Required SOP, Policy and Guideline Training

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# Foreword

## 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).

## This work instruction applies to all ACCORD personnel.

## All staff within ACCORD require an understanding of relevant Standard Operating Procedures (SOPs), policies and guidelines that govern aspects of their roles and responsibilities. SOPs, policies and guidelines in which each role requires training are defined below. This includes reference to NHS Research Scotland (NRS) SOPs and guidance documents.

Instructions

## It is the responsibility of all staff to ensure that evidence of review/understanding or training in the required SOPs, policies and guidelines (including updates) for their role are included in each staff member’s Training Record.

Required SOP, Policy and Guideline Training

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| **JOB TITLE** | **REQUIRED DOCUMENT READING/TRAINING** |
| Administrative Assistant | AD003, AD004, AD005, AD007, HR001, HR002, GS001, GS003, GS005, GS006, GS007, GS008, GS009, GS011, GS014, GS015, CR014, CR018, GL007, POL006, POL009, NRS-SOP-001, NRS-SOP-008, NRS-SOP-019, NRS-SOP-22, NRS-GUI-001, NRS-GUI-002, NRS-GUI-003, NRS-GUI-009, NRS-GUI-010 |
| Champion Support Manager | AD003, AD005, AD007, QA001, QA007, QA008, HR001, HR002, GS001, GS007, GS009, GS015, CR014, CR018, GL007, POL001, POL002, POL003, POL006, POL009, NRS-SOP-021, NRS-SOP-22, NRS-SOP-026, NRS-SOP-027, NRS-GUI-003, NRS-GUI-008, NRS-GUI-020 |
| Clinical Research Facilitation Manager | AD007, QA001, QA007, QA008, QA009, HR001, HR002, PV001, PV002, PV003, PV004, PV005, GH001, GH002, GS001, GS002, GS003, GS005, GS008, GS010, GS011, GS012, GS013, CM001, FA001, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR014, CR015, CR016, CR017, CR018, GL003, GL007, GL009, all Policies, NRS-SOP-019 |
| Clinical Research Facilitator | AD007, QA001, QA007, QA008, QA009, HR001, HR002, PV001, PV002, PV003, PV004, PV005, GH001, GH002, GS001, GS002, GS003, GS005, GS008, GS010, GS011, GS012, GS013, CM001, FA001, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR014, CR015, CR016, CR017, CR018, GL003, GL007, GL009, all Policies, NRS-SOP-019 |
| Clinical Trials Monitor | AD001, AD007, QA001, QA004, QA007, QA008, QA009, HR001, HR002, HR003, PV001, FA001, GH001, GH002, GS001, GS002, GS003, GS005, GS008, GS009, GS010, GS011, GS013, CM001, CM002, CM003, CM004, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR013, CR014, CR015, CR016, CR018, GL007, all Policies |
| Communications Manager | AD007, QA001, QA007, QA008, HR001, HR002, GL007, POL001, POL002, POL003, POL006, POL009 |
| Contracts Manager | AD007, QA001, QA007, QA008, HR001, HR002, GS001, GS008, GS015, CR014, CR018, GL007, POL001, POL002, POL003, POL006, POL009, NRS-SOP-008, NRS-GUI-013 |
| Deputy R&D Director | AD007, QA001, QA007, HR001, HR002, GS001, GS002, GS003, GS005, GS008, GS009, GS011, GS012, GS015, CR003, CR005, CR006, CR012, CR014, CR018, GL004, GL005, GL007, all Policies, NRS-SOP-22, NRS-SOP-027 |
| Global Health Clinical Research Facilitator | AD007, QA001, QA007, QA008, QA009, HR001, HR002, PV001, PV002, PV003, PV004, PV005, GH001, GH002, GS001, GS002, GS003, GS005, GS008, GS010, GS011, GS013, CM001, FA001, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR014, CR015, CR016, CR017, CR018, GL003, GL007, GL009, all Policies, NRS-SOP-019 |
| Head of Research Governance (NHS Lothian) | AD001, AD007, QA001, QA007, QA008, QA009, HR001, HR002, GS001, GS002, GS003, GS005, GS006, GS007, GS008, GS009, GS010, GS011, GS012, GS013, GS014, GS015, CM001, CM002, CM003, CM004, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR014, CR015, CR016, CR017, CR018, GL003, GL004, GL005, GL007, All Policies, NRS-SOP-001, NRS-SOP-008, NRS-SOP-013, NRS-SOP-019, NRS-SOP-021, NRS-SOP-22, NRS-GUI-001, NRS-GUI-006, NRS-GUI-015, NRS-GUI-019, NRS-GUI-024 |
| Head of Research Governance (University of Edinburgh) | AD007, QA001, QA007, QA008, QA009, HR001, HR002, PV001, GH001, GH002, GS001, GS002, GS003, GS005, GS008, GS010, GS011, GS012, GS013, CM001, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR014, CR015, CR016, CR018, GL003, GL007, GL009, POL001, POL002, POL005, POL006, POL007, POL008, POL009, POL010, POL011, POL013 |
| NRS Generic Review Manager | AD007, QA001, QA007, QA008, QA009, HR001, HR002, GS001, GS002, GS003, GS005, GS006, GS007, GS008, GS009, GS010, GS011, GS012, GS013, GS014, GS015, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR014, CR015, CR016, CR017, CR018, GL003, GL006, GL007, POL001, POL002, POL003, POL005, POL006, POL007, POL008, POL009, POL010, POL011, NRS-SOP-001, NRS-SOP-004, NRS-SOP-008, NRS-SOP-013, NRS-SOP-019, NRS-SOP-021, NRS-SOP-22, NRS-GUI-001, NRS-GUI-003, NRS-GUI-006, NRS-GUI-13, NRS-GUI-015, NRS-GUI-019, NRS-GUI-022, NRS-GUI-024 |
| NRS Portfolio Performance Manager | AD003, AD005, AD007, QA001, QA007, QA008, HR001, HR002, GS001, GS007, GS009, GS015, CR014, CR018, GL007, POL001, POL002, POL003, POL006, POL009, NRS-SOP-22, NRS-SOP-026, NRS-SOP-027, NRS-GUI-003, NRS-GUI-008, NRS-GUI-020, NRS-GUI-023, NRS-GUI-025 |
| NRS Portfolio Administration Officer | AD003, AD005, AD007, QA001, QA007, QA008, HR001, HR002, GS001, GS007, GS009, GS015, CR014, CR018, GL007, POL001, POL002, POL003, POL006, POL009, NRS-SOP-021, NRS-SOP-22, NRS-SOP-026, NRS-GUI-003, NRS-GUI-008, NRS-GUI-020, NRS-GUI-023, NRS-GUI-025 |
| Principal R&D Manager | AD007, QA001, QA007, QA008, QA009, HR001, HR002, GS001, GS003, GS005, GS006, GS007, GS008, GS009, GS011, GS012, GS013, GS014, GS015, CR014, CR018, GL003, GL007, POL001, POL002, POL003, POL005, POL006, POL008, POL009, POL011, NRS-SOP-004, NRS-SOP-008, NRS-SOP-013, NRS-SOP-019, NRS-SOP-021, NRS-SOP-22, NRS-SOP-026, NRS-GUI-001, NRS-GUI-006, NRS-GUI-013, NRS-GUI-015, NRS-GUI-019, NRS-GUI-022, NRS-GUI-024 |
| Project Information Manager | AD003, AD005, AD007, QA001, QA007, QA008, GS001, GS007, GS009, GS015, HR001, HR002, CR014, CR018, GL007, POL001, POL002, POL003, POL006, POL009, NRS-SOP-021, NRS-SOP-22, NRS-SOP-026, NRS-GUI-003, NRS-GUI-008, NRS-GUI-020, NRS-GUI-023, NRS-GUI-025 |
| QA Administrator | AD007, QA001, QA002 QA003, QA004, QA006, QA007, QA008, QA009, HR001, HR002, GS001, GS002, GS003, GS005, GS008, GS015, CR001, CR003, CR009, CR010, CR014, CR018, CM001, CM002, CM003, CM004, GL007, POL001, POL002, POL003, POL005, POL006, POL007, POL009, POL011 |
| QA Manager | All SOPs, Policies and Guidelines (ACCORD only) |
| QA Coordinator | All SOPs, Policies and Guidelines (ACCORD only) |
| R&D Administration Manager | AD003, AD004, AD005, AD007, QA001, QA007, HR001, HR002, GS001, GS003, GS005, GS006, GS007, GS008, GS009, GS011, GS014, GS015, CR009, CR014, CR018, GL007, POL006, POL009, NRS-SOP-001, NRS-SOP-008, NRS-SOP-019, NRS-SOP-22, NRS-GUI-001, NRS-GUI-002, NRS-GUI-003, NRS-GUI-009, NRS-GUI-010 |
| R&D Amendments Officer | AD003, AD004, AD005, AD007, HR001, HR002, GS001, GS003, GS006, GS007, GS008, GS009, GS011, GS014, GS015, CR014, CR018, GL007, POL006, POL009, NRS-SOP-001, NRS-SOP-008,, NRS-SOP-019, NRS-SOP-22, NRS-GUI-001, NRS-GUI-002, NRS-GUI-003, NRS-GUI-009, NRS-GUI-010 |
| R&D Commercial Lead | AD007, QA001, QA007, QA008, HR001, HR002, GS001, GS005, GS006, GS007, GS008, GS009, GS012, GS015, CR003, CR014, CR017, CR018, GL006, GL007, POL001, POL003, POL006, POL009, POL010, POL011, NRS-SOP-001, NRS-SOP-004, NRS-SOP-008, NRS-SOP-013, NRS-SOP-019, NRS-SOP-021, NRS-GUI-001, NRS-GUI-003,, NRS-GUI-006, NRS-GUI-013, NRS-GUI-015, NRS-GUI-019, NRS-GUI-022, NRS-GUI-024 |
| R&D Coordinator | AD003, AD007, QA001, QA007, QA008, QA009, HR001, HR002, GS001, GS002, GS003, GS005, GS006, GS007, GS008, GS010, GS011, GS012, GS013, GS015, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR014, CR015, CR016, CR017, CR018, GL003, GL006, GL007, NRS-SOP-001, NRS-SOP-004, NRS-SOP-008, NRS-SOP-013, NRS-SOP-019, NRS-SOP-021, NRS-GUI-001, NRS-GUI-003, NRS-GUI-006, NRS-GUI-013, NRS-GUI-015, NRS-GUI-019, NRS-GUI-022, NRS-GUI-024, POL001, POL002, POL003, POL005, POL006, POL007, POL008, POL009, POL010, POL011 |
| Pharmacovigilance Manager | AD007, QA001, QA006, QA007, QA008, QA009, HR001, HR002, PV001, PV002, PV003, PV004, PV005, GH001, GH002, GS001, GS002, GS003, GS005, GS008, GS010, GS011, GS012, GS013, CM001, CM002, CM003, FA001, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR014, CR015, CR016, CR018, GL003, GL007, POL001, POL002, POL003, POL005, POL006, POL007, POL008, POL009, POL010, POL011 |
| Pharmacovigilance Officer | AD007, QA001, QA006, QA007, QA008, QA009, HR001, HR002, PV001, PV002, PV003, PV004, PV005, GH001, GH002, GS001, GS002, GS003, GS005, GS008, GS010, GS011, GS012, GS013, CM001, CM002, CM003, FA001, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR014, CR015, CR016, CR018, GL003, GL007, POL001, POL002, POL003, POL005, POL006, POL007, POL008, POL009, POL010, POL011 |
| R&D Information Governance Lead | AD007, QA001, QA007, HR001, HR002, GS008, GS015, GS014, CR014, CR018, GL007, POL001, POL002, POL003, POL006, POL009, POL010, POL012 |
| Research Governance Coordinator | AD007, QA001, QA007, QA008, QA009, HR001, HR002, PV001, PV002, PV003, PV004, PV005, GH001, GH002, GS001, GS002, GS003, GS005, GS008, GS010, GS011, GS012, GS013, GS014, CM001, FA001, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR014, CR015, CR016, CR017, CR018, GL003, GL007, GL009, all Policies, NRS-SOP-019 |
| Research Governance Administration Assistant | AD007, QA008, GH001, GH002, HR001, HR002, FA001, GS001, GS002, GS003, GS005, GS006, GS008, GS011, GS014, CR001, CR003, CR007, CR009, CR014, CR015, CR017, CR018, GL007, GL009, POL001,POL002, POL003, POL005, POL006, POL007, POL008, POL009, POL010, POL011, NRS-SOP-019 |
| Research Governance Assistant | AD007, QA001, QA007, QA008, QA009, HR001, HR002, PV001, GH001, GH002, GS001, GS002, GS003, GS005, GS008, GS011, GS012, GS013, CM001, CR001, CR003, CR004, CR006, CR007, CR008, CR009, CR010, CR011, CR014, CR015, GL003, GL007, GL009, all Policies, NRS-SOP-019 |
| Research Governance Officer | AD003, AD007, QA001, QA007, QA008, HR001, HR002, GS001, GS003, GS005, GS006, GS007, GS008, GS011, GS012, GS015, CR014, CR018, GL006, GL007, POL001, POL002, POL003, POL005, POL006, POL007, POL008, POL009, POL010, POL011, NRS-SOP-001, NRS-SOP-004, NRS-SOP-008, NRS-SOP-013, NRS-SOP-019, NRS-SOP-021, NRS-SOP-22, NRS-GUI-001, NRS-GUI-003, NRS-GUI-006, NRS-GUI-013, NRS-GUI-015, NRS-GUI-019, NRS-GUI-022, NRS-GUI-024 |
| Senior Clinical Trials Monitor | AD001, AD007, QA001, QA004, QA007, QA008, QA009, HR001, HR002, HR003, PV001, FA001, GH001, GH002, GS001, GS002, GS003, GS005, GS008, GS009, GS010, GS011, GS013, CM001, CM002, CM003, CM004, CR001, CR003, CR004, CR005, CR006, CR007, CR008, CR009, CR010, CR011, CR012, CR013, CR014, CR015, CR016, CR018, GL007, all Policies |

References

* HR001 Establishing and Maintaining a Training Record
* HR002 Induction, Training and Competency Assessment
* QA001 SOP Preparation and Control
* NRS-SOP-001 Management of Documents
* NRS-SOP-004 Procedure for Study Wide Review
* NRS-SOP-008 Procedure for use of SReDA within NHS Research Scotland and Development Offices
* NRS-SOP-013 Procedure for NHS R&D Management Permission for NHS Research Scotland (NRS) Projects – High Level
* NRS-SOP-019 **Management of Amendments for NRS PCC**
* NRS-SOP-021 Updating SReDA Recruitment Tab for Commercial Studies
* NRS-SOP-022 Updating SReDA Recruitment Tab for Non-Commercial Studies
* NRS-SOP-026 Centralised Feasibility Service
* NRS-SOP-027 Managed Recovery Process involving Networks and Specialty Groups and Health Boards
* NRS-GUI-001 Guidance for Measuring NRS Approval Times
* NRS-GUI-002 NRS Document Set by Study Type
* NRS-GUI-003 ReDA 3 Minimum Dataset
* NRS-GUI-006 Guidance for Research in Prisons
* NRS-GUI-008 Searching for Scottish-led pre-submission CPMS study records prior to record creation
* NRS-GUI-009 NRS Permission CC - Document Standard Naming Convention
* NRS-GUI-010 Permissions CC SReDA Minimum Dataset
* NRS-GUI-013 National Contract Value Review Escalation Process Guidance
* NRS-GUI-015 Guidance for the Initiation of PIC Sites
* NRS-GUI-019 NRS PCC – Interactive Costing Tool
* NRS-GUI-020 NRS ReDA – CPMS Recruitment User Guide
* NRS-GUI-022 CTIMP Combined Review – Study Wide Review Guideline
* NRS-GUI-023 NRS ReDA/CPMS Exemption Study Recruitment Import Guideline
* NRS-GUI-024 National Contract Value Review Guidance
* NRS-GUI-025 CPMS Record Creation for Commercial and Non-Commercial Studies