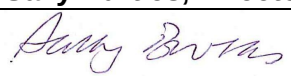
Standard Operating Procedures (SOP) for:			
Creating, maintaining and distributing JRMO Standard Operating Procedures (SOPs)			
SOP Number:	**30**	Version Number:	**6.0**
Effective Date:	**23RD November 2015**	Review Date:	**22nd November 2017**

Author:	**M. Rickard, GCP and Governance Manager**
Reviewer:	**Liz Clough, R&D Governance Operations Manager**

Authorisation:	
Name / Position	**Sally Burtles, Director of Research Services & Business Development**
Signature	
Date	**9th November 2015**

Purpose and Objective:
Purpose: To ensure that all Standard Operating Procedures (SOPs) adhere to a uniform standard format. To outline a clear procedure for formulating and writing an SOP. To ensure that SOPs are administered, reviewed and amended appropriately. To ensure that all staff have an understanding of the maintenance process for SOPs. To outline the process of disseminating relevant research SOPs to internal and external research staff.
Scope:
This SOP applies to all staff within the JRMO. This SOP is linked with the QMS Manual which can be found within the JRMO QMS folder

Abbreviations:	
BH	Barts Health NHS Trust
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
PDF	Portable Document Format (usually a file viewable using Adobe Acrobat)
PI	Principal Investigator
QA	Quality Assurance
QMUL	Queen Mary University of London
QMS	Quality Management System
ReDA	Research Database Application
RG	Research Governance
SOP	Standard Operating Procedure

Definitions
QMS Lead: Role undertaken by a designated GCP Manager or QA manager.

Relevant SOP s
SOP 34 JRMO Staff Training Records

SOP Text		
	Responsibility	Activity
Creating JRMO SOPs		
1.	Line manager/ individual staff member	• When the need for a new SOP is identified, or when it has been agreed to update an existing SOP, notify the relevant Operations Manager.
2.	R&D Operations Manager	• Nominate an individual to be the author of the SOP and notify the JRMO Quality Management System Lead (QMS lead).
3.	QMS Lead	• Allocate a new SOP number or, if updating an existing SOP, update the SOP Log to show it is under revision.
4.	Author	• Draft the SOP using the SOP template and guidance in Appendix A. • Disseminate draft SOP to one or two relevant work colleagues, who where ever possible have experience of the process, for review (one of whom should be the author's line manager). • Incorporate the reviewer's comments (if appropriate), then forward the SOP to team's Operations Manager.
5.	Operations Manager	• Review the draft SOP • If changes are required inform the Author and provide guidance. Author to amend SOP and return to the Operations Manager for review. • Set review date: All new SOPs will have a 12 -18 months renewal period all other SOPs can have 2-3 year renewal periods. Date should be set with QMS led to ensure the whole SOP suite does not need renewal in the same period. • When finalised send to the QMS Lead and Director of Research Services & Business Development.
6.	Director of Research Services & Business Development	• Review SOP. If further changes are required then discuss them with the author or appropriate Operations Manager. Author or Operations Manager must amend the SOP and resend it to the Director of Research Services & Business Development. • Approve the final version and inform Governance and GCP Managers and QMS lead.
7.	QMS Lead	• Complete the *Version*, *Authorised by*, *Effective Date* and *Review Date* boxes on the SOP. • Insert electronic signature of Director of Research Services & Business Development. • Print Word version and obtain wet signature of Director of Research Services & Business Development on same documents. • Insert effective date which must be after the date of the Director of Research Services & Business Development's wet signature. • Save the final Word version and create a locked PDF version with electronic signatures. The PDF version must be locked to editing with watermark "Uncontrolled if printed." • Ensure signed PDF version is uploaded on to ReDA and the JRMO website. • Update the SOP Index. • File the wet signed paper copy in the SOP Master File.

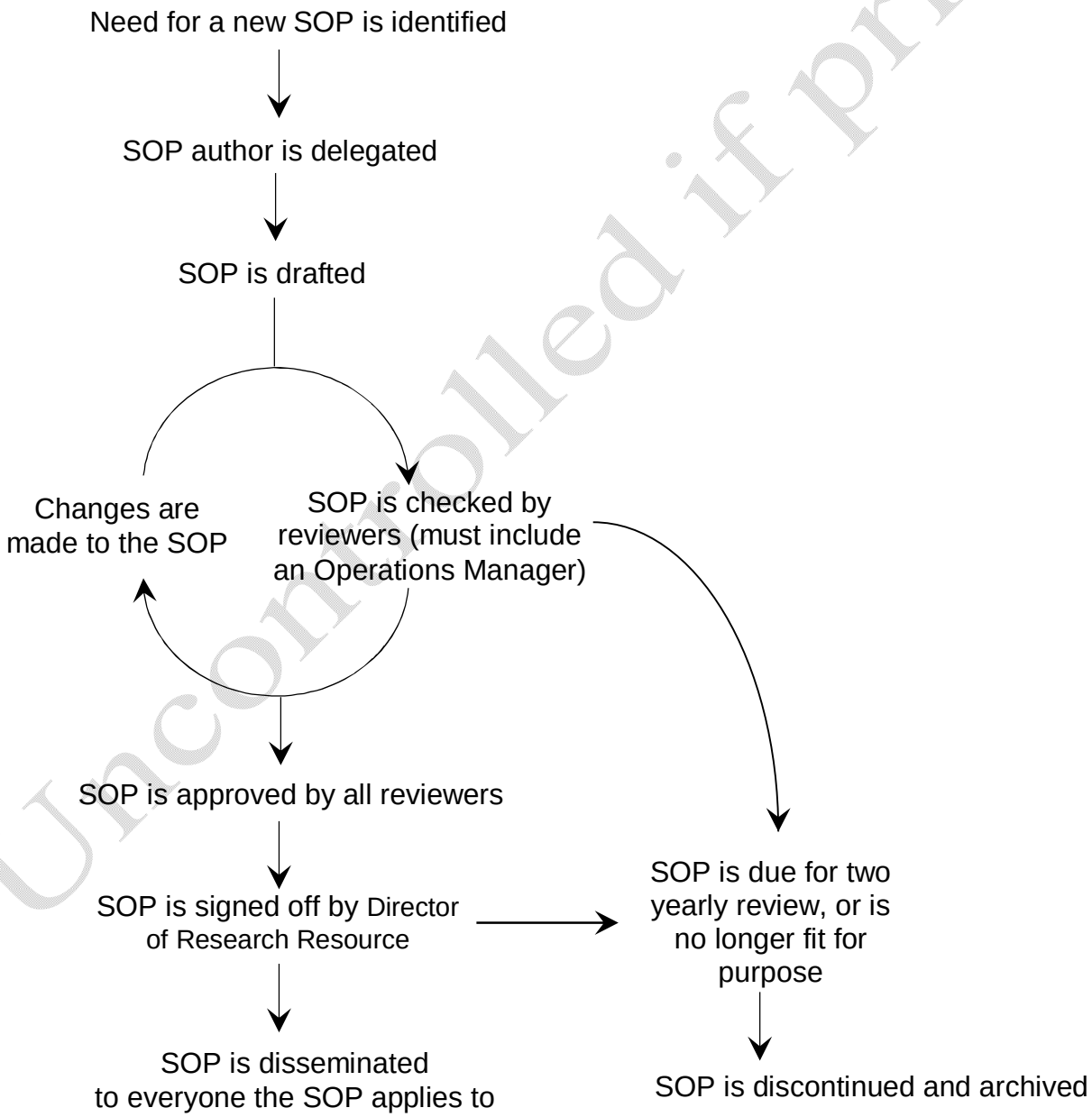
Maintaining JRMO SOPs		
8.	QMS Lead	• Maintain an up to date SOP index. • Two to three months before an SOP review date, inform relevant team's Operations Manager and agree a timeline for review.
9.	Individual staff member	• If a staff member identifies the need to update an SOP outside the regular review dates then this should be discussed and agreed with the relevant team's Operations Manager.
10.	Operations Manager	• Allocate a reviewer for every SOP. If no changes are currently needed this should be documented and the QMS Lead informed.
11.	Author	• Review the SOP for compliance to requirements and current best practice. If no amendments are required, set appropriate date for the next review. • Send to Operations Manager and state that no amendments were required. Go to step 13.
12.	Delegated person	• If an amendment is required revise the SOP and disseminate to two colleagues with experience of the process for review and comment (one of whom should be the delegated person's line manager). • After reviewing and incorporating reviewer's comments (where appropriate), forward the SOP to the team's Operations Manager. • Update the change control section of the SOP. Provide a summary of the changes and include corrections of typographical errors or administrative changes that are not detailed separately.
13.	Operations Manager	• Provide final review of amended SOP. • If changes are required inform delegated person and provide guidance on the changes. • If there are no changes required send to Head of Research Resources or Director of Research Services & Business Development and the QMS Lead
14.	Director of Research Services & Business Development	• Review SOP. If further changes are required then discuss them with the author or appropriate Operations Manager. Author or Operations Manager must amends the SOP and resend it to the Director of Research Services & Business Development. • Approve the final version and inform Governance and GCP Managers and QMS lead.
15.	QMS Lead	• Complete the *Version*, *Authorised by*, *Effective Date* and *Review Date* boxes on the SOP. • Insert electronic signature of Director of Research Services & Business Development. • Print Word version and obtain wet signature of Director of Research Services & Business Development on same documents. • Insert effective date which must be after the date of the Director of Research Services & Business Development's wet signature. • Save the final Word version and create a locked PDF version with electronic signatures. The PDF version must be locked to editing with watermark "Uncontrolled if printed." • Ensure signed PDF version is uploaded on to ReDA and the JRMO website. • Update the SOP Index.

		• File the wet signed paper copy in the SOP Master File.
16.	QMS Lead	**Storing and archiving the SOPs** • File current versions of SOPs in the SOP Master file and an electronic PDF version in ReDA and on the network. • Superseded or discontinued SOPs should be archived in the SOP Archive file.

Distribution and notification of JRMO SOPs		
Internal Distribution to the JRMO		
17.	QMS Lead	• Provide PDF version that will be uploaded on the JRMO website. • Upload signed PDF version to ReDA SOP Store. • Notify Operations Managers and Projects and Communications Manager of new or revised SOP. • Update training matrix as applicable (see SOP 34 JRMO Staff Training Records).
18.	Projects and Communications Manager	• Update website with new PDF version of the SOP, state new version number and remove superseded SOP. • Included notice of updated SOP is in the next JRMO R&D Bulletin.
19.	Operations Manager	• Read the SOP and sign the individual SOP reading log. • Assess relevance of the SOP to teams and staff and notify teams of new or revised SOP as applicable. • It is the responsibility of the Operations manager to ensure that their staff are familiar with and working to the SOP relevant to their work
20.	All staff members who receive updated SOP	• It is the responsibility of each staff member to read and understand the SOPs relevant to their role, as directed by their line manager. • Read the SOP and sign the individual SOP reading log, to confirm they have read and understood the updated SOP. This should be done in a timely fashion. • Direct queries regarding the new SOP to line manager (with escalation, as required, to section Operations Manager).
21.	Operations Manager	• Review training logs annually and following probationary periods of new staff. • Review training logs to ensure staff in team have read SOPs as directed.
22.	All staff	• Direct all requests for copies of SOPs to the JRMO website. • Direct SOP queries to the QMS Lead, including requests for Word or unsigned versions. The QMS Lead will assess such requests in conjunction with R&D Governance Operations Manager and/or GCP Managers.
External Distribution from the JRMO		
	QMS Lead	• Provide notification of all updated SOPs for inclusion in the JRMO R&D Bulletin to the Projects and Communication Manager. • Assess the need to notify Chief Investigators of active sponsored CTIMP studies (and their research teams where appropriate) of new or revised SOPs. If this is unclear this should be discussed with the GCP managers.

	Operations Manager	• Assess the need to notify Principal Investigators of JRMO active studies of new or revised SOPs. • Provide dissemination instructions to the JRMO Office Manager or other delegate if appropriate.
	JRMO Office Manager	• Maintain an up to date dissemination list of active PIs, research teams and units. • Disseminate notification of new or revised SOP as per Operations Manager's instructions and using wording provided.
	Projects and Communications Manager	• Include notification of all updated SOPs in the JRMO R&D Bulletin.

Flow chart



Change Control

This section outlines changes from version 5.0 to version 6.0 of this SOP.

Summary and description of change
1. Section 7 and 16 changed to indicate new signing and PDF arrangements for SOPs.
2. Throughout, "Head of Research Services" changed to "Director of Research Development".

List of appendices

Appendix	Appendix name
Appendix A	SOP Writers' Guide

List of Associated Documents

	Document name
Associated Document 1	SOP template

Appendix A

SOP Writers' Guide

1. **Page Format**
   - Use SOP template attached
   - Each page of the SOP text must include the standard header
   - In addition, the first page of the SOP must include an author, two reviewers, and an authorisation box
   - The standard header must not be included on attachments

2. **Page numbers**
   - Page numbers must appear in the footer as Page X of Z.

3. **Text**
   - Point size = 11
   - Font = Arial
   - (**Bold**) for first section and (non Bold) for Purpose and Objective text & SOP text

4. **SOP Identification**
   - SOP number allocated at authorisation
   - A new version of a SOP must be identified by a sequential version number
   - Each SOP must have a unique number indicated in SOP number box and in the footer. This will be allocated by the QMS Lead.
   - Version will be as follows: 0.1, 0.2, etc until final version which will be 1.0, any following revision will be 1.1, 1.2 etc until the next final version which will be 2.0.

5. SOP Effective date

- Date the SOP is authorised

6. SOP Review date

- Decided by QMS Lead in conjunction with the author, but with a maximum of 2 years. Any member of staff who may be concerned that a SOP needs updating should contact the author, or relevant section Operations Manager.

7. Author

- Identified in author box.

8. Authorisation

- The Head of Research Resources or the Director of Research Development will authorise the SOPs.

9. Purpose and Objective

- This section briefly outlines the intention of the SOP and includes any Trust/ QMUL objective, standards or policies to be met or achieved as a result of following the procedure.

10. SOP Text

- The SOP text must be presented in activity/responsibility format
- SOPs are written for use by trained staff. Explanatory detail is not required.
- SOPs must be written as a set of instructions i.e. do this/ document that or this must/should be done
- Where possible each process point should start with a short summary in bold lettering.