

SOP-QA-1 V6

Title: Management of SOPs

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GRAMPIAN CLINICAL RESEARCH OFFICE



Document History

Version	Description of update	Date Effective
5	Revised responsibilities at 2 Reformatted and updated GRO office details at 3.5 Updated SOP Review Form reference at 3.6 and 3.8 to 3.10	01-08-23
6	Update electronic Quality Management System name to Ideagen.	15-09-26

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 clinical 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	Technically competent person, responsible for writing or reviewing an SOP and training assessment of users.
QA Manager (QAM)	Management of SOPs (with CROG) including QA approval.
CROG	Ratification of SOPs.

3. Procedure

Preparation of a new SOP

- 3.1 Any personnel involved in clinical research can request a new SOP. They must complete a Document Creation Form (TMP-QA-29) and forward to the QAM 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 'high' shall be addressed immediately. The remainder shall be reviewed at the next scheduled Clinical Research Operational Group (CROG).
- 3.2 SOPs shall be written by an appropriate technically competent person (SOP Owner/Author) identified by CROG, QAM, or CI for study specific SOPs. New SOPs shall be allocated a unique number by the Ideagen Quality Management system (Ideagen QMS) and shall become version 1. SOPs shall be approved by the R&D Director, Head of School and QAM; their names shall be assigned to the SOP, with the owner/author.

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Key to symbols ⓘ = Important point to note ⚠ = Warning

- 3.3 SOPs shall be written in accordance with this procedure using 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, 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 the Ideagen QMS and the Grampian Research Office (GRO) webpage www.abdn.ac.uk/gro/qa-and-sops/
- 3.6 The QAM, or delegate, shall email 'Grampian Globals' and UoA to request insertion in the next available all-staff bulletins, and shall complete the SOP Creation Form (TMP-QA-29).
 Consider updating sites/users out with UoA and NHSG as appropriate.

Review of existing SOPs

- 3.7 All 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 in liaison with the SOP owner and allocate a severity of 'high', 'normal' or 'low'. Those allocated 'high' shall be addressed immediately. Those allocated 'normal' shall be reviewed at the next scheduled CROG. Those allocated 'low' shall be reviewed at the next formal review.
- 3.8 The QAM, or delegate, shall notify the SOP owner by forwarding an 'SOP Review Form' (TMP-QA-30) listing any outstanding change request, two months prior to review date. The QAM, CROG or existing SOP owner may identify an alternate SOP owner if appropriate.
- 3.9 If the SOP owner deems the SOP still fit for purpose, the SOP Review Form (TMP-QA-95) shall be completed and returned to QA. The SOP shall be prepared for reissue unchanged.
- 3.10 If amendments/updates are required, these may be incorporated as track changes into the SOP. The SOP Review Form (TMP-QA-30) shall be completed and returned to QA. Once prepared by QA the SOP shall be ratified by CROG, who may recommend additional changes.
- 3.11 The review shall be recorded in the Document History (including a review with no changes).
 Version numbers shall increase by one (never by 0.1, 0.01 etc).
- 3.12 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).
- 3.13 Obsolete SOPs shall be permanently archived electronically within the Ideagen QMS.

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	SOP Review Form

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