Title: Management of SOPs

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Author: Richard Cowie, QA Manager  QA Approval: Richard Cowie, QA Manager
Approver: Prof Maggie Cruickshank, R&D Director  Approver: Prof Siladitya Bhattacharya, Head of School

Document History

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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) and/or NHS Grampian (NHSG) for use in research.

1.2 Sponsor SOPs may be used in conjunction with study specific SOPs and local documented procedures, held by the various research teams and departments conducting or supporting clinical research, but Sponsor SOPs shall always be followed.

1.3 Any study specific SOPs used shall be submitted to the Quality Assurance Manager (QAM), or delegate, for approval prior to use in a UoA/NHSG sponsored or co-sponsored study.

2. Responsibilities

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

3. Procedure

Preparation of a new SOP

3.1 Any personnel involved in research can request a new SOP. They must complete either a Document Creation Form (TMP-QA-29) and forward to the QAM, or raise a Change Request in Q-Pulse.

Uncontrolled when printed. Please ensure that you are working on the most up to date version of this SOP.

Key to symbols 📝 = Important point to note 🚨 = Warning
Pulse. 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 Clinical Research Operational Group (CROG).

3.2 SOPs shall be written by an appropriate competent person (SOP Owner/Author) identified by the CROG, QAM, or CI for study specific SOPs. New SOPs shall be allocated a unique number by Q-Pulse and shall become version 1. New SOPs shall be approved by the R&D Director, Head of School 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 SOP template (TMP-QA-4). For readability and consistency, all SOPs shall be written in ‘Calibri’ (11 point); underlining and 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 Sponsor 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 QAM, or delegate, shall email ‘Grampian Globals’ and UoA to request insertion in the next available all-staff bulletins, and shall also complete a Document Revision Checklist (TMP-QA-83).

️ Consider updating sites out with UoA and NHSG as appropriate.

Review of existing SOPs
3.7 All joint UoA-NHSG 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 CROG (the CI shall oversee the management of study specific SOPs). 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 CROG. 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 using Q-Pulse, or 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 CROG. CROG may also recommend additional changes to the SOP prior to approval, or identify an alternate SOP owner if appropriate.

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

CI          Chief Investigator
CROG        Clinical Research Operational Group
QAM         Quality Assurance Manager

5. Related documentation and references

| TMP-QA-4  | SOP Template                     |
| TMP-QA-29 | Document creation, amendment and approval form |
| TMP-QA-30 | Notification of periodic review of SOP       |
| TMP-QA-83 | Document Revision Checklist |