Title: Management of SOPs

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Approver: Dr Nimesh Mody, Technical Manager
Approver: Prof Paul Fowler, IMS Director

Document History

<table>
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<tr>
<th>Version</th>
<th>Description of update</th>
<th>Date Effective</th>
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<tr>
<td>1</td>
<td>New SOP</td>
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1. Scope

1.1 This Standard Operating Procedure (SOP) applies to any individual delegated the task of writing, reviewing, approving or distributing an SOP on behalf of University of Aberdeen (UoA) for use in work covered by ISO/IEC 17025:2017 accreditation.

1.2 Institute of Medical Science (IMS) SOPs may be used in conjunction with study specific SOPs and local documented procedures, held by the various teams and departments conducting or supporting testing activity, but IMS SOPs shall always be followed.

1.3 Any local SOPs used shall be submitted to the Quality Assurance Manager (QAM), or delegate, for approval prior to use in testing activity.

2. Responsibilities

SOP Owner/Author: Writing or reviewing an SOP and training assessment of users.
QA Manager (QAM): Management of SOPs and QA approval.
Technical Manager: Oversight of writing and reviewing of SOPs.
IMS Director: Oversight of writing, reviewing and approval of SOPs.

3. Procedure

Preparation of a new SOP

3.1 Any personnel involved in testing can request a new SOP. They must complete either a Document Creation Form (TMP-QA-29) and forward to the QAM. The request must be initiated as soon as the need for a new SOP has been identified. The QAM shall review all SOP requests and allocate a severity of ‘high’, ‘normal’ or ‘low’. Those allocated as ‘high’ severity shall be addressed immediately. Those allocated as ‘normal’ or ‘low’ shall be reviewed at the next scheduled Management Review meeting (see SOP-IMS-39 – Management Review).

3.2 SOPs shall be written by an appropriate competent person (SOP Owner/Author) identified by the Technical Manager, QAM or IMS Director. New SOPs shall be allocated a unique number by Q-Pulse and shall become version 1. New SOPs shall be approved by the IMS Director and QAM; their names shall be assigned to the SOP, along with the owner/author.

3.3 SOPs shall be written in accordance with this procedure using the IMS SOP template (TMP-QA-85). For readability and consistency, all SOPs shall be written in ‘Calibri’ (11 point); underlining and

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Key to symbols

= Important point to note
= Warning
block capitals shall not be used. Important points may be emphasised with ☑️. Warnings may be emphasised with ⚠️.

3.4 An assessment of any training requirements shall be made by the SOP owner and QAM before issue. If required, SOP specific training shall be facilitated by Senior Management prior to the effective date.

3.5 The QAM, or delegate, shall ensure that new SOPs are uploaded to Q-Pulse and the Clinical Research Governance & Quality Assurance webpage www.abdn.ac.uk/clinicalresearchgovernance

3.6 The Technical Manager shall ensure all staff to whom the new SOP applies shall acknowledge and update their training record (see SOP-IMS-30 – Training and Competence) using the SOP sign-off sheet (TMP-QA-40).

Review of existing SOPs
3.7 All SOPs shall be formally reviewed every three years, or earlier should changes in legislation or local practices deem this necessary. This shall be overseen by the QAM and Technical Manager. The QAM shall review all change requests and allocate a severity of ‘high’, ‘normal’ or ‘low’. Those allocated as ‘high’ severity shall be addressed immediately. Those allocated as ‘normal’ shall be reviewed at the next scheduled Management Review. Those allocated as ‘low’ severity shall be reviewed when the SOP is due for its next formal review.

3.8 The QAM, or delegate, shall notify the SOP owner by completing and forwarding a ‘Notification of periodic review of SOP’ (TMP-QA-30), two months prior to review date.

3.9 If amendments are required, these may be incorporated as track changes into the SOP and shall be reviewed by the QAM and Technical Manager. The QAM and/or Technical Manager may identify other technically competent person(s) to assist in review.

3.10 The review shall be recorded in the Document History (including a review which results in no changes). A Document Revision Checklist (TMP-QA-83) shall be completed by the QAM, or delegate. ☑️ Version numbers shall increase by one (never by 0.1, 0.01 etc).

3.11 Amended SOPs shall be approved (as detailed in 3.2) and an assessment of any training requirements shall be made (as detailed in 3.4). SOP users shall be notified (as detailed in 3.6).

3.12 Obsolete SOPs shall be permanently archived electronically within Q-Pulse.

4. Abbreviations and definitions

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<tr>
<td>IMS</td>
<td>Institute of Medical Science</td>
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<td>QAM</td>
<td>Quality Assurance Manager</td>
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5. Related documentation and references

<table>
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<th>Document Code</th>
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<td>SOP-IMS-30</td>
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