## 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

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| --- | --- |
| **Name** | **Role** |
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## 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. |