**Monitoring Visit Checklist**

**Protocol:**

**Principal Investigator:**

**Date:**

|  |
| --- |
|  Action Items:  |

|  |  |  |
| --- | --- | --- |
| Notification of monitoring visit to the Principal Investigator, key study personnel, staff and support services i.e., investigational pharmacy, lab services, nutrition lab, etc. | [ ]  |  |
| Reserve a private room or area with internet access for the monitor to review the study documents. | [ ]  |  |
| Send Monitoring Visit calendar invitation to all study personnel, including any support services with the agenda and location for the visit | [ ]  |  |
| Schedule the Principal Investigator to meet with the monitor. | [ ]  |  |
| Request EMR access for Monitor, if applicable. | [ ]  |  |
| Verify that all subject’s medical records, source documents, case report forms or electronic data entry are complete and accurate.  | [ ]  |  |
| Verify that the study regulatory file is up to date and that all required regulatory documents are complete, accurate, submitted, up to date and filed. | [ ]  |  |
| Assign research team members to assist the monitor with copy and fax requests, clarification of inquiries and corrections, EMR access and travel to support service locations, as applicable. | [ ]  |  |
| Prior to study visit, hold pre-visit meeting with research team to confirm that everyone knows their roles and responsibilities | [ ]  |  |
| Subject’s medical records, source documents, case report forms and regulatory files made available for the monitoring visit. | [ ]  |  |
| At the conclusion of the visit, sign the monitoring log | [ ]  |  |
| Return all study documents, including medical records, to their secure locations.  | [ ]  |  |
| Ensure that a follow up letter or monitoring report is received from the monitor regarding any findings. | [ ]  |  |
| Review the monitoring report findings with the PI and key study personnel. | [ ]  |  |
| Develop any necessary process changes and document any corrective and preventative action (CAPA). | [ ]  |  |
| Complete and send the requested corrections or responses to the monitor (by the deadline date, if specified) and ensure that the PI has signed the letter.  | [ ]  |  |
| Place a copy of the monitoring and corrections letter in the Regulatory Binder. | [ ]  |  |

Signature of individual completing the form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_