AUDIT PREPARATION, CONDUCT AND REPORTING

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AUTHOR:	[redacted]
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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 ICH-GCP E6(R2) Guidelines define audit as: “A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, Sponsor’s Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirement(s)”.

2 PURPOSE

2.1 To document the procedure for the conduct of audits by ACCORD Quality Assurance (QA) personnel, or conducted on behalf of ACCORD.

3 SCOPE

3.1 This SOP applies to ACCORD QA personnel and any other appropriately trained individuals that may conduct internal system, facility or study management audits on behalf of ACCORD.

4 RESPONSIBILITIES

4.1 The QA Manager and QA Coordinator are responsible for assigning auditors to audits, for reviewing draft audit reports, for issuing audit certificates and circulating final audit reports as necessary.

4.2 The auditor is responsible for initiating, conducting and reporting the audit.

4.3 The QA Manager, or designee, auditor and Deputy Director are responsible for reviewing and approving final audit reports.

4.4 The Auditee is responsible for ensuring corrective and preventative actions (CAPAs) identified during the audit process are completed within agreed specified timelines.

5 PROCEDURE

5.1 Audit Preparation

5.1.1 Audit of ACCORD internal systems, facility audits and study management audits will be performed in accordance with annual audit schedules, determined according to QA003 (Risk Analysis Used to Develop Annual Audit Schedules), GS002 (Combined Risk Assessment) or "for cause" e.g. in response to a concern or complaint.

5.1.2 The objectives and scope of an audit, and auditee, will depend on the nature of the audit (see below);

	INTERNAL SYSTEMS	STUDY SPECIFIC	FACILITY
OBJECTIVE	To examine system related activities and documents to determine whether the system is functioning in accordance with the ACCORD SOPs, regulatory requirements and GCP.	To examine study related activities and documents in order to determine whether the study is being conducted and reported in accordance with the study protocol, ACCORD SOPs, regulatory requirements and GCP.	To establish whether study related activities are conducted, and relevant documentation is in place in accordance with the study protocol, ACCORD/Sponsor SOPs, regulatory requirements and GCP.
SCOPE	All activities and records related to the system in question during a specified time period.	All activities and records related to the conduct of the particular study in question, or a specified study system, during a specified time period.	All activities and records related to the conduct of the particular study or studies in question.
AUDITEE	The most senior member of staff directly implicated in the system.	The Principal Investigator, designated trial manager or a Responsible Scientist.	The manager of the facility or equivalent.

5.1.3 The auditor will provide formal notification to the auditee, or nominated designee, using template QA002-T01 (Audit Notification).

5.1.4 The Audit Notification will be issued at least 20 working days before the intended audit date or following agreement of an audit date.

5.1.5 When audit dates have been confirmed with the auditee, the auditor will create an audit plan, including agenda, using template QA002-T02 (Audit Plan).

5.2 Audit Conduct

5.2.1 An opening meeting will be conducted (open to all individuals that the auditee deems appropriate) to reiterate the plan for the audit and to answer any questions that the auditee may have regarding the conduct and reporting of the audit.

5.2.2 Reviews of documents, records, data, tour of facilities and staff interviews will be conducted where appropriate.

5.2.3 Depending on the nature of the audit, the following may also be reviewed/conducted;

- Informed consent process and records
- Investigator Site File (ISF)
- Drug accountability (storage and dispensing)
- Source data verification e.g. inclusion/exclusion criteria, SAEs and primary and secondary end points
- Project specific plans/work instructions
- Equipment maintenance and calibration
- Sample storage
- Data storage and archiving
- Staff training records, job descriptions and CVs

5.2.4 The auditor will employ sampling of data when 100% verification is not required or possible.

5.2.5 The auditor will take notes and use audit tools template QA002-T03 (Audit Checklist/Prompt) and template QA002-T04 (Audit Interview Script) as necessary.

5.2.6 The auditor will ensure that all observations are supported by tangible evidence.

5.2.7 A closing meeting will be conducted (open to all individuals that the auditee deems appropriate), where the auditor will briefly discuss the most significant audit observations.

5.3 Audit Reporting

5.3.1 The auditor (if not the QA Manager) will inform the QA Manager of any critical findings as soon as reasonably practical.

5.3.2 A draft audit report will be created by the auditor, using template QA002-T05 (Audit Report) and sent to the QA Manager or QA Coordinator (if the auditor is the QA Manager), for review.

5.3.3 The reviewed draft audit report will be issued to the auditee within 15 working days of the closing meeting.

5.3.4 The auditor will advise the auditee that they should return responses and corrective/preventive actions to each observation within 15 working days, unless another timeframe is agreed between the QA Manager and the auditee.

5.3.5 If the auditee does not provide responses within the agreed time frame, the QA Manager will inform the ACCORD Deputy Director and agree a method to resolve the situation.

5.3.6 A final report will be generated by the auditor within 5 working days of receiving the auditees final responses and corrective/preventive action.

5.3.7 The final report will be circulated to the QA Manager, auditor and the Deputy Director for review and signature.

5.3.8 The report will be signed by all signatories within 10 working days of the final report being generated.

5.3.9 The Deputy Director will ensure that the ACCORD Director is made aware of any critical findings and any other findings that are deemed to warrant the attention of the Director.

5.3.10 The report will be provided to any other parties deemed necessary by the QA Manager e.g. Senior Clinical Trials Monitor, Heads of Research Governance (NHSL and UoE).

5.3.11 The QA Manager, or QA Coordinator, will follow-up the status of any corrective/preventative actions with the auditee to ensure they are initiated or completed by the agreed date. A monthly report will be sent to the Heads of Research Governance (NHSL and UoE) and to the Deputy R&D Director, flagging audits actions that are overdue. These will be escalated if considered appropriate.

5.3.12 An Audit Certificate (QA002-T06) will be issued to the auditee when it has been demonstrated that all corrective/preventive actions have been initiated or completed, as deemed necessary.

5.3.13 Once the audit certificate has been issued, the audit will be considered closed.

5.3.14 The QA Manager or QA Coordinator will ensure that all audit documents, correspondence and tools are retained and filed in the ACCORD QA files when the audit has been closed and the audit certificate issued.

6 REFERENCES AND RELATED DOCUMENTS

- ICH-GCP E6(R2) Guidelines
- QA002-T01 Audit Notification
- QA002-T02 Audit Plan
- QA002-T03 Audit Checklist/Prompt
- QA002-T04 Audit Interview Script
- QA002-T05 Audit Report
- QA002-T06 Audit Certificate
- QA003 Risk Analysis Used to Develop Annual Audit Schedules
- GS002 Combined Risk Assessment

7 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	23 DEC 2010	n/a new procedure
1.1	22 MAR 2011	Changes to format and minor clarifications
1.2	27 FEB 2012	Investigator site audits will now be known as study specific audits
1.3	07 MAY 2013	Clarification of report distribution and follow-up
2.0	04 APR 2016	New SOP template. The introduction and purpose sections have been simplified. Audit specific objectives/scope/auditee has been added to the section 5.1. Examples of which documents may be audited have been added (sections 5.2.3 and 5.2.4). References to obsolete working instructions have been removed. Formatting and wording changed throughout document. Title of QA Officer has been amended to QA Coordinator throughout.
3.0	19 SEPT 2016	New SOP template. Addition of section 5.3.11 to capture procedure for when CAPA is not initiated by the agreed date.
4.0	05 OCT 2018	Change of author. Minor administrative changes. Update to the ICH-GCP E6(R2) Guidelines.

8 APPROVALS

Sign	Date
SIGNATURE KEPT ON FILE AUTHOR: [redacted] QA Manager, NHSL, ACCORD	
SIGNATURE KEPT ON FILE APPROVED: [redacted] Head of Research Governance, NHSL, ACCORD	
SIGNATURE KEPT ON FILE AUTHORISED: [redacted] ,QA Coordinator, NHSL, ACCORD	