## SOP 9: Site Preparations for Monitoring Visits and Quality Assurance Audits

## Overview:

The purpose of this document is to outline the responsibilities of site coordinators in preparing for monitoring visits and quality assurance (QA) audits:

1. During study accrual and intervention, the National Cancer Institute (NCI)/ Division of Cancer Prevention (DCP) requires monitoring visits at each Participating Organization (PO), and at each accruing Consortium Lead Organization (CLO) to ensure all study activities are consistent with the current, approved protocol version, Data Management Plan (DMP), DCP Standard Operating Procedures (SOPs), and applicable regulations. Monitoring visits are scheduled annually and may be scheduled more frequently based on study complexity, staffing changes, accrual patterns, or performance concerns.

* Monitoring visits to the POs are conducted by the CLO Monitors (or, in select instances, with prior DCP approval, by the DCP monitoring contractor)
* Monitoring visits to the CLOs are conducted by the DCP monitoring contractor

1. NCI/DCP requires QA audits at each CLO to ensure all consortium-led activities are consistent with the DMP, Data and Safety Monitoring Plan (DSMP), Multi-Institutional Monitoring Plan (MIMP), SOPs, and applicable regulations. Audits include a review of selected PO charts, from all studies with active participants under the CLO, previously monitored by the CLO Monitor. Audits are conducted by the DCP monitoring contractor and are scheduled annually (or more frequently based on staffing changes or performance concerns).

In addition, NCI/DCP requires a closeout visit at each PO as the final participants complete study participation*.* [SOP 13: Site Preparations for Study Closeout](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13-Site-Prep-Closeout.docx) outlines the responsibilities for preparing for a closeout visit.

## Responsibilities – Monitoring Visit:

In preparation for a monitoring visit the CLO Site Coordinator/designee or PO Site Coordinator/designee will:

1. Collaborate with the monitor to identify a mutually agreeable visit date to allow maximum staff participation.
2. Acknowledge receipt of the confirmation letter with an email response confirming the date and objectives of the visit.
3. Communicate the monitoring visit logistics and objectives to staff.
   1. Within three (3) business days from receipt of confirmation email, the study coordinator needs to provide the monitor with requirements for access to EMR, EDC, and site if applicable.
4. Ensure the monitor will have adequate workspace during the visit.
5. Ensure that all regulatory documentation is current, accessible, and filed in an organized manner. Refer to [SOP 1: Regulatory Documents](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP1-Regulatory-Documents.doc) for a list of required documents.
6. Ensure the original or a Principal Investigator (PI) certified copy (per ICH GCP E6: 1.51) of the signed and dated informed consent form(s) for each participant consented since the last monitoring visit is accessible.
7. Ensure that all logs and documentation for enrollment, screening, protocol deviation, and SAEs are current and available.
8. Ensure entries in the research specimen tracking log or research specimen tracking system are current, accurate, and accessible, as applicable.
9. Ensure the monitoring visit log is accessible. The monitor will provide visit log to the study coordinator at the first monitoring visit. The log must be maintained at the site for the duration of the study.
10. Ensure all action items from the previous visit have been successfully resolved, and support documentation is accessible, as applicable.
11. Confirm a meeting time with pharmacy staff to ensure the monitor will be able to discuss pharmacy operations and review drug storage procedures, and study drug documentation such as Drug Accountability Record Forms(s) (DARF) and shipment records/receipts in comparison with available stock.

* When a monitoring visit is conducted remotely, the monitor, in advance of the remote visit, will request a written response (email is acceptable) from the pharmacist on the below items:
* Investigational pharmacy is secure, and access is limited to appropriate staff
* Balance from DARF matches the balance in stock
* Outdated investigational agent is stored separately from active supply
* Investigational agent is stored separately from commercially available supply

1. Ensure all source documentation (original records or PI certified copies of original records) is accessible and organized for each participant selected for chart review. If the source documentation involves an electronic medical record (EMR), ensure the monitor will have appropriate access to the EMR or PI certified copies.

* If redacted records were provided during the remote monitoring visit, a subset of these records may be reviewed during the next onsite monitoring visit.

1. Ensure the completed case report forms (CRFs) are accessible and organized for each participant selected for chart review.
2. Ensure entries in the database of record are current and accurate, and the monitor will have appropriate access to the database of record or a printed, certified copy of the entries.
3. Ensure data QA activities are complete and documented, as applicable.
4. Ensure all serious adverse event (SAE) documentation and protocol deviations (PDs) are complete and accessible. Refer to [SOP 3: Reporting Serious Adverse Events](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP3-Reporting-Serious-Adverse-Events.doc) and [SOP 4: Reporting Protocol Deviations](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP4-Reporting-Protocol-Deviations.docx) for requirements.
5. Assist the monitor in coordinating an exit meeting at the conclusion of the monitoring visit. This may include reserving meeting room space and/or a conference phone line and ensuring relevant staff participation. The exit summary meeting invite should be distributed by the monitor.
6. The PI must ensure 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.

## Responsibilities – QA Audit:

The CLO Site Coordinator, and/or designee, in preparation for a QA audit by the DCP monitoring contractor will:

1. Collaborate with the auditor to identify a mutually agreeable date for the visit to allow maximum participation by site staff.
2. Acknowledge receipt of the confirmation letter with an email response confirming the date and objectives of the visit.
3. Communicate audit logistics and objectives with staff.
4. Ensure adequate work space will be available for the auditor during the visit.
5. Ensure documentation is accessible to support methods of tracking the receipt of regulatory documents from the PO(s) and forwarding of these documents to the DCP regulatory contractor.
6. Ensure documentation is accessible to support methods of communicating information to the PO(s). Examples include: meeting minutes, email documentation or an active website link.
7. Ensure documentation is accessible to support methods of tracking staffing changes, accrual and retention patterns, PDs, SAEs, data entry, and query resolution at the PO(s).
8. Ensure the DMP, DSMP, and MIMP are current and are approved by DCP.
9. Ensure documentation indicating that all sites have adopted the most current DCP SOPs as written or have exceptions on file with DCP approval is accessible.
10. Ensure the PO(s) submit(s) certified copies of all source documentation (with identifiers removed) and CRFs for each participant selected for chart audit as applicable, and the materials are accessible and organized. If the source documentation involves an electronic medical record (EMR), request appropriate access to the EMR or certified copies of the EMR for the auditor.
11. Ensure entries in the database of record (Electronic Data Capture [EDC] system) are current and accurate, and the auditor will have appropriate access to the database of record or a printed certified copy of the entries from the database.
12. All logs and documentation for enrollment, screening, and monitoring/auditing visits are current and available.
13. Ensure all serious adverse event (SAE) documentation and protocol deviations (PDs) are complete and accessible. Refer to [SOP 3: Reporting Serious Adverse Events](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP3-Reporting-Serious-Adverse-Events.doc) and [SOP 4: Reporting Protocol Deviations](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP4-Reporting-Protocol-Deviations.docx) for requirements.
14. Assist the auditor in coordinating an exit meeting at the conclusion of the audit. This may include reserving meeting room space and/or a conference phone line and ensuring relevant staff participation. The exit summary meeting invite should be distributed by the auditor.
15. The PI must ensure 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.

## Documentation Requirements:

The CLO or PO Site Coordinator will respond to all action items identified during a site visit or QA audit within thirty (30) calendar days of receipt of the report using [SOP 12c: Action-Item Site Response Form](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP12c-Action-Item-Site-Response-Form.docx). This response will indicate either resolution of the action item or include a corrective action plan with a projected resolution date. For items with a projected resolution date, the DCP monitoring contractor or CLO Monitor will follow-up on those items every 30 days until all items are resolved.

## Additional Information:

Refer to the [DCP Acronym List](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/DCP-Acronym-List.docx) to see the description of commonly used acronyms in this SOP.

**Please send questions and comments to the DCP Help Desk at  
1-844-901-4357 or** [**dcphelpdesk@dcpais.com**](mailto:dcphelpdesk@dcpais.com)