

DOCUMENT VERSION CONTROL

DOCUMENT NO.:	QA008 v3.0
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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 Document version control is the management of revisions to a document, and enables users to track document changes, and differentiate between versions of a document.

2 PURPOSE

- 2.1 The purpose of this SOP is to detail how documents used in the conduct of clinical research, sponsored by NHSL and/or UoE, are managed and version controlled.

3 SCOPE

- 3.1 This SOP will apply to all ACCORD personnel involved in document control and clinical research, and to clinical researchers designing and participating in studies sponsored by NHSL and/or UoE.

4 RESPONSIBILITIES

- 4.1 It is the responsibility of the individual creating or altering the document to ensure that they do so in accordance with this SOP, that the new/updated document is reviewed/approved by the appropriate person(s) and circulated/available to the staff who will use it.
- 4.2 It is the responsibility of staff, printing and using documents, to ensure they are using the appropriate 'active' version.

5 PROCEDURE

5.1 Creating or Updating a Document

- 5.1.1 When creating or updating an electronic document, apply a name and version number e.g. Study Name_Protocol DRAFT v1.0.

- 5.1.2 The document name/version should be used when saving the electronic document, and should be detailed in the document header or footer. GL007 (Electronic Filing: Naming Convention & Quality Control) provides a common set of rules to apply to the naming of electronic documents.
- 5.1.3 Draft documents should be indicated as such e.g. Study Name_Protocol DRAFT v1.0.
- 5.1.4 A new document will always begin as v1.0, and will remain v1.0 throughout the review process, and once approved as final.
- 5.1.5 Multiple versions of a draft document can be tracked by the use of a date to differentiate it from the previous version of the draft document during the review process e.g. Study Name_Protocol DRAFT v1.0_01Jan2015, once revised but not finalised, may become Study Name_Protocol DRAFT v1.0_31Jan2015.
- 5.1.6 When a new document is finalised, the document, 'DRAFT' should be removed from the filename e.g. Study Name_Protocol_DRAFT v1.0 becomes Study Name_Protocol_v1.0.
- 5.1.7 When making changes to a finalised document e.g. changes to Study Name_Protocol_v1.0, the version number should increase by one whole number with each new revision, and 'DRAFT' indicated where appropriate during the review process of the new revision e.g. Study Name_Protocol DRAFT v2.0.
- 5.1.8 Any minor or major revision to a document will result in the use of the next consecutive whole number e.g. v2.0, v3.0, v4.0 etc.
- 5.1.9 When the revised document has been finalised, 'DRAFT' should be removed from the filename e.g. Study Name_Protocol DRAFT v2.0 becomes Study Name_Protocol v2.0.
- 5.1.10 New/updated documents, once finalised and effective, should be filed in the appropriate electronic folder and paper file if applicable.
- 5.1.11 Superseded documents should be clearly identified as superseded, removed from circulation and archived electronically, so they are not available for general use once the new/update document is effective.

5.2 Tracking Changes to Documents

- 5.2.1 A history of changes to documents should be maintained. This can be done in different ways, and examples of how to do this are provided below;
- Include a version control/history table in the document, or save the table separately. Update the table each time a change is made to the document,

documenting the new version number, what was changed, who made the change and when the change was made.

- Save a 'track changes' version of the document on file, showing all the changes that have been made to the document since the previous version.




6 REFERENCES AND RELATED DOCUMENTS

- GL007 Electronic Filing: Naming Convention & Quality Control

DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	08 MAR 2016	New SOP.
2.0	29 JAN 2018	Minor administrative updates. Change of authorship.
3.0	13 MAR 2024	Addition of GL007 reference at section 5.1.2.

APPROVALS

Sign	Date
 AUTHOR: Lorn Mackenzie, QA Manager, NHS Lothian, ACCORD	Feb 26, 2024
 <small>Heather Charles (Feb 26, 2024 14:49 GMT)</small> APPROVED: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD	Feb 26, 2024
 AUTHORISED: Lorn Mackenzie, QA Manager, NHS Lothian, ACCORD	Feb 26, 2024










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Final Audit Report

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