## SOP 9a: Site Preparations for Quality Assurance Monitoring Audits

## Overview:

The purpose of this document is to outline the responsibilities of Site Coordinators in preparing for quality assurance (QA) audits of DCP AIS contracted CLO monitors:

1. NCI/DCP requires an annual QA audit of each DCP AIS contracted CLO monitor to ensure adequate monitoring oversight of consortium-led activities, the Data Management Plan (DMP), Data and Safety Monitoring Plan (DSMP), Multi-Institutional Monitoring Plan (MIMP), Standard Operating Procedures (SOPs), and applicable regulations. Audits include a review of selected CLO charts, from a subset of studies previously monitored by the CLO Monitor. Audits are conducted by the DCP Monitoring Contractor and are scheduled with the CLO site approximately four to six weeks in advance.

## Responsibilities – CRA Audit Visit:

Coordinator/designee will:

1. Collaborate with the auditor to identify a mutually agreeable visit date.
2. Acknowledge receipt of the confirmation letter with an email response confirming the date and objectives of the visit.
3. Communicate the audit logistics and objectives to staff.
   1. Confirmed access to applicable databases or electronic medical records (EMR) such as system training, access/facility IDs should be outlined once the visit is confirmed.
4. Ensure the Auditor will have adequate workspace during the audit.
5. Ensure that the Auditor will have access to the same documents the monitor reviewed at the visit related to the conduct of the audit. The documents include but are not limited to the following:
   1. Essential Regulatory documents (see DCP 2012 Consortia for Early Phase Prevention Trials SOP 1: Regulatory Documents)
   2. Previous monitoring visit reports, and Action Item-Site Response Forms.
   3. Study-specific processes and procedures, staff credentials (e.g., CVs and medical licenses) and training documentation
   4. Any records used as source documentation (e.g., clinic charts, hospital medical records, laboratory reports, patient questionnaires, procedure results)
   5. The study database and study CRFs
   6. Investigational agent and biospecimen management and accountability records
   7. Calibration documentation for site equipment (e.g., freezers, refrigerators, temperature monitors)
   8. Protocol Deviations
6. Adverse Events (AEs) and Serious Adverse Events (SAEs)
7. Study pharmacy records
8. Confirm a meeting time with pharmacy staff to ensure the Auditor 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.

## Documentation Requirements:

The audit may uncover data or other study related discrepancies not previously identified by the monitor. This may result in action items that will need to be addressed by the CLO. Action items will be documented using the DCP 2012 Consortia for Early Phase Prevention Trials SOP 12c: Action Item-Site Response Form (refer to PSP-DCP-SM-07, Follow-up of Site Visit Action Items). The Action Item-Site Response Form will be sent to the site by the auditor and follow-up of action items will conform to procedures outlined in SOP12c.

## 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  
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