Standard Operating Procedure
Preparation and Control

Document No.:	QA001 v9.0
Author:	Lorn Mackenzie
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Effective date:	10 Sep 2024

1 Introduction

1.1 The Academic and Clinical Central Office for Research and Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 SOPs are designed to describe processes and procedures in compliance with relevant ACCORD, NHSL and UoE policies and with Good Clinical Practice (GCP), applicable regulations and the UK policy framework for health and social care research.

2 Purpose

2.1 To document the procedure for preparation and control of ACCORD SOPs, and for recording SOP deviations.

3 Scope

3.1 This SOP will apply to all ACCORD (NHSL and UoE) personnel involved in the governance, facilitation and oversight of clinical research.

4 Responsibilities

4.1 The Quality Assurance (QA) Manager, QA Coordinator and QA Administrator are responsible for control of SOPs and related documents.

4.2 The QA Manager, together with the most senior ACCORD staff member in the relevant topic area is responsible for:

- selecting an appropriately experienced member of staff to prepare a new SOP, or review a new or existing SOP
- reviewing and approving SOPs
- determining training requirements for new/updated procedures

4.3 The SOP author is responsible for consulting the relevant staff, regulations, guidelines, policies and SOPs prior to writing/reviewing the procedure, and for making an assessment as to whether training on new/updated procedures is required.

4.4 ACCORD (NHSL and UoE) personnel involved are responsible for:

- reading SOPs appropriate to their line of work, as advised by QA,
- informing ACCORD QA of any SOP deviations
- informing ACCORD QA of any requirements for new procedures or necessary changes to existing procedures/documents.

5 Procedure

5.1 Preparing a Draft SOP

5.1.1 The author will use the SOP template QA001-T01 (SOP Template) to write the draft SOP.

5.1.2 The author will describe the procedure in a concise manner with sufficient detail and description to facilitate accurate performance of the procedure described.

5.1.3 If it is necessary to prepare specific work instructions to describe detailed tasks separately, the author will use QA001-T02 (Work Instruction Template).

5.1.4 If any forms or template documents are required to supplement the SOP, the author will prepare draft forms and templates.

5.2 Reviewing a Draft SOP

5.2.1 Once the draft SOP and any associated documents are complete, the author will forward these by e-mail to the reviewer(s), assigned by the QA Manager and most senior ACCORD staff member in the relevant topic area.

5.2.2 Comments and suggested changes will be considered and included if there is general agreement from the author and reviewer(s).

5.3 Finalising and Releasing an SOP

5.3.1 When the document is considered final, the QA Coordinator, or designee, will assign unique document numbers.

5.3.2 SOP numbers will consist of 5 characters. The first 2 characters will represent the topic area of the SOP e.g. QA=Quality Assurance. The final 3 characters will represent the number of the SOP in the topic sequence i.e. 001 will be the first SOP in that topic.

5.3.3 For work instructions, templates or forms allied to the SOP, an extra character will be added to signify the nature of the document i.e. ‘W’, ‘T’ or ‘F’, respectively. In addition,

a two digit suffix will be added to represent the number of document in the SOP sequence e.g. the first template of SOP QA001 will be QA001-T01.

5.3.4 The QA Manager, or designee, will ensure that the final version is signed by the author, reviewer(s) and authorised by QA, and set an issue date and an effective date. Where possible, there will be a period of 2-6 weeks between the issue and effective dates to allow applicable parties to become familiar with the new/revised procedures before they become effective. If the SOP is a revision and the update is minor in nature, for example administrative changes, then this effective period may be shorter.

5.3.5 If there are any new or updated forms, templates or work instructions associated with the SOP, the version number of the document will be recorded in the SOP Document History table (e.g. QA001-T01).

5.3.6 The SOP author, in consultation with the QA Manager or designee, will determine training requirements before the SOP is issued. A final decision on training requirements will be communicated by the SOP author via email to the QA Manager, or designee.

5.3.7 If SOP specific training is required, this shall be facilitated by the SOP author prior to the effective date, where possible. Such training will be recorded by the QA Manager, or designee, within the ACCORD QA Files using form QA001-F01 (SOP/Document Training Form).

5.3.8 The QA Administrator, or designee, will ensure that applicable parties are notified via email that the SOP has been issued and advise of the effective date, instructions regarding the location of the document(s) until effective (for example attached to the email), and subsequent to effectiveness. Applicable parties will be identified from the QA Administrator, or designee, reviewing the SOP responsibilities/scope section (QA001-T01 sections 3 & 4) and may be, but not limited to ACCORD staff, Trial Managers, ACCORD e-mail distribution list. Details of SOP training sessions and/or materials will also be provided where applicable. The Required SOP, Policy and Guideline Training (HR001-W01) will detail which SOPs, Policies and Guidelines ACCORD staff are required to read.

5.3.9 If the SOP is a revision, a short explanation of the revision may be given by the QA Administrator, or designee. Depending on the update to the SOP, the Sponsor(s) may decide that use of the previous version may continue for active studies e.g. update of the TMF/ISF index template. The QA Manager and SOP author may seek guidance at the monthly Sponsorship meeting should a decision of this nature be required. This decision will be communicated when the procedure is circulated by the QA Manager, or designee.

5.3.10 When all that is required is for applicable parties to read a new/revised SOP, staff will confirm they have read and understood the procedure by completing form QA001-F02 (SOP/Document Circulation Form).

5.3.11 Forms will be retained in individuals' training records.

5.3.12 Master and draft electronic copies of SOPs (including signed copies of SOPs) and related documents (e.g. forms, templates, WIs, email communication) will be securely stored by the QA Manager, or designee, within the ACCORD QA Files on SharePoint. Only members of the QA team will have controlled access to these documents.

5.3.13 Copies of the effective SOPs and associated documents are available to ACCORD personnel on the ACCORD SharePoint and to research teams on the ACCORD website. The QA Administrator, or designee, will set a calendar reminder to upload the SOP and associated documents to the ACCORD SharePoint/website on the effective date and update the SOP Index List on the ACCORD SharePoint to confirm the date of upload to the website.

5.4 Reviewing an Existing SOP

5.4.1 The QA Manager, or designee will ensure that an existing SOP, and associated documents, is subject to formal review by the author before 2 years have elapsed since its effective date, or earlier should changes in legislation or local practices deem this necessary. The QA Manager, or designee shall notify the SOP author three months prior to the review date.

5.4.2 The review shall be recorded in the Document History. If the SOP requires no changes, the SOP version will remain and a new review date will be assigned. This will be recorded by the QA Coordinator, or designee, in the Document History section.

5.4.3 If the SOP requires changes, the author will prepare a draft document accordingly, in line with section 5.1 of this SOP.

5.4.4 If the author is no longer in post, another author will be selected by the QA Manager and the most senior ACCORD staff member in the relevant topic area.

5.4.5 Review, finalisation and release of the revised document(s) will proceed in line with sections 5.2 and 5.3 of this SOP. The review will be recorded in the SOP Document History table (QA001-T01), including a review which results in no changes to the SOP. The version number will increase by 1 whole number.

5.4.6 If the SOP author has failed to review the SOP by the review date, the QA Manager will escalate this to an appropriate line manager for resolution. The QA Administrator, or designee, will create a file note to document where a SOP has not been reviewed within agreed timelines.

5.5 SOP Deviations

5.5.1 Researchers working on a study sponsored by NHSL and/or UoE should inform the ACCORD QA Manager, or designee, of any action taken that may be considered an SOP deviation in accordance with CR010 (Management of Protocol and GCP Deviations and Violations).

5.5.2 ACCORD staff members will report internal SOP deviations to the QA Manager, or designee. The QA Manager, or designee, will record the deviation in the ACCORD QA records, and devise corrective and/or preventative action where necessary.

5.6 Archiving

5.6.1 Superseded and obsolete SOPs and associated documents, and electronic copies, will be archived indefinitely by the QA Manager or designee, on the ACCORD SharePoint site.

6 References and related documents

- UK policy framework for health and social care research
- ICH-GCP E6 (R2) guidelines
- QA001-T01 – SOP template
- QA001-T02 – Work Instruction template
- QA001-F01 – SOP/Document Training Form
- QA001-F02 – SOP/Document Circulation Form
- HR001-W01 - Required SOP, Policy and Guideline training
- CR010 - Management of Protocol and GCP Deviations and Violations

7 Document history

Version Number	Effective Date	Reason for Change
v1.0	23 DEC 2010	Minor administrative corrections
v1.1	23 DEC 2010	Revision and integration of deviation procedures
v2.0	22 MAR 2011	Change of SOP title and SOP number. Update of author selection, SOP preparation and review and release of SOP. Update of SOP deviation management.
V3.0	16 NOV 2015	New SOP template. Addition of section on archiving. Formatting and minor text changes throughout document. Reference to a new SOP/Document Circulation Form (QA001-F02) added to section 5.3 and title of QA001-F01 changed (see section 5.3.4).

V4.0	16 OCT 2017	Change of author. Document history added for QA001 v2.0, effective 22-Mar-11. Minor administrative changes throughout.
V5.0	29 JAN 2018	Reference to the UK policy framework for health and social care research, replacing the Research Governance Framework for Health and Community Care (Scotland 2006 2nd ed).
V6.0	15 OCT 2019	Section 5.3.3 added detailing process for the assessment of SOP training requirements. Detail added to section 5.3.5 regarding the continued use of obsolete or updated SOPs. Further details added to section 5.3.9 in relation to process for uploading SOP to ACCORD website.
V7.0	10 MAR 2022	SOP updated to reflect a change in how records are signed/stored following COVID-19. Electronic SOP and signature is now permissible in ACCORD.
V8.0	30 AUG 2023	QA Administrator responsibilities added throughout. Clarification added to section 5.3.2 regarding use of document history table (section 7). Section 5.3.6 added outlining escalation process for SOPs past their review date.
V9.0	10 SEP 2024	SOP and associated documents QA001-T01, QA001-T02, QA001-F01, QA001-F02 updated to align with new ACCORD branding.

8 Approvals

Sign	Date
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Gavin Robertson (Aug 26, 2024 15:33 GMT+1)	Aug 26, 2024

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