

JRMO Document Writers' Guide

SOPs and supporting documents

1. SOP Identification

Each SOP must have a unique number indicated in the SOP number box and in the footer. This will be allocated by the JRMO QA Manager. All supporting documents will reference the SOP for which its associated.

2. Version Control

The first published version will be 1.0; draft versions will be 0.1, 0.2, along with reviewer initials etc. until the final version which will be 1.0. Following any revisions draft versions will be 1.1, 1.2 along with reviewer initials etc. until the next final version which will be 2.0, and so on.

3. Page Format

Use Associated document 2 for all SOPs. The first page of the SOP must include an author, at least two reviewers, and an authorisation box.

Supporting documents can be drafted in a variety of forms therefore no set template is necessary.

4. Page number

Page numbers must appear in the footer as Page X of Y.

5. Font

- Headings can have a point size range between 12 to 16
- The main text body point size = 11
- Footer point size = 8
- Font = Arial

6. SOP Effective date

Date the SOP is to be implemented.
The effective date is also noted in the footer

7. SOP Review date

Decided by QMS group in conjunction with the author.

8. Author/Reviewers

Identified in the "Authorship & reviewers" box. All identified authors and reviewers must confirm approval with the document via wet signature/electronic signature/confirmation email. Supporting documentation does not require a signature process.

9. Authorisation

The Senior Operations Manager must authorise all JRMO SOPs.
Supporting Documentation can be authorised by the authors Operations Manager

10. Background

Where deemed necessary, a brief description of the background to the SOP can be given.

11. Purpose

This section briefly outlines the intention of the SOP and includes any Barts Health/Queen Mary objective, standards, or policies to be met or achieved as a result of following the procedure.

12. Scope

This section outlines who the SOP applies to.

13. Abbreviations

This section contains a summary of all abbreviations used in the document

14. Definitions

This section outlines definitions which would be beneficial to the understanding of the SOP

15. Relevant SOPs

This section contains a summary of all other JRMO SOPs relevant to support this SOP.

16. Change Control

This section outlines the changes made to this SOP from the previous version

17. Supporting documentation

Appendices: Information/further detail to support the process of the SOP which is noted at the end of the SOP.

Associated Documents: Documents that can be additional guidance notes, forms, checklists, email templates to support the SOP. The use of these documents is mandatory. Unless otherwise stated, these documents cannot be altered without agreement from the JRMO QMS team. (See [SOP 41 JRMO oversight of CTG and study-specific SOPs](#) for further details on document waivers)

Templates: These are for use when documents, forms or checklist are created as an example of a process but are not mandatory to use. These documents can be altered to user specifications without the permission of the JRMO QMS.

18. EDGE Updates

This section outlines any changes that will be required to the EDGE database at the time of SOP implementation. This section should be written in conjunction with the JRMO performance team to ensure the changes are feasible.