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| **SOP-QA-X VX** | |
| **Title: XXX** | |
| **Effective Date: XXX** | **Review Date: XXX** |
| **Author: XXX** | |
| **QA Approval: Richard Cowie, QA Manager** | |
| **Approver: Prof Maggie Cruickshank, R&D Director** | |
| **Approver: XXX** | |

**Document History**

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| **Version** | **Description of update** | **Date Effective** |
| 1 | XXX | 1-1-17 |

1. **Scope**

### 1.1 This SOP applies to any individual delegated the task of writing, reviewing, approving or distributing a Standard Operating Procedure (SOP) on behalf of University of Aberdeen (UoA) and/or NHS Grampian (NHSG).

### 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, warning signsbut 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.

1.4 This SOP may also be used by staff from other NHS areas, or organisations, with prior agreement.

1. **Responsibilities**

SOP Owner 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.

1. **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 sent it to the QAM, or a Change Request in Q-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 CROG.

3.2 SOPs shall be written by an appropriate competent person (SOP owner) identified by the Clinical Research Oversight Group (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.

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[](http://www.google.co.uk/url?url=http://cliparts.co/warning-icons&rct=j&frm=1&q=&esrc=s&sa=U&ved=0ahUKEwio1dHRvazNAhUqKsAKHZn8Co8QwW4IIDAF&usg=AFQjCNHRAGbmphtyJeuto0cj_diWb1aORw). Warnings may be emphasised withwarning signs.

3.4An assessment of any training requirements shall be made by the SOP owner and CROG **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](http://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. [](http://www.google.co.uk/url?url=http://cliparts.co/warning-icons&rct=j&frm=1&q=&esrc=s&sa=U&ved=0ahUKEwio1dHRvazNAhUqKsAKHZn8Co8QwW4IIDAF&usg=AFQjCNHRAGbmphtyJeuto0cj_diWb1aORw)Consider updating sites out-with UoA and NHSG as appropriate.

**Review of existing SOPs**

### 3.7All 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.

3.9If 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 table (including a review which results in no changes to the SOP). [](http://www.google.co.uk/url?url=http://cliparts.co/warning-icons&rct=j&frm=1&q=&esrc=s&sa=U&ved=0ahUKEwio1dHRvazNAhUqKsAKHZn8Co8QwW4IIDAF&usg=AFQjCNHRAGbmphtyJeuto0cj_diWb1aORw) Version numbers shall increase by one (never by 0.1, 0.01 etc).

### 3.11Amended SOPs shall be approved (as detailed in 3.2) and an assessment of any training requirements shall be made (as detailed in 3.6). SOP users shall be notified (as detailed in 3.7).

1. **Abbreviations and definitions**

None

1. **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 SOPs