## Monitoring Visit Report

## Site Information

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| --- | --- |
| **Site Name:** |       |
| **NCI Protocol Number:** |       |
| **NCI Protocol Title:** |       |
| **Visit Number/Type:****(1st AMV, 2nd AMV, Interim AMV, etc.)** |       |
| **Visit Date(s):** | **From:** Enter a date. **To:** Enter a date. |
| **Visit Modality:** | Choose one. |
| **Visit Conducted By:** |       |

**Visit Participants:**

|  |  |
| --- | --- |
| **Name** | **Role** |
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**Source documentation (original, certified, etc.) accessible to CRA at time of visit:**

[ ]  Original, paper source documentation [ ]  Current EMR

[ ]  PI-certified copies of original paper source documentation and/or current EMR [ ]  Other (please specify in Additional Comments)

|  |
| --- |
| **Additional Comments:** |
|       |

|  |
| --- |
| **STUDY PROGRESS PER MDS ACROSS ALL SITEs**  |
| Date Study Open | Study Status | Target Enrollment | Number Screened | Number Enrolled | Number Randomized | Number Currently on Intervention | Number Successfully Completed Study |
| Enter a date. |       |       |       |       |       |       |       |
| **MDS Date** Enter a date. |
| Comments:       |
| **STUDY PROGRESS at *[insert name of the site currently being monitored]*:** |
| Date Study Open | Study Status | Target Enrollment | Number Screened | Number Enrolled | Number Randomized | Number Currently on Intervention | Number Successfully Completed Study |
| Enter a date. |       |       |       |       |       |       |       |
| **MDS Date** Enter a date. |
| Comments:       |

**Completion Instructions for the CLO Monitor:** Mark each item in Sections II, III and IV 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 below. An itemized of all findings/discrepancies resolved during the visit must be listed in each applicable comment section.

## Regulatory Document Review Review not done [ ]

| **REGULATORY ITEMS EVALUATED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. IRB/CIRB approval of new versions of the protocol, since last visit. *List protocol and amendment versions with corresponding IRB/CIRB approval dates.*
 | Choose one. | Initial Protocol, dated:      Amendment version(s), dated:      |
| 1. No interruption in the IRB/CIRB continuing review approval of the protocol since last visit. *List IRB/CIRB continuing review dates.*
 | Choose one. |       |
| 1. For the Studies open under the CIRB, review of the following documents:
2. Annual Signatory Institution Worksheet content and approval letter
3. Boilerplate language included in the Annual Signatory Institution Worksheet approval letter
4. Annual Principal Investigator Worksheet content and approval letter
5. Study-Specific Worksheet approval letter
 | Choose one. |       |
| 1. IRB/CIRB approval of the informed consent form (ICD) and all revisions since last visit. *List ICD versions with corresponding IRB/CIRB approval dates.*
 | Choose one. | ICD version(s), dated:       |
| 1. Participant recruitment material received DCP and IRB/CIRB approval prior to use. *List DCP and IRB/CIRB approval dates.*
 | Choose one. | DCP approval date:      IRB/CIRB approval date:       |
| 1. Federal-wide Assurance (FWA) Number for local IRB only\*. *List FWA number and expiration date.*

*\*Per OHRP, the NCI CIRB does not hold an FWA because it is not the entity conducting the research.*  | Choose one. | FWA Number:      , expires       |
| 1. Investigator’s Brochure (IB) is on file. *List name of agent(s) and version date(s).*
 | Choose one. | IB version(s), dated:      |
| 1. FDA Form 1572 is current. *List date of current form, and all previously signed forms since last visit.*
 | Choose one. | Form 1572 version(s), dated:      |
| 1. NCI, DCP Financial Disclosure Form for each investigator and sub-investigator listed on Form FDA 1572.
 | Choose one. |       |
| 1. Delegation of Tasks form for each staff member.
 | Choose one. |       |
| 1. CV for staff listed on Form FDA 1572 and Delegation of Tasks form.
 | Choose one. |       |
| 1. Good Clinical Practice Training for staff listed on Form FDA 1572 and Delegation of Tasks form.
 | Choose one. |       |
| 1. Professional licensure is current for applicable staff listed on FDA Form 1572 and Delegation of Tasks form.
 | Choose one. |       |
| 1. CLIA and CAP certification is current for each clinical laboratory listed on Form FDA 1572.
 | Choose one. |       |
| 1. Laboratory normal values available for each clinical laboratory listed on Form FDA 1572.
 | Choose one. |       |
| **Additional Comments:**       |

## Site Operations Review

| **SITE OPERATIONS ITEMS EVALUATED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. 100% of signed and dated Informed Consent Documents (ICDs) have been reviewed and are on file for each consented participant to date, including screen failures. *Begin review at stopping point from last visit. List range of all participant ID numbers reviewed during this visit.*
 | Choose one. |       |
| 1. Correct/latest version of ICD was used for each participant.
 | Choose one. |       |
| 1. Only appropriate personnel consented each participant (refer to Delegation of Tasks form).
 | Choose one. |       |
| 1. The response(s) of each participant to all future specimen use questions in the ICD were collected and recorded in the database or other electronic tracking system*. Please indicate storage location.*
 | Choose one. |       |
| 1. Adequate resources to conduct study (e.g., facilities, staffing, training). *Describe any significant changes since last visit.*
 | Choose one. |       |
| 1. Participant accrual and retention are on target per RRA plan.
 | Choose one. |       |
| 1. Database/electronic data capture (EDC) system is used to capture study-specific data. *Describe database of record /EDC system.*
 | Choose one. |       |
| 1. Internal quality assurance (QA) measures are in place and are being followed to ensure data quality. *Describe QA activities.*
 | Choose one. |       |
| 1. Study records are stored in a secure manner.
 | Choose one. |       |
| 1. Screening/enrollment logs are current (including screen failures).
 | Choose one. |       |
| 1. Research specimen log or research specimen management system is current.
 | Choose one. |       |
| 1. Monitoring visit log is current and includes this visit (refer to SOP 12b).
 | Choose one. |       |
| 1. The PI has ensured that all staff participating in the conduct of the study have received adequate training and have been informed of pertinent changes during study conduct, and receive additional training, as appropriate.
 | Choose one. |       |
| **Additional Comments:** |
|       |

## Pharmacy Review Review not done [ ]

**Pharmacy Location:**

|  |  |
| --- | --- |
| **Pharmacy Personnel:** | **Role** |
|       |       |
|       |       |

| **PHARMACY ITEMS EVALUATED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. Investigational pharmacy is secure, and access is limited to appropriate staff.
 | Choose one. |       |
| 1. Inventory system is in place to account for investigational agent. *Document whether pharmacy is using a manual Drug Accountability Record Form (DARF) or a computerized method.*
 | Choose one. |       |
| 1. All information requested on the DARF is provided and corrections (as applicable) were made appropriately. *Document whether site is maintaining a master DARF, master DARF for each dosage and strength, or an individual DARF for each participant on a double-blind study.*
 | Choose one. |       |
| 1. Balance from DARF matches the balance in stock.
 | Choose one. |       |
| 1. Investigational agent has been given only to eligible participants and only at protocol specified doses.
 | Choose one. |       |
| 1. All investigational agent orders, transfers, and returns are properly documented, and the receipts are maintained. Quantity of study agent that has been logged in corresponds with the amount received.
 | Choose one. |       |
| 1. Investigational agent is stored according to recommended conditions. *If refrigerator and/or freezer used,* *describe the location of unit and method of monitoring temperature.*
 | Choose one. |       |
| 1. Outdated investigational agent is stored separately from active supply.
 | Choose one. |       |
| 1. Investigational agent is stored separately from commercially available supply.
 | Choose one. |       |
| 1. Investigational agent is dispensed to each participant according to protocol. *Describe the procedure for dispensing study agent, including who prepares the agent and dispenses to participant, use of prescriptions, and how administration instructions are communicated to participant.*
 | Choose one. |       |
| **Additional Comments:** |
|       |

## Participant Chart Review Review not done [ ]

| **PARTICIPANT CHARTS REVIEWED DURING THIS VISIT** |
| --- |
| Participant ID | ICD | Eligibility | From Visit  | Through Visit  |
|       | [ ]  | [ ]  |       |       |
|       | [ ]  | [ ]  |       |       |
|       | [ ]  | [ ]  |       |       |
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|       | [ ]  | [ ]  |       |       |
|       | [ ]  | [ ]  |       |       |

**Completion Instructions for the CLO Monitor:** Mark each item below 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 below. Complete a table for each participant chart reviewed. Insert a blank page, then copy and paste a table for each additional chart reviewed.

| **CHART REVIEW SUMMARY OF FINDINGS****PID Number:**       | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. Informed consent was signed prior to all study activities.
 | Choose one. |       |
| 1. Inclusion and exclusion criteria were met, and eligibilityconfirmed by review of source documentation.
 | Choose one. |       |
| 1. Source documentationis adequate, and any corrections were made according to the DCP Guidance Document on Source Documentation.
 | Choose one. |       |
| 1. Evidence of compliance with all required evaluations outlined in protocol, unless previously reported as a protocol deviation. For any missed visits or examinations, there is documentation of an attempt to locate and/or communicate with participant.
 | Choose one. |       |
| 1. All protocol deviations were identified, reported, tracked, and filed per SOP 4 prior to this visit.
 | Choose one. |       |
| 1. Investigational agent was administered according to protocol, including any dose modifications.
 | Choose one. |       |
| 1. AllAEs (including SAEs) were appropriately documented and reported in the database and MDS.
 | Choose one. |       |
| 1. All SAEs were communicated appropriately per SOP 3.
 | Choose one. |       |
| 1. All concomitant medications were appropriately documented and reported in the database.
 | Choose one. |       |
| 1. All database and MDS entrieswere complete, timely and accurate when compared with the source documentation.
 | Choose one. |       |
| 1. All specimens were collected, processed, and shipped/stored as evidenced by review of specimen tracking documentation.
 | Choose one. |       |
| **Additional Comments:** |
|       |

## Summary of Previous Action Items

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| --- |
| Were action items from the previous visit resolved? (If no, please specify in comments) Choose one. |
| Comment:       |

## Action Items for this Site Visit

**Completion Instructions for the CLO Monitor**: List each visit finding 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](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP12c-Action-Item-Site-Response-Form_01-06-2017.docm) for any item marked as ***Site* *follow-up of action items required***.

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

## Assessment of Site Performance

**Completion Instructions for the CLO Monitor:** Mark each item as: ***Acceptable, no site follow-up of action items required*** (no deficiencies identified or few deficiencies identified, but corrected/addressed during the visit; no further action required); ***Acceptable, site follow-up of action items required:*** (multiple deficiencies identified, but not corrected/addressed during the visit); or, ***Unacceptable, site follow-up of action items required:*** (major deficiency(ies) or excessive number of lesser deficiencies identified).

| Visit Components | Assessment Rating |
| --- | --- |
| Regulatory  | Choose one. |
| Site Operations  | Choose one. |
| Pharmacy | Choose one. |
| Participant Chart Review | Choose one. |

Based on the findings of this visit, the CLO Monitor recommends the next monitoring visit be an: Choose one..

A subset of records reviewed during this remote visit will be reviewed at the next in-person monitoring visit:

Yes [ ]

No [ ]

**Report Prepared By:**

|  |  |  |
| --- | --- | --- |
| **Printed Name** | **Signature** | **Date** |
|       |       | Enter a date. |