# ACCORD COMPETENCY RECORD

**Name: Start Date:**

**Job Title: Review Date: (12 weeks following start date)**

**Follow-up Review Due: (at approx. 6 months if necessary)**

**Induction**

All new employees will cover a formal Induction programme with an expectation that by Week 12 they have completed all mandatory training and are assessed as being competent to be assigned activities relevant to their role. Any areas requiring follow up for competency should be assessed at approx. 6 months. Ongoing competency assessment is captured by the ACCORD internal audit program and employee annual review processes.

*Competency rows not relevant to a role may be deleted.*

|  | **Competency** | **Reviewer**  **(Sign/Date)** | **Employee**  **(Sign/Date)** | **Documents to be Read or Evidence Used To Train** | **Courses** |
| --- | --- | --- | --- | --- | --- |
|  | Awareness/Understanding of relevant ACCORD SOPs, Policies and Guidelines |  |  | Check QA001-F02 is up to date ☐ |  |
| **Comments** | |  | | | |
|  | Principles of GCP |  |  | Last GCP training course date:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | GCP update required every 2 years  [www.clinical-research-facility.ed.ac.uk/courses-and-events](http://www.clinical-research-facility.ed.ac.uk/courses-and-events) |
| **Comments** | |  | | | |
|  | Principles of GMP |  |  | Last GMP training course date:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Departmental GMP training will be arranged periodically |
| **Comments** | |  | | | |
|  | Awareness/Understanding of the UK Policy Framework for Health and Social Care Research |  |  | Policy read ☐ | Consider any other courses relevant to areas of Research Governance  [www.clinical-research-facility.ed.ac.uk/courses-and-events](http://www.clinical-research-facility.ed.ac.uk/courses-and-events) |
| **Comments** | |  | | | |
|  | Awareness/Understanding of Regulations and Legislation (Medicines for Human Use, AWI, ARSAC, Data Protection) |  |  |  | Consider any other courses relevant to regulatory areas  [www.clinical-research-facility.ed.ac.uk/courses-and-events](http://www.clinical-research-facility.ed.ac.uk/courses-and-events) |
| **Comments** | |  | | | |
|  | Awareness/Understanding of the Human Tissue Act (HTA) |  |  |  | Departmental training will be arranged periodically.  [www.clinical-research-facility.ed.ac.uk/courses-and-events](http://www.clinical-research-facility.ed.ac.uk/courses-and-events)  Human Tissue Workshop. |
| **Comments** | |  | | | |
|  | Awareness of Research Passports in the NHS |  |  | SOP GS006 Research Passports: ☐ |  |
| **Comments** | |  | | | |
|  | Awareness of Caldicott Guardians in the NHS |  |  | SOP GS008 Patient Identifiable Information: Caldicott Guardian Approval & Information Governance Review: ☐ |  |
| **Comments** | |  | | | |
|  | Research Management and Governance Systems (IRAS, SReDA) |  |  | NRS-SOP-008 SReDA Use in R&D Offices: ☐ | Consider IRAS training course  V[www.clinical-research-facility.ed.ac.uk/courses-and-events](http://www.clinical-research-facility.ed.ac.uk/courses-and-events) |
| **Comments** | |  | | | |
|  | Funding Application Review |  |  | Shadow member of department |  |
| **Comments** | |  | | | |
|  | Costing a Research Project (NIHR Industry Costing Template, Service Support costs, Excess Treatment Costs) |  |  | Attributing the costs of health and social care research (AcoRD) Guidance: ☐ Shadow member of department (use of costing template) | NIHR online AcoRD training  AcoRD Specialist training |
| **Comments** | |  | | | |
|  | Sponsorship Review |  |  | GS003 Sponsorship Approval: ☐  Review performed competently ☐ | A review to be performed and checked. At discretion of trainer to decide if another check required. |
| **Comments** | |  | | | |
|  | Facilitating a Research Project (CTIMPs/CIMDs) |  |  | FA001 Facilitating a Regulated or Complex Research Project ☐  Review performed competently ☐ | A review to be performed and checked. At discretion of trainer to decide if another check required. |
| **Comments** | |  | | | |
|  | R&D Governance Review |  |  | GS001 R&D Governance Review of Non-Commercial Studies: ☐  GS015 R&D Governance Review of Commercial Studies  ☐  Review performed competently ☐  GS007 R&D Review of Amendments: ☐  Review performed competently ☐ | A review to be performed and checked. At discretion of trainer to decide if another check required. |
| **Comments** | |  | | | |
|  | Amendment Review (Sponsorship) |  |  | GS011 Preparation and Approval of Amendments: ☐ | A review to be performed and checked. At discretion of trainer to decide if another check required. |
| **Comments** | |  | | | |
|  | Contracts for Research (Table of Responsibilities) |  |  |  | Departmental training will be arranged periodically.  A review to be performed and checked. At discretion of trainer to decide if another check required. |
| **Comments** | |  | | | |
|  | Serious Breach Review & Reporting |  |  | CR003 Suspected Serious Breaches: ☐ |  |
| **Comments** | |  | | | |
|  | AE/SAE/SUSAR Review & Reporting |  |  | CR005/CR006 Identifying, Recording and Reporting AEs and USMs for CTIMPs/Non CTIMPs: ☐  PV001 Pharmacovigilance: Receipt, Onward Reporting & Follow-up of Safety Reports: ☐ | A report to be prepared and checked. At discretion of trainer to decide if another check required. |
| **Comments** | |  | | | |
|  | DSURs and APRs |  |  | CR008 Preparing and Submitting Progress and Safety Reports: ☐ | A report to be prepared and checked. At discretion of trainer to decide if another check required. |
| **Comments** | |  | | | |
|  | Review of IB/SPC/RSI updates |  |  | PV003 Pharmacovigilance Reference Safety Information & Drug Alerts: ☐ | RSI review to be performed and checked. At discretion of trainer to decide if another check required. |
| **Comments** | |  | | | |
|  | MedDRA Coding |  |  | PV004 Pharmacovigilance: MedDRA Coding SAEs for DSURs: ☐ | Coding with MedDRA course www.meddra.org/training/schedule |
| **Comments** | |  | | | |
|  | End of Study Reporting Requirements |  |  | CR011 Research Study Reports & Publication of Results: ☐ |  |
| **Comments** | |  | | | |
|  | Archiving requirements |  |  | GS005 Archiving Essential Study Documentation: ☐ |  |
| **Comments** | |  | | | |
|  | Electronic and Paper Filing of Trial Master Files (TMFs) |  |  | CR001 Establishing and Maintaining Investigator Site Files, Trial Master Files and Sponsor Files: ☐ |  |
| **Comments** | |  | | | |