Title: Lead Academic Organization Oversight of Affiliated Organizations

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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
1.0	AUG-17-2020	Original version of document

1. INTRODUCTION AND PURPOSE

The CP-CTNet Lead Academic Organization (LAO) Principal Investigator (PI) is responsible for continuous oversight of study activities performed by each of her/his Affiliated Organizations (AOs) to ensure all study activities are consistent with the current approved protocol version, Network Data Management Plan (DMP), Network Multi-Institutional Monitoring Plan (MIMP), CP-CTNet Standard Operating Procedures (SOPs), and applicable regulations. The LAO PI may delegate specific tasks associated with this oversight to qualified personnel; however, the LAO PI retains overall oversight responsibility. This continuous oversight is typically performed remotely and is in complement with auditing visits conducted by the Data Management, Auditing, and Coordinating Center (DMACC).

2. SCOPE

This document details the responsibilities of LAO PIs in relation to the oversight of study activities for their respective AOs.

3. ROLES AND RESPONSIBILITIES

The LAO PI and/or designee(s) will:

1. Communicate, in a timely and systematic manner to the AOs, information regarding changes to procedures, new and revised policies on the DMACC Portal Gateway, and announcements from the Division of Cancer Prevention (DCP).
2. Distribute all relevant information about a protocol and operations to the AO staff, including details about pending and final decisions.
3. Schedule conference calls as needed with the AO staff, prepare an agenda of topics prior to the call, and distribute meeting minutes after the call.
4. Develop electronic mail distribution lists for immediate dissemination of important information from DCP, DMACC and DCP contractors.
5. Request that AO staff send questions about protocol implementation and other protocol-specific issues to the LAO Site Coordinator so that s/he may reply or search for solutions in a consistent manner across sites.
6. Develop an appropriate file structure for saving electronic documents so they can be readily retrieved.
7. Review AO regulatory documents and ensure timely submission of the documents to the DCP Regulatory Contractor as outlined in SOP 01-01: Regulatory Documents, and verify:
   - AO compliance with local institutional requirements regardless of CIRB approval; and
   - Form FDA 1572 and all supporting documentation remains current, if staffing changes occur.
8. Ensure representatives from each AO attend a study initiation meeting before participant enrollment.
9. Ensure AO staffing is adequate for protocol implementation, and throughout the conduct of the study.
10. Ensure the training of new AO staff is timely and adequate.
11. Track participant enrollment by each AO in relation to accrual targets.
12. Review recruitment and/or retention strategies with each AO as appropriate to meet accrual targets.
13. Ensure research specimen management is consistent and adequate at each AO 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.

14. Ensure Serious Adverse Events (SAEs) are reported according to SOP 02-01: Reporting Serious Adverse Events.
15. Ensure Protocol Deviations (PDs) are reported according to SOP 02-02: Reporting Protocol Deviations.
16. Ensure all AO data is keyed into Medidata Rave within the timeframes specified in the DMP.
17. Ensure internal Quality Assurance (QA) activities are completed within the timeframes and specifications of REFGD03 Data Management Plan (DMP) and Multi-institutional Monitoring Plan (MIMP, currently in development).
18. Ensure data discrepancies and/or data queries are resolved in a timely and complete manner.

4. DOCUMENTATION REQUIREMENTS

The LAO PI and designee(s) are responsible for maintaining documentation of all oversight activities and related communications with AO sites. These documents should be readily accessible, and may be requested by DCP, the DCP Regulatory Contractor, and/or the DMACC at any time during the duration of the study. Types of documentation include:

- Minutes and reports of relevant internal meetings, including study calls;
- Reports regarding protocol implementation and operations, and other major issues or changes;
- Documents that describe progress, barriers, and outcomes in 'notes to file' as necessary; and
- Communications from DCP, DMACC, the DCP Regulatory Contractor and AO. Communication documents may be requested by DCP or by the DMACC during on-site quality assurance audits.

5. ADDITIONAL INFORMATION

Refer to the CP-CTNet Acronym List to see the description of commonly used acronyms in this SOP.

The DMACC is a resource for both LAO and AO staff. Please contact the DMACC email support groups below for questions or guidance:

Category	Email Support Group
Data Entry in Rave / Data Management / Protocol	DataManagement_CP-CTNet@frontierscience.org
Audit	Audit_CP-CTNet@frontierscience.org
Registration / Randomization	Enrollment_CP-CTNet@frontierscience.org
Access to Systems (e.g., Portal Gateway, Medidata)	UserSupport_CP-CTNet@frontierscience.org
Contact Management	ContactAdmin_CP-CTNet@frontierscience.org

6. REFERENCES

- None

7. APPENDICES

- None