

Induction, Training and Competency Assessment

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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 All new ACCORD staff will undergo an induction and training programme. This will be tailored to suit the job description by their Line Manager.

2 Purpose

- 2.1 To document the procedure for induction and continuity of training requirements for ACCORD staff.

3 Scope

- 3.1 This procedure applies to all ACCORD staff.
- 3.2 This ACCORD procedure is in addition to any induction/training requirements detailed in NHSL or UoE policies, and out with the scope of this SOP.

4 Responsibilities

- 4.1 It is the responsibility of the Line Manager to;
- Ensure that new staff are appropriately inducted.
 - Ensure that training requirements are fulfilled wherever possible, and any further needs are identified and addressed as an ongoing process.
 - Assess competency in task specific training.
 - Conduct a handover meeting if a staff member is scheduled to cease their employment/role.

4.2 It is the responsibility of the individual to maintain their own training record.

5 Procedure

5.1 On Commencing Employment

5.1.1 The Line Manager will ensure their new members of staff are aware of the appropriate procedures for, although not exclusively, applying for leave, reporting absence, any applicable dress code, hours or working and probation/annual review procedures. This will include and take into consideration the policies and procedures of the employing organisation.

5.1.2 The Line Manager will fully appraise the new staff member of the nature of their responsibilities and tasks in line with their job description and the structure of the department.

5.1.3 The Line Manager will ensure that the new staff member is introduced to all relevant staff including a member of the ACCORD Quality Assurance (QA) group.

5.1.4 The Line Manager or QA Manager, or designee, will discuss the relevant ACCORD SOPs and policies, and explain requirements regarding the creation and maintenance of a training record as detailed in HR001 (Establishing and Maintaining a Training Record).

5.2 Within 4-12 Weeks and 6 Months of Employment

5.2.1 Within one month of commencing employment, new members of ACCORD staff will be asked to prepare their training record in accordance with SOP HR001 (Establishing and Maintaining a Training Record).

5.2.2 Within 4-12 weeks of commencing employment (or as soon as reasonably practical), the Line Manager, together with the new member of staff, will identify specific training needs in relation to the individuals' role and responsibilities e.g. internal/external training or on-job training.

- 5.2.3 The ACCORD Competency Record template (HR002-T01) will be used to document on-job training and assess competency once trained.
- 5.2.4 The Line Manager will edit the ACCORD Competency Record template (HR002-T01) to remove tasks that are not relevant to the individuals job description and/or add task as appropriate.
- 5.2.5 The Line Manager will assess progress in competency as a minimum at 12 weeks of employment and again at approximately 6 months of employment (if deemed necessary).
- 5.2.6 The completed ACCORD Competency Record template (HR002-T01) will be retained in individuals' training records.
- 5.2.7 The appropriate Line Manager, or designee, will assess the competency of new Monitoring and QA ACCORD staff as per HR003 (Clinical Trials Monitor and Auditor Competency).

5.3 Additional Training Requirements and Continuity

- 5.3.1 Overall assessment of competency by individuals performing within specific areas of ACCORD will be assessed routinely as part of the ACCORD Internal Systems Audit Schedule (QA002 Audit Preparation, Conduct and Reporting), and an appropriate Corrective/Preventative action documented where required.
- 5.3.2 Any further training requirements may be identified by the member of staff, the Line Manager or the QA Manager. These requirements will be discussed with the Line Manager and a decision made on how to address the training identified.
- 5.3.3 Individuals and their Line Manager will agree a Personal Development Plan at annual review, and this will be documented in accordance with the organisations procedures/policies.

5.4 Staff Exit

- 5.4.1 If a staff member is scheduled to cease their employment/role within the ACCORD office (NHSL or UoE personnel), the Line Manager, or designee, will conduct a handover meeting with the departing member of staff, to maintain continuity and prevent a loss of functional knowledge in the department/activities affected. This

handover meeting shall be documented e.g. in meeting minutes or via email and will be retained by the Line Manager.

5.4.2 If a member of the Monitoring team is scheduled to cease their employment/role in the ACCORD office, or hand over a study or study site, Study Handover Form (HR002-F01) will be used to document the handover process to the newly assigned Clinical Trials Monitor(s).

5.4.3 In conjunction with the staff member, the Line Manager or designee, will complete the Staff Exit Checklist (HR002-T02), ensuring access to premises and data systems is revoked and retrieval of equipment or other items.

5.4.4 The Line Manager will file the completed Staff Exit Checklist (HR002-T02) in the appropriate ACCORD personnel file.

5.5 Planned Period of Absence

5.5.1 If a staff member is schedule to have a temporary and planned period of absence (e.g. maternity leave), a handover meeting should be conducted and documented between the staff member and line manager.

6 References and Related Documents

- HR002-T01 ACCORD Competency Record
- HR002-T02 Staff Exit Checklist
- HR002-F01 Study Handover Form
- HR001 Establishing and Maintaining a Training Record
- HR003 Clinical Monitoring and Auditing Competency
- QA002 Audit Preparation, Conduct and Reporting

7 Document History

Version Number	Effective Date	Reason for Change
1.0	12 AUG 2011	New SOP.
2.0	16 MAR 2017	New SOP template and SOP title change. Introduction of a new ACCORD Competency Record form (HR002-F01), together with timelines for completion (section 5.2). Reference to SOP HR003 added to section 5.2.4. Additional training added to

		Continuity section, including re-assessment of competencies (section 5.3.1).
3.0	19 DEC 2018	ACCORD Competency Record changed from a form (HR002-F01) to a template (HR002-T01). Information provided regarding use of template and requirement for Line Managers to assess competency at specified timepoints (sections 5.2.4 & 5.2.5). Addition of requirement for Personal Development Plans to be agreed between individuals and staff members at annual appraisal (section 5.3.3)
4.0	16 OCT 2019	Section 5.4 added detailing procedure for Line Manager when a staff member ceases employment within ACCORD. HR002-T02 staff exit checklist added to SOP.
5.0	30 NOV 2023	Section 5.2.4 updated to include addition of tasks to the HR002-T01, where appropriate. Minor changes to HR002-T01 (e.g. change to website links and SOP titles) and HR002-T02 (i.e. requirement to contact building secretary to revoke building access).
6.0	28 APR 2026	Updated to align with new Clinical Trial Regulations and ICH-GCP (R3). Minor changes to terminology throughout SOP. Reference added to Study Handover Form (HR002-F01) in section 5.4.2. Responsibilities added for Line Managers to document handover meeting for prolonged/planned absences.

8 Approvals

Sign	Date
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Final Audit Report

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