# Guidelines for Modifications to a Lead Academic Organizational Roster

Modifications to a Lead Academic’s organizational roster must be requested via the web-based Roster Management System from the Lead Academic Organization (LAO) Principal Investigator (PI) or anyone designated as a site coordinator. All roster modifications must be approved by the Director of the CP-CTNet.

Lead Academic Organization modifications include:

* Adding an Affiliate Organization (AO)
* Inactivating an AO

## I. Adding a new Affiliate Organization

An institution may be added to an LAO’s roster as an AO at the request of the LAO PI after approval from the DCP CP-CTNet Director.

The request must be submitted via the CP-CTNet Roster Management System available at: https://applications.prevention.cancer.gov/cp-ctnet independent of the review cycle. Proposed AOs should *not* be included as performance sites in a concept’s proposed organizational roster without prior DCP approval.

A. The following documentation must be submitted.

1. A request from the LAO PI or a designated site coordinator to add the institution as an AO.
2. An LAO Letter of Commitment stating the proposed AO’s potential contributions to the LAO in successfully conducting clinical trials within the DCP Cancer Prevention Clinical Trials Network Program.

This should include a description of:

* the clinical skills and expertise of the investigator(s) and other staff in completing multi-institutional clinical trials,
* the access to and ability to accrue appropriate/targeted populations,
* the laboratory and staff resources to support translational research and correlative studies,
* an institution’s “track record” in participating in clinical trials research (i.e. timely accrual to clinical trials, few deficiencies noted during site monitoring visits, etc.).
1. A Site Letter of Commitment from the proposed AO’s investigator(s) stating the willingness to participate in the Consortium.
2. A Site PI Curriculum Vitae or NIH Biosketch of the proposed AO investigator(s).

**Note: The Letters of Commitment for the LAO and AO as well as the Site PI CV or NIH Biosketch must be uploaded into the Roster Management System.**

B. The request will be reviewed and approved or disapproved by the CP-CTNet Director. When a decision has been made by the CP-CTNet Director, the Associate Director for Clinical Research will be notified.

The following criteria will be considered during this review:

* Based on its “track record”, will the proposed AO complement and/or expand the capabilities of the LAO?
* Are the facilities and staff qualifications adequate and appropriate to support the LAO’s objectives?
* Does the proposed AO have access to relevant study populations and experience in participant recruitment and retention in clinical trials?
* Are there concerns regarding the proposed AO’s ability to participate effectively in multi-center clinical trials?
* Are there other criteria specific to the proposed AO and the LAO that should be evaluated prior to final approval, e.g. competing commitments to other clinical trials groups, or competing trials?

Approval of the AO does *not* constitute approval of additional funds. If funds are required for a new site to accrue to a specific trial, a revised budget request must be submitted to the CP-CTNet Director, study Medical Monitors and Scientific Leads.

C. The decision about adding theAO will be sent via an e-mail notification from the CP-CTNet Roster Management System. The LAO site coordinators will receive one of the following two responses:

* 1. AO Approved

If the AO will participate in a specific clinical trial (new or ongoing), then the LAO must collect and submit all required regulatory and administrative documents for the AO.

* 1. AO Disapproved

The reason(s) for not approving the AO will be documented in the Roster Management system. The LAO may be given the opportunity to address the problem areas and resubmit the request via the Roster Management System. All resubmitted requests will be reviewed by the CP-CTNet Director. Resubmitted requests will be subject to the same review process as the original submission.

II. Adding an Affiliate Organization that is a Member of Another LAO

If an LAO wants to add a site that is already a member of another LAO, the requesting LAO will only need to provide a justification letter which should include the following information:

* a rationale for adding a new site
* the relevant PI (or PIs) at the site
* Outline the specific capabilities that the site has

The approval process is the same as outlined above.

### III. Inactivating an Affiliate Organization

An AO may be inactivated from an LAO roster at the discretion of the LAO PI or as required by DCP.

A. The LAO PI should notify the CP-CTNet Director and the Protocol Information Office of the intent to inactivate an AO from the roster.

* 1. DCP may choose to inactivate an AO from an LAO roster if the institution fails to meet the performance requirements specified in the grant. This may include but not be limited to non-compliance with regulatory requirements, data and safety monitoring guidelines, participation in competing studies, and/or competing commitments to other clinical trials groups.