## SOP 14: CLO Monitor Instructions for Conducting Closeout Visits

### Overview:

1. The Consortium Lead Organization (CLO) monitor will conduct a closeout visit for all active Participating Organization (PO) for each study after all study activities are complete, or at the discretion of DCP Medical Monitor and COR. An active PO is defined as an institution or clinical site that, after having completed regulatory and DCP requirements for study initiation, is responsible for accrual of study participants.
2. The CLO monitor will conduct a closeout visit at a PO when:
	* + All participants enrolled at the PO have completed study-related activities; and
		+ All data have been entered into the database of record and outstanding data discrepancies have been resolved.
3. If an active site fails to accrue participants, DCP and the CLO may elect to close the site early.
* If DCP and the CLO elect to close the site due to poor enrollment, the CLO will inform the site of the intention to close, and a closeout visit will be scheduled.
* The closeout visit may be conducted remotely or on-site at the discretion of the DCP Medical Monitor and COR.
* If the site has received study agent, agent return or disposal must be handled as outlined in the protocol.
1. If a proposed accrual site has not been activated, a closeout visit is not required.
	* + The CLO will send a letter to the PO (with a copy to DCP, TRI, and CCSA) stating that the site was not activated; therefore, a closeout visit is not required.
		+ Regulatory documents that have been collected will be managed as directed by the CLO and/or as required by institutional policy.
		+ Any regulatory documents from the site that have been submitted to CCSA will be managed per CCSA’s SOPs.

All visits, remote or on-site, will be reported on a visit report form.

1. When the CLO also serves as an enrolling site, the DCP monitoring contractor will conduct a closeout visit at the CLO.

### Schedule the Closeout Visit:

The CLO monitor will:

1. Identify a mutually convenient date with the PO Principal Investigator and the PO Site Coordinator.
	1. The duration of the closeout visit is typically one full day on site.
	2. The visit will include an exit summary meeting with PO and DCP staff to discuss the visit findings.
	3. The duration and timing of the closeout visit may be adjusted to include a combination monitoring and closeout visit when additional chart reviews are indicated. Refer to [SOP 12: CLO Monitor Instructions for Conducting Monitoring Visits](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP12-CLO-Monitoring-Instructions.docx)*.*
2. Send an email confirmation to the PO Principal Investigator and Site Coordinator and copy the DCP Help Desk. The email will state the purpose and objectives of the visit, documents that will be reviewed, and the scheduled date(s) for the visit. The exit summary meeting invite should be distributed by the CLO monitor.

### Prepare for the Closeout Visit:

The CLO monitor will:

1. Review the protocol and study materials.
2. Review enrollment and randomization numbers for the PO.
3. Review regulatory documents due and submitted by the PO to the CLO since the last monitoring visit.
4. Assess status of data entry and remaining queries in the database of record.
5. Review the most recent Minimum Data Set (MDS) submission.
6. Review all action items and findings identified in the report from the last monitoring visit.
7. Contact the CLO Site Coordinator to inquire if there are any specific questions or concerns that can be addressed during the monitoring visit.

### Conduct the Close-Out Visit:

The CLO monitor will:

1. Verify the following closeout items have been completed or determine the completion status, as outlined in [SOP 14a: Closeout Visit Report](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP14a-Closeout-Visit-Report.docx)template.
	1. All regulatory documents, including all required IRB approvals (either local IRB or CIRB) are current and on file.
	2. The local IRB and/or CIRB has been informed of study closure to accrual at the site.
	3. The site understands the local IRB and/or CIRB will need to be informed of final study closure once all study analyses and activities at all enrolling sites are complete.
	4. An original, or a certified copy of the original, signed and dated informed consent form(s) is on file for each participant.
	5. All logs and documentation for enrollment, screening, protocol deviations, monitoring/auditing visits, and SAEs are current and available.
	6. Documentation is present in each participant’s record indicating that study participation has ended.
	7. There are no adverse events or serious adverse events that require further follow-up for any participant.
	8. All case report forms for each participant have been completed.
	9. All data entry in the database of record is complete.
	10. All data queries have been resolved.
	11. All Drug Accountability Record Forms (DARFs) have been reconciled.
	12. All unused investigational agent has been returned to the repository according to the protocol.
	13. There is no evidence to suggest the study blind was compromised, if applicable. If unblinding occurred, there is sufficient documentation to explain the appropriateness of the un-blinding.
	14. Research specimen log(s) or research specimen management system is current.
	15. All study analyses involving research specimens are complete or are in progress.
	16. All action items from previous monitoring visits have been resolved.
	17. If the Lead Principal Investigator (PI) is at the PO, the monitor will confirm plans to submit the draft manuscript to DCP.
	18. The PO understands the requirement for retention and access of study records as outlined in the study protocol.
		1. NCI/DCP will be notified prior to the planned destruction of any study materials.
2. Note all findings identified during the review. The [SOP 14a: Closeout Visit Report](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP14a-Closeout-Visit-Report.docx) template includes prompts in italics for specific findings that must be reported. Additional findings may be recorded in the comments section.
3. Report deficiencies identified during the review. A deficiency is any incomplete, incorrect, or missing finding that is not in keeping with the study plan, federal regulations, DCP Consortia 2012 Standard Operating Procedures, DCP Guidance Documents or institutional requirements.
	1. The CLO monitor is required to label a deficiency as ‘major’ if it is severe in nature or scope, compromises patient safety, or impacts data integrity. Minor deficiencies that are repetitive, process-related, or involve multiple participants may also be considered a major deficiency.
	2. Examples of major deficiencies specific to a closeout visit, include:
		1. Regulatory Documentation
			1. Failure to obtain IRB/CIRB approval for the protocol or informed consent form.
			2. Interruption in the IRB/CIRB continuing review approval of the protocol
		2. Informed Consent Form (ICF) Documentation
			1. Missing ICF.
			2. Failure to obtain appropriate signatures on the ICF.
			3. Use of wrong ICF version.
		3. Site Operations
			1. Failure to comply with Data Management Plan.
			2. Screening and/or enrollment logs missing or incomplete.
			3. Specimen log and/or specimen management system missing or incomplete.
			4. Action items from previous site visit unresolved.
			5. Excessive delinquent data entry in database and/or MDS.
		4. Pharmacy Operations
			1. Balance on Drug Accountability Record Form(s) (DARF)(s) does not match drug supply.
			2. Missing DARF(s), or failure to maintain DARF(s) correctly.
			3. Excessive instances of failure to maintain documentation of agent order receipts and returns.
			4. Study blind compromised without sufficient documentation to support the appropriateness of the un-blinding.
	3. Major deficiencies that are corrected and/or appropriately documented by the site prior to the monitoring visit may be down-graded to a minor deficiency, at the discretion of the CLO monitor.
4. Note all action items identified during the review. An action item is any action required of the site following the monitoring visit. Each action item should be written in a manner that clearly conveys the expected action or outcome.
5. Prepare and conduct a summary meeting with the DCP staff, PI, Site Coordinator, and other key study staff to review the findings of the monitoring visit. During the summary meeting the CLO Monitor will:
	1. Summarize findings from the closeout visit.
	2. Describe any major deficiencies and/or action items identified.

### Document the Close-Out Visit:

The CLO monitor will:

1. Update the monitoring visit log. [SOP 12b: Monitoring Visit Log](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP12b-Monitoring-Visit-Log.docx) or an equivalent document is to be completed, dated and then signed by the CLO monitor and a staff member from the PO site during each visit.
2. Complete the [SOP 14a: Closeout Visit Report](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP14a-Closeout-Visit-Report.docx) template, including a description of all deficiencies and action items.

When CLO monitor conducts both monitoring and closeout visits at the same time, separate reports should be completed - one for the monitoring visit and one for the closeout visit. Both reports should be sent to the site together. If any action items are identified during the visit, one Action Item Site Response Form can be sent with the reports, and:

1. If the action items result from the monitoring part of the visit, they should also be documented in the monitoring report.
2. If the action items result from the closeout part of the visit, they should also be documented in the closeout report.
3. If a finding applies to an item listed in both monitoring and closeout reports, “No” should be answered in both reports to this particular item, but it should be documented only once in the Action Item Site Response Form.
4. The site cannot be closed out until all action items are resolved.
5. Distribute the completed report via email to the DCP Help Desk **within 15 business days of the site visit date**. The DCP Help Desk will forward the report to all applicable DCP representatives.
6. Distribute the completed report via email to the PO site.
7. Ensure the PO site resolves all action items **within 30 calendar days of distribution of the report**. Forward a copy of the PO response to the DCP Help Desk.
8. Notify the PO site and the DCP Help Desk once the action item response is acceptable.

### Important Information on Reporting Scientific Misconduct:

1. The CLO monitor must immediately notify the DCP Medical/Scientific Monitor of any findings that may suggest intentional misrepresentation of data and or disregard for regulatory safeguards for any of the components of the monitoring visit.
2. The notification will be conducted by phone to permit clarification and discussion of the issues. Documentation should be included in the closeout visit report.

### 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**