# CLINICAL TRIALS MONITOR COMPETENCY RECORD

**Name of Clinical Trials Monitor: Start date:**

## Overall Assessment of Competency to Perform Monitoring Unaccompanied

|  | **Monitoring Competency** | **Date Competency Confirmed**  | **Reviewer****(Sign)** | **Monitor****(Sign)** | **Study Used To Train (*if more than 1, please list all)*** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| **File management and approvals** |
| 1 | Understand file review process and what is meant by GCP essential documentation as required for all study file types (TMF/SF/ISF) |  |  |  |  |  |
| 2 | Management of initial approvals and amendment (substantial and non-substantial) process |  |  |  |  |  |
| 3 | ISF management: managing the Delegation of Responsibilities log, site staff training, reconciliation of CVs and GCP certificates  |  |  |  |  |  |
| 4 | ISF management: training and management of Deviations / Violations / Serious Breaches at site |  |  |  |  |  |
| 5 | Archiving of study materials |  |  |  |  |  |
| **Site Initiation Visits (SIVs) and Sponsor’s Authorisation to Open (SATO)** |
| 1 | Understand SIV process, including completion of SIV report and follow up letter |  |  |  |  |  |
| 2 | Understand Regulatory Greenlight Checklist process, including checklist completion |  |  |  |  |  |
| 3 | Understand SATO process, including form completion |  |  |  |  |  |
| 4 | Review of delegated SIV reports and SATO forms |  |  |  |  |  |
| **Monitoring Visits** |
| 1 | Following Monitoring and Source Data Verification plans |  |  |  |  |  |
| 2 | Managing participant medical notes at sites in accordance with local NHS policy |  |  |  |  |  |
| 3 | Monitoring of the informed consent process (including AWI consent) |  |  |  |  |  |
| 4 | Verifying inclusion and exclusion criteria  |  |  |  |  |  |
| 5 | Monitoring of randomisation and enrolment procedures |  |  |  |  |  |
| 6 | Monitoring of dosing (including dose escalation) and IMP compliance |  |  |  |  |  |
| 7 | Monitoring pharmacy as a support department - including IMP storage, handling, accountability and dispensing |  |  |  |  |  |
| 8 | Monitoring of concomitant medications and prohibited medications  |  |  |  |  |  |
| 9 | Monitoring of safety events: SDV of AEs and SAEs |  |  |  |  |  |
| 10 | Lab sample checks: including sample accountability and storage  |  |  |  |  |  |
| 11 | Completion of monitoring visit reports and follow-up letters  |  |  |  |  |  |
| **Close Out Visits (COVs)** |
| 1 | Understand COV process, including completion of COV report, checklists and follow up letters |  |  |  |  |  |
| 2 | Review of delegated COV reports  |  |  |  |  |  |

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

Reviewer Name: Monitor Name:

Title: Title:

Signature: Signature:

Date: Date: