**DOM CTU Competency Assessment**

**Staff Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- | --- | --- | --- | --- |
| **Skill** | **Initial Training Date** | **Trainer** | **Test** | **Date(s) Passed Competency Test** | **Test Administrator** | |
| **Clinical Skills** | | | | | | |
| Vital signs, temp, height, weight |  |  | Obtain 3 vital signs from different subjects |  |  |
| Waist Measurement |  |  | X1 |  |  |
| Hip Circumference |  |  | X1 |  |  |
| Urine Dipstick Pregnancy Test |  |  | X1 |  |  |
| ECG setup and recording |  |  | Perform x3 at different times |  |  |
| 6MWT |  |  | Perform x2 at different times |  |  |
| **Blood Draw & Lab Skills** | | | | | | |
| Phlebotomy |  |  | Perform x3 from different subjects |  |  |
| Lab Processing |  |  | Centrifuges and aliquots 1 serum and 1 plasma tube |  |  |
| Shipping |  |  | Ships 2 biological sample shipments |  |  |
| **Regulatory Skills** | | | | | | |
| Regulatory Binder |  |  | Label and file regulatory documents |  |  |
| HSERA Submissions |  |  | Drafts a modification, deviation, exception, & continuing review |  |  |
| Documenting AEs |  |  | Document 3 different events accurately |  |  |
| Documenting Protocol Deviations |  |  | 2 times |  |  |
| How to address a reportable event |  |  | X3 |  |  |
| Create Note to File |  |  | X3 different times |  |  |
| **Study Operations Skills** | | | | | | |
| How to document study communications |  |  | X3 different times |  |  |
| How to complete source documents |  |  | Completes 3 source docs with no errors |  |  |
| How to document meeting minutes |  |  | Drafts meeting minutes for 2 meetings |  |  |
| How to document trainings |  |  | Save all training certificates to Central Repository |  |  |
| How to add new staff to a study |  |  | X1 |  |  |
| How to consent a subject |  |  | Mock consents for 2 different studies |  |  |
| How to complete study trackers |  |  | Complete tracker accurately |  |  |
| Other: \_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |  |
| Other: \_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |  |