## SOP 10: CLO Oversight of Participating Organizations

### Overview:

The Consortium Lead Organization (CLO) Principal Investigator (PI) is responsible for continuous oversight of study activities performed by each of their Participating Organizations (POs) to ensure all study activities are consistent with the current version of the protocol, Data Management Plan (DMP), Multi-Institutional Monitoring Plan (MIMP), Division of Cancer Prevention (DCP) Standard Operating Procedures (SOPs), and applicable regulations. The CLO PI may delegate specific tasks associated with this oversight to qualified personnel, but the CLO PI retains overall responsibility for the oversight. This continuous oversight is typically performed remotely and is in complement with monitoring visits conducted by the CLO Monitor.

### Responsibilities:

The CLO PI and designee(s) will:

1. Review PO regulatory documents and ensure timely submission of the documents to the DCP Regulatory Contractor as outlined in [SOP 1: Regulatory Documents](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP1-Regulatory-Documents.doc)*,* and verify:
   1. PO compliance with local institutional requirements regardless of whether the protocol is reviewed by the IRB or CIRB; and
   2. Form FDA 1572 and all supporting documentation remains current, if staffing changes occur.
2. Ensure representatives from each PO attend a study initiation meeting prior to participant enrollment.
3. Assure PO staffing is adequate for protocol implementation and throughout the conduct of the study.
4. Ensure the training of new PO staff is timely and adequate. Changes in PO staff (PI or Site Coordinator) and contact information should be forwarded to the DCP Help Desk ([dcphelpdesk@dcpais.com](mailto:dcphelpdesk@dcpais.com)).
5. Track participant enrollment by each PO in relation to accrual targets.
6. Review recruitment and/or retention strategies with each PO as appropriate to meet accrual targets.
7. Ensure research specimen management is consistent and adequate at each PO site, including the use of a research specimen tracking system or tracking log. A research specimen tracking log will include basic elements applicable to the protocol such as the type of research specimen, specimen number, date and time of collection and shipping, and storage location.
8. Ensure Serious Adverse Events (SAEs) are reported according to [SOP 3: Reporting Serious Adverse Events](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP3-Reporting-Serious-Adverse-Events.doc)*.*
9. Ensure Protocol Deviations (PDs) are reported according to [SOP 4: Reporting Protocol Deviations](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP4-Reporting-Protocol-Deviations.docx).
10. Ensure all PO data is keyed into the database of record within the timeframes specified in the DMP.
11. Ensure internal Quality Assurance (QA) activities are completed within the timeframes and specifications of the DMP and MIMP.
12. Ensure data discrepancies and/or data queries are resolved in a timely and complete manner.
13. Ensure all specified administrative, participant demographic and adverse event data is communicated to DCP in a monthly Minimum Data Set (MDS) submission.

14. Ensure all Amendments and Continuing Reviews are provided to each site to be processed per local IRB policy until final study closure. Final study closure occurs when all study analysis and activities at all enrolling sites are complete.

### Documentation Requirements:

The CLO PI and designee(s) are responsible for maintaining documentation of all oversight activities and related communications with PO sites. This documentation should be readily accessible, and may be requested by DCP, the DCP Regulatory Contractor, and/or the DCP Monitoring Contractor at any time during the duration of the study.

### 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)