**Close-Out Visit Checklist**

**Protocol:**

**Principal Investigator:**

**Date:**

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

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| --- | --- | --- |
| Notification of the close-out 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 a close-out 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.  | [ ]  |  |
| Contact your RFS of close-out visit so that they can assess all patient claims have been dropped and paid. | [ ]  |  |
| Verify that the study drug/device is either prepared for return to sponsor/CRO or disposed of at the site per the agreement with sponsor and verification that the IP and device accountability logs are complete. Copies of study IP and device packing slips and shipment receipts are filed as required.  | [ ]  |  |
| Verify that the study regulatory file is up to date and that all required regulatory documents are completed, accurate, submitted, up to date and filed including Note-to-Files clarifying any discrepancies or errors with study procedures and personnel. | [ ]  |  |
| 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. | [ ]  |  |
| 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 secured locations.  | [ ]  |  |
| Ensure that a final letter or monitoring report is received from the monitor regarding any findings and review the findings in the monitoring report with the PI and key study personnel. | [ ]  |  |
| Complete and send the requested corrections or responses to the monitor and ensure that the PI has signed the letter.  | [ ]  |  |
| Place a copy of the monitoring and corrections letter in the Regulatory Binder. | [ ]  |  |
| Verify and ensure that all CRFs have been submitted to the sponsor. | [ ]  |  |
| Ensure or obtain confirmation that all study-related costs and expenses have been charged to the study. | [ ]  |  |
| Store and secure all study records per institution, FDA and/or sponsor requirements. | [ ]  |  |
| Close the study with the IRB, when required. | [ ]  |  |

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

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