Clinical Trials Monitor and Auditor Competency

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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 state;

"*Monitors should be appropriately trained and should have the scientific knowledge needed to monitor the trial adequately*".

"*The sponsor should ensure that the auditors are qualified by training and experience to conduct audits properly. An auditor's qualifications should be documented.*"

2 Purpose

2.1 To outline the procedures for preparing/training an ACCORD Clinical Trial Monitor or Quality Assurance (QA) Coordinator to undertake monitoring or auditing activities, respectively, and the procedure for employing external monitors/auditors.

3 Scope

3.1 This SOP is applicable to ACCORD Clinical Trial Monitors and any other monitors identified by the Senior Clinical Trials Monitor, and the ACCORD QA Coordinators, and any other auditors identified by the QA Manager.

4 Responsibilities

4.1 The Senior Clinical Trial Monitor is responsible for training and assessing competency of ACCORD Clinical Trials Monitors, and for ensuring that external monitors, used by ACCORD, are suitably trained and familiar with ACCORD monitoring procedures.

4.2 The QA Manager is responsible for training and assessing competency of ACCORD QA Coordinators, and for ensuring that external auditors, used by ACCORD, are suitably trained and familiar with ACCORD auditing procedures.

4.3 Clinical Trial Monitors and QA Coordinators are responsible for maintaining their training record.

5 Procedure

5.1 Comprehension

5.1.1 New and/or untrained Clinical Trial Monitors and QA Coordinators will be instructed, by their Line Manager (or designee), to review with The Medicines for Human Use (Clinical Trials) Act (SI 2004/1031), as amended, ICH GCP E6 (R2) Guidelines, and any other directive/statutory instruments as deemed necessary.

5.1.2 The Senior Clinical Trials Monitor, or designee, will instruct a new/untrained Clinical Trial Monitor to read, and become familiar with study protocols from studies where they are the assigned monitor.

5.2 SOP Reading/Training

5.2.1 New and/or untrained Clinical Trials Monitors and QA Coordinators will be instructed, by their Line Manager, or designee, to read SOPs appropriate to their role (HR001 Establishing and Maintaining a Training Record). This will be documented in QA001-F02 (SOP/Document Circulation).

5.2.2 Training on SOPs may be provided as necessary by the Line Manager or QA Manager and documented in QA001-F01 (SOP/Document Training Form).

5.2.3 For Clinical Trial Monitors, these tasks will be completed before the Clinical Trial Monitor undertakes any substantial, unaccompanied tasks in relation to a specific study.

5.2.4 For QA Coordinators, these tasks will be completed before they perform an audit unaccompanied.

5.3 Competency

5.3.1 The appropriate Line Manager, or designee, will assess the competency of a new and/or untrained Clinical Trial Monitor or QA Coordinator in relation to stated competencies in HR003-F01 (Clinical Trials Monitor Competency Record) or HR003-F02 (Auditor Competency Record), respectively.

5.3.2 This may be achieved through directed training or observing the Clinical Trial Monitor/QA Coordinator perform the task correctly.

5.3.3 When competency has been achieved, this will be recorded in HR003-F01 or HR003-F02, respectively. Forms will be retained in individuals' training records.

5.3.4 The Clinical Trial Monitor/QA Coordinator cannot perform a monitoring task/audit unaccompanied until competency has been achieved and documented.

5.3.5 Competencies will be achieved within 12 weeks of appointment or as soon as practically possible.

5.4 Contract Monitors and Auditors

5.4.1 Where the need for a contract monitor or auditor is identified, this will be documented in the study combined risk assessment (GS002).

5.4.2 The Senior Clinical Trials Monitor and/or QA Manager employing the use of external contract monitors or auditors, respectively, will ensure that they are familiar with relevant ACCORD procedures and document this using QA001-F02 (SOP/Document Circulation).

5.4.3 If specific monitoring or auditing training is required, this will be documented in QA001-F01 (SOP Document Training).

5.4.4 A training file containing the monitors/auditors signed/dated CV (including evidence of relevant experience), GCP certificate and completed forms QA001-F01 and/or QA001-F02) will be retained by the QA Manager or QA Coordinator. Where a contract is required to document responsibilities, a fully signed copy will be filed alongside their training file.

5.4.5 Where a contracting company has been selected for monitoring or auditing for example a Contract Research Organisation (CRO), the QA Manager will approve the vendor for use following QA009 (Vendor Assessment).

5.4.6 The Senior Clinical Trials Monitor or QA Manager will ensure that external monitors/auditors are kept up to date with changes in ACCORD procedures and that comprehension is documented in QA001-F02 (SOP/Document Circulation).

6 References and Related Documents

- The Medicines for Human Use (Clinical Trials) Act (SI 2004/1031), as amended
- ICH GCP E6 (R2) Guidelines
- HR003-F01 Clinical Trial Monitor Competency Record
- HR003-F02 Auditor Competency Record
- QA001-F01 SOP/Document Training
- QA001-F02 SOP/Document Circulation
- QA009 Vendor Assessment

7 Document History

Version Number	Effective Date	Reason for Change
1.0	21 MAY 2012	New procedure.
2.0	22 MAY 2014	Addition of auditing competency.
3.0	01 APR 2016	New SOP template and new SOP title. Minor changes to text throughout SOP. Addition of section 5.4 on the use of contract monitors/auditors. Reference to QA001-F01/QA001-F02 added to document reading/comprehension of procedures.
4.0	17 APR 2018	Change of author. Minor administrative changes.

5.0	15 MAY 2020	Sections 5.4.4 and 5.4.5 updated to confirm QA personnel will hold the training file of contract Monitors/Auditors, and the use of a CRO will be subject to SOP QA009 Vendor Assessment.
6.0	04 FEB 2025	Minor updates made to HR003-F01. SOP, HR003-F01 (now v4.0) and HR003-F02 (now v3.0) also transferred to new ACCORD templates

8 Approvals

Sign	Date
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Elizabeth Craig Elizabeth Craig (Jan 17, 2025 15:36 GMT) APPROVED: Elizabeth Craig, Senior Clinical Trials Monitor, NHS Lothian, ACCORD	Jan 17, 2025
Gavin Robertson (Jan 17, 2025 13:42 GMT) AUTHORISED: Gavin Robertson, QA Coordinator, NHS Lothian, ACCORD	Jan 17, 2025

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