

**United States-Latin America-Caribbean HIV/HPV-Cancer Prevention Clinical Trials Network (ULACNet), Audit Plan for Affiliate Organizations (AOs)  
Author, NCI Division of Cancer Prevention**

The National Cancer Institute (NCI)/Division of Cancer Prevention (DCP) requires Quality Assurance (QA) audits of clinical trial data and processes at each ULACNet Affiliate Organization (AO). The Frederick National Laboratory (FNL) Clinical Monitoring Research Program Directorate (CMRPD)/Leidos Biomedical Research, Inc. (Leidos Biomed) will support ULACNet by conducting audits at each Affiliate Organization (AO).

Auditing is an independent quality assurance function for the systematic evaluation of trial processes and documents. It is used to determine whether trial-related activities are conducted—and whether data is recorded, analyzed, and accurately reported—according to the protocol, ULACNet Program Guidelines, relevant Good Clinical Practice (GCP) guidelines, and other applicable regulatory requirements. This plan is a living document that will be updated ad hoc to meet NCI/ULACNet program needs.

Each AO audit will be protocol-specific, focusing on the review of protocol-specific requirements and the AO's conduct of the protocol that is being audited. The protocol-specific auditing plan will be outlined on the Audit Confirmation Letter. The protocol number will be included in the Audit Confirmation Letter, Agenda, Report, and Follow-Up Letter sent to the AO.

This audit plan details: the scope and timing of the audit; the person responsible for conducting the audit; reference documents required for the audit; and timelines for audit reporting and audit finding resolutions.

Each protocol an AO conducts will be audited at least annually, and ad hoc as needed. It is possible that during a single multi-day visit from the CTM auditor, more than one protocol will be scheduled for an audit. If more than one audit will be conducted during a single audit visit, the scheduling, confirmation, follow-up letters, and audit reports will be generated separately for each protocol.

### **Audit Overview**

During the audit, monitoring reports including noted deficiencies, randomly selected participant case report forms, regulatory files, and pharmacy/drug accountability and/or review of equipment, supplies, and training will be evaluated. The audit scope may include all or some of the below items:

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**Audit Scope**

**Participant Case Review**

- Informed Consent
- Eligibility
- Investigational Agent Compliance (administration, dose modification, etc.) or Screening Compliance
- Adverse Event (AE)/Serious Adverse Event (SAE) Reporting
- General Data Management Quality (e.g., timely, complete, and accurate eCRF data entry and query response)
- Participant-Specific AQUIP Data (strategies, reasons not enrolled, etc.)
- Specimen Collection, Processing, Storage, Shipment
- Secure Record Storage

**Site Regulatory files**

- IRB or Ethics Committee (EC) Continuous Reviews and Approvals
- Delegation of Tasks Logs (DTLs)
- Training Files
- AE/SAE Log
- Monitoring Visit Follow-Up Letters, Communications, Signed Site Visit Log (if applicable)
- Evidence of Monitoring Visit Findings and Action Item Resolution

**Pharmacy/Drug Accountability**

- Completion and Accuracy of Drug Accountability
- Records of Satellite Dispensing Area (if applicable)
- Return of Study Agent
- Study Agent Storage
- Recording of Temperature Excursion
- Recording of Drug Expiration
- Adequacy of Security
- Authorized Prescriptions

**Audit Frequency**

The audit may be conducted any time between study initiation and study completion. Throughout the conduct of the study, audits will be conducted off-site/remotely and/or in-person at least annually, and ad hoc.

**The Auditor**

The CMRPD Clinical Trials Manager (CTM) will conduct the audits on behalf of the National Cancer Institute (NCI) and ULACNet Leadership.

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**Audit Preparation**

**In preparation for an audit, the auditor will:**

- Contact the AO six to eight weeks prior to the audit to schedule an agreed-upon audit date(s) and time
- Specify how the audit will be conducted (i.e., remote or in-person)
- Prepare an agenda for the audit day(s)
- Prepare an Audit Confirmation Letter detailing the audit scope, the documents to be reviewed during the audit, personnel required to be present throughout the audit (i.e., during the opening meeting, the course of the audit itself, and the closing meeting). The Audit Confirmation Letter and Audit Agenda will be sent to the AO, LAO, and DCP ULACNet staff two to four weeks prior to the audit date
- Obtain access to appropriate database
- Prepare for the audit by reviewing data and documents, including but not limited to:
  - Site Monitoring Visit Reports, current IRB/EC approvals and continuous reviews, Clinical Research Organization (CRO)/Clinical Research Associate (CRA) correspondence with the AO (if applicable)
- Generate a list of items to review during the audit based on the review of Site Monitoring Visit Reports
- Randomly generate a list of Participant IDs to be reviewed. The number of participant records that will be reviewed will be based on site enrollment and the number of records reviewed by the site monitor

**In preparation for the audit, AO staff will:**

- Collaborate with the auditor to identify a mutually agreeable date and time for the audit to allow maximum participation by site staff.
- Acknowledge receipt of the confirmation email, including audit dates and objectives.
- Communicate audit logistics and objectives to site and pharmacy staff.
- If on-site, ensure adequate workspace will be available for the auditor during the visit.
- Ensure all relevant materials are available for review at the time of the audit including:
  - Regulatory binder(s)
  - IRB permission to review files, if applicable
  - Approved ICF version(s), as well as the signed Informed Consent Forms for all participants.
  - All relevant Investigational Agent forms
  - Complete medical records (or copies) for participant charts selected for case review, including any investigational reports, laboratory data, worksheets, etc. If the institution utilizes electronic medical records (EMRs) and/or scans, the records may be printed for viewing by the

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auditors, or computers with EMR access may be provided for the auditor to use. A staff member must be present to assist with navigating through the EMR system throughout the course of the audit. For remote visits, ensure identifiers are removed

- SAE documentation and protocol deviations (PDs)
- Logs and documentation for enrollment, screening, and monitoring/auditing visits
- Ensure the auditor has appropriate database access
- AOs that do not use an Electronic Data Capturing System should ensure that they have access to a secure data transferring system.

### **Post-Audit**

At the end of the audit, the auditor will hold a closing meeting with AO staff to review audit findings, including items corrected during the audit and items pending correction for which a corrective and preventative action plan (CAPA) is recommended, and discuss the timing for the next audit.

The auditor will send an email within 48-hours of the visit to ULACNet staff outlining the overall audit findings. For major findings, the auditor may elect to call ULACNet staff in addition to sending the post-audit email.

The auditor will prepare an audit report outlining items audited, audit findings, and recommended corrective and preventative actions (CAPAs) that need to be taken. The finalized audit report is an internal report that will be sent to ULACNet Leadership. A detailed follow-up letter will be sent to the AO's study Principal Investigator, Study Coordinator, LAO, and ULACNet Leadership.

Audit findings addressed during the audit and pending audit findings will be included in the letter. Responses and corrective actions to be taken to resolve all pending audit findings, including CAPAs, are expected within thirty (30) calendar days of receipt of the follow-up letter. Audit findings related to monitoring activities will be clearly outlined on the follow-up letter. LAOs will be responsible for forwarding findings related to monitoring activities to the LAO-designated CRO/CRA. The CRO/CRA will need to provide written responses to the audit findings, indicating the corrective actions/resolutions taken. The LAO will be responsible for collecting the responses for each audit finding from the AOs and/or CRA/CRO and submitting them to the auditor.

CMRPD will send a letter to the AO PI, LAO PI and ULACNet staff if the AO does not address action items within 30-days of receipt of the follow-up letter.

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**AUDIT COMMUNICATION FLOW**

