## Closeout Visit Report

## I. Site Information

|  |  |
| --- | --- |
| **Site Name:** |       |
| **NCI Protocol Number:** |       |
| **NCI Protocol Title:** |       |
| **Visit Date(s):** | **From:** Enter a date. **To:** Enter a date. |
| **Visit Modality:** | Choose an item. |
| **Visit Conducted By:** |       |

## II. Visit Participants

|  |  |
| --- | --- |
| **Name** | **Role** |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |

## III. Closeout Checklist

**Completion Instructions:** Mark each item as ***Yes***, verified and compliant; ***No***, unable to verify or noncompliant; ***Not Applicable***; or, ***Not Reviewed***. Provide comments for items marked ***No***, and as indicated.

| **ITEMS EVALUATED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. All regulatory documents, including local IRB/CIRB approvals, are current and on file.
 | Choose one. |       |
| 1. The local IRB/CIRB has been informed of study closure to accrual at the site according to institutional requirements. *If not complete, discuss the timeline for completion in the comments.*
 | Choose one. |       |
| 1. The site understands the local IRB/CIRB will need to be informed of final study closure once all study analyses and activities at all enrolling sites are complete.
 | Choose one. |       |
| 1. Signed and dated informed consent form(s) is on file for each participant.
 | Choose one. |       |
| 1. Enrollment log(s) and/or screening log(s) are current.
 | Choose one. |       |
| 1. Documentation is present in each participant’s record indicating that study participation has ended.
 | Choose one. |       |
| 1. There are no adverse events (AEs) or serious adverse events (SAEs) that require further follow-up for any participant.
 | Choose one. |        |
| 1. All case report forms (CRFs) for each participant have been completed. *If not complete, discuss the timeline for completion in the comments.*
 | Choose one. |       |
| 1. All data entry in the database of record is complete. *If not complete, discuss the timeline for completion in the comments.*
 | Choose one. |       |
| 1. All data queries have been resolved. *If not resolved, discuss the timeline for completion in the comments.*
 | Choose one. |       |
| 1. All unused investigational agent has been returned to the repository according to the protocol.
 | Choose one. |       |
| 1. All Drug Accountability Record Form(s) (DARFs) have been reconciled.
 | Choose one. |       |
| 1. There is no evidence to suggest the study blind was compromised. If unblinding occurred, there is sufficient documentation to explain the appropriateness of the unblinding.
 | Choose one. |       |
| 1. Research specimen log and/or research specimen management system is current.
 | Choose one. |       |
| 1. All study analyses involving research specimens are complete. *Discuss the disposition of any remaining research specimens, including plans for future shipments or period of time they will be stored in comments.*
 | Choose one. |       |
| 1. All action items from previous monitoring visits have been resolved.
 | Choose one. |       |
| 1. Lead Principal Investigator has plans to submit the draft manuscript to DCP. *Discuss the timeline for completion in the comments.*
 | Choose one. |       |
| 1. The site understands the requirements for retention of study records.
 | Choose one. |       |
| **Additional Comments:** |
|       |

**IV. Action Items for the Site**

**Completion Instructions for the CLO Monitor**: List visit findings below in order of severity and mark Major Deficiency as ***Yes*** or ***No*** and Status as ***Resolved*** or ***Site* *follow-up of action items required***. Complete an Action Item-Site Response Form for any item marked as ***Site* *follow-up of action items required***.

|  |  |  |
| --- | --- | --- |
| **Visit Findings** | **Major Deficiency?** | **Status** |
| 1. |       | Choose one. | Choose one. |
| 2. |       | Choose one. | Choose one. |
| 3. |       | Choose one. | Choose one. |
| 4. |       | Choose one. | Choose one. |

\*Choose one.\*

**Report Prepared By:**

|  |  |  |
| --- | --- | --- |
| **Printed Name** | **Signature** | **Date** |
|       |       | Click here to enter a date. |