# AUDITOR COMPETENCY RECORD

**Name of QA Coordinator: Start Date:**

## Overall Assessment of Competency to Perform an Audit Unaccompanied

|  |  |  |  |  |  |  |
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|  | **Auditing Competency** | **Competency**  **Confirmed (🗸)** | **Reviewer**  **(Sign/Date)** | **Auditor**  **(Sign/Date)** | **Study/Documents Used To Train or Training Provided** | **Comments** |
| 1 | Writing and review of SOPs, Policies and Guidelines |  |  |  |  |  |
| 2 | Understanding control of ACCORD documents and records |  |  |  |  |  |
| 3 | Plan and conduct Facility Audits |  |  |  |  |  |
| 4 | Plan and conduct Internal Audits |  |  |  |  |  |
| 5 | Plan and conduct Study Management Audits |  |  |  |  |  |
| 6 | Audit report preparation and review |  |  |  |  |  |
| 7 | Corrective and preventative action assessment and follow up |  |  |  |  |  |

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| 8 | Understand and contribute to risk analysis and development of ACCORD annual audit schedule |  |  |  |  |  |
| 9 | Review and assessment of vendor quality questionnaires |  |  |  |  |  |
| 10 | Understand and contribute to Combined Risk Assessments |  |  |  |  |  |
| 11 | Preparing a study specific audit plan |  |  |  |  |  |
| 12 | Understand requirements for approval of databases |  |  |  |  |  |
| 13 | Review and assessment of deviation logs |  |  |  |  |  |
| 14 | Review and assessment of violation reports |  |  |  |  |  |
| 15 | Understanding requirements for serious breach reporting |  |  |  |  |  |
| 16 | Review of TMF, ISF, Sponsor Files |  |  |  |  |  |
|  | **Auditing Competency** | **Competency**  **Confirmed (🗸)** | **Reviewer**  **(Sign/Date)** | **Auditor**  **(Sign/Date)** | **Study/Documents Used To Train or Training Provided** | **Comments** |
| 17 | Understanding and checking informed consent |  |  |  |  |  |
| 18 | Understanding and checking drug accountability and storage |  |  |  |  |  |
| 19 | Understanding requirements for AE, SAE and SUSAR reporting |  |  |  |  |  |
| 20 | Review monitoring plans, SDV plans and monitoring reports |  |  |  |  |  |
| 21 | QC of SAEs |  |  |  |  |  |
| 22 | Understanding clinical study report requirements |  |  |  |  |  |
| 23 | Understanding archiving requirements |  |  |  |  |  |
| 24 | Understanding of training requirements e.g. training records, GCP |  |  |  |  |  |
| 25 | Understanding of GMP requirements for CTIMPs |  |  |  |  |  |
|  | **Auditing Competency** | **Competency**  **Confirmed (🗸)** | **Reviewer**  **(Sign/Date)** | **Auditor**  **(Sign/Date)** | **Study/Documents Used To Train or Training Provided** | **Comments** |
| 26 | Understanding of guidance on analysis of clinical trial samples |  |  |  |  |  |
| 27 | Awareness of Phase I Accreditation Scheme |  |  |  |  |  |

In the reviewer’s opinion the post holder has demonstrated adequacy in the above competencies.

Reviewer Name: Auditor Name:

Title: Title:

Signature: Signature:

Date: Date: