. Appendices	

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1. Purpose

Please insert a short summary as to the purpose of this SOP…

2. 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):

2.1 Insert relevant text

Insert text to define the above…

4.2 Insert relevant text

Insert text to define the above…

3. 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.

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6.1 Investigator Procedure

Please Insert relevant text…

6.2 VI Procedure

Please Insert relevant text…

4. Relevant JREO SOPs or other SOPs

Please Insert relevant SOPs…

5. References

Add any references used (see examples given below)

www.myresearchproject.org.uk

6. Appendices

Add any appendices.

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