Policy and Guideline Preparation and Control

DOCUMENT NO.:	**QA007 v7.0**
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1 Introduction

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

1.2 ACCORD policies and guideline documents are designed to provide a set of rules and principles in compliance with relevant ACCORD procedures 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 policies and guidelines.

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 policy and guideline 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 policy or guideline, or review a new or existing document,
- Reviewing and approving policies and guidelines,
- Determining training requirements for new/updated documents.

4.3 The author is responsible for consulting the relevant staff, regulations, and Standard Operating Procedures (SOPs) prior to writing/reviewing the policy or guideline, 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 policy and guideline documents appropriate to their line of work, as advised by QA,
- Informing ACCORD QA of any requirements for new policies/guidelines or necessary changes to existing documents.

5 Procedure

5.1 Preparing a Draft Policy or Guideline

5.1.1 The author will use the template QA007-T01 (Policy and Guideline Template) to write the draft document.

5.1.2 The author will describe the rule and/or guidance in a concise manner with sufficient detail and description.

5.1.3 If any forms or template documents are required to supplement the Policy or Guideline, the author will prepare draft forms and templates.

5.2 Reviewing a Draft Policy or Guideline

5.2.1 Once the draft document is complete, the author will forward it 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 a Policy or Guideline

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

5.3.2 Policy numbers will consist of 6 characters. The first 3 characters will be POL. The final 3 characters will represent the number of the policy i.e. 001.

5.3.3 Guideline numbers will consist of 5 characters. The first 2 will be GL. The final 3 will represent the number of the guideline i.e. 001.

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 document before they become effective. If the Policy

or Guideline 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, the version number of the document will be recorded in the Document History table (e.g. QA007-T01).

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

5.3.7 If specific training is required, this shall be facilitated by the 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 policy or guideline has been issued and advise of the effective date, instructions regarding the location of the document 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 document scope section (QA007-T01 section 2) and may be, but not limited to ACCORD staff, Trial Managers, ACCORD e-mail distribution list. Details of training sessions 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 document is a revision, a short explanation of the revision may be given by the QA Administrator, or designee.

5.3.10 When all that is required is for applicable parties to read a new/revised policy or guideline, 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 policies and guidelines (including signed copies) 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 policies and guidelines documents are available to ACCORD personnel on the ACCORD SharePoint and to research teams at www.accord.scot. The QA Administrator, or designee, will set a calendar

reminder to upload the documents to the ACCORD SharePoint/website on the effective date and update the Policy and Guideline Index List in the QA Admin folder on the ACCORD SharePoint to confirm the date of upload to the website.

5.4 Reviewing an Existing Policy or Guideline

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

5.4.2 The review shall be recorded in the Document History. If no change is required, the 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 changes are required, 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 will proceed in line with sections 5.2 and 5.3 of this SOP. The review will be recorded in the Document History table (QA007-T01), including a review which results in no changes to the policy or guideline. The version number will increase by 1 whole number.

5.4.6 If the author has failed to review the policy or guideline 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 policy or guideline has not been reviewed within agreed timelines.

5.5 Archiving

5.5.1 Superseded and obsolete policies and guideline documents, hard copies 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
- QA007-T01 – Policy and Guideline 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	16 NOV 2015	New SOP.
V2.0	16 OCT 2017	Minor administrative changes
V3.0	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).
V4.0	15 OCT 2019	Section 5.3.3 added detailing process for the assessment of policy or guideline training requirements. Further details added to section 5.3.9 in relation to process for uploading SOP to ACCORD website.
V5.0	10 March 2022	SOP updated to reflect a change in how records are signed/stored following COVID-19. Electronic policy, guidelines and signature is now permissible in ACCORD.
V6.0	26 APR 2024	QA Administrator responsibilities added throughout. Clarification added to section 5.4.2 regarding use of document history table. Section 5.4.6 added outlining escalation process for policies or guidelines past their review date.
V7.0	10 SEP 2024	SOP and QA007-T01 updated to align with new ACCORD branding.

8 Approvals

Sign	Date
 AUTHOR: Lorn Mackenzie, QA Manager, NHSL, ACCORD	Aug 26, 2024

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Gavin Robertson (Aug 26, 2024 15:34 GMT+1) AUTHORISED: Gavin Robertson, QA Coordinator, NHSL, ACCORD	Aug 26, 2024

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