

Title: CP-CTNet Responsibilities for Personnel Changes

Version: 3.0

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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
3.0	NOV-03-2025	Updated DMACC to DMASC throughout the document. Updated the contact information for the CP-CTNet Program Director in Appendix III <i>Checklist for Change of CP-CTNet LAO, Accruing LAO, or AO PI</i> .
2.0	JUN-17-2025	Clarified that the LAO Coordinator or designee is responsible for the activities outlined in this document (unless otherwise noted). Removed the step of DMACC sending the checklists to the requestors since the checklists are included in the appendices of this document. Made major updates throughout the document to simplify how the information is presented. Also made editorial updates throughout the document.
1.0	OCT-23-2023	Original version of document.

1. INTRODUCTION AND PURPOSE

If there is a change in personnel at an institution participating in the Cancer Prevention Clinical Trials Network (CP-CTNet), the LAO providing oversight for the institution is expected to contact the Data Management, Auditing, and Statistical Center (DMASC) to ensure that all personnel access is set up or amended appropriately. Examples of personnel changes include, but are not limited to, a staff member being hired or leaving a Lead Academic Organization (LAO), accruing LAO, or Affiliated Organization (AO), or a change in a Principal Investigator (PI). Sending appropriate and timely notifications of staffing changes to DMASC ensures the security of CP-CTNet data and facilitates the network's overall responsiveness to staffing changes. Additional steps are required for a change in an LAO, accruing LAO, or AO PI and are outlined below.

This policy also includes procedures for requesting updates to email groups, including adding or removing members, and creating new email groups. This reference guide applies to all CP-CTNet LAOs, accruing LAOs, and AOs.

2. DEFINITIONS

Term	Definition
AO	Affiliated Organization
CIRB	Central Institutional Review Board
CP-CTNet	Cancer Prevention Clinical Trials Network
CTEP	Cancer Therapy Evaluation Program
DCP	Division of Cancer Prevention
DMASC	Data Management, Auditing, and Statistical Center
DTL	Delegation of Tasks Log
I-SCORE	Investigators' and Site Coordinators' Opportunity for Research Excellence
LAO	Lead Academic Organization
M-SOP	Manual of Standard Operating Procedures
PI	Principal Investigator
PIO	Protocol Information Office
RCR	Registration and Credential Repository
SOP	Standard Operating Procedure

3. RESPONSIBILITIES FOR THE ADDITION OF OR CHANGES TO LAO, ACCRUING LAO, OR AO PERSONNEL

1. When adding new personnel, the LAO Coordinator or designee must follow the steps outlined in Appendix I *Checklist for New Personnel at CP-CTNet LAOs, Accruing LAOs, and AOs*. The completed checklist is for LAO use only and does not need to be submitted to DMASC.
2. When there is a change in roles for existing personnel (e.g., a Data Manager becomes a Coordinator, etc.), the LAO Coordinator or designee must:
 - 2.1. Send an email to Admin_CP-CTNet@frontierscience.org to notify DMASC. This email should include the following information:
 - The individual's name, contact information (email address, work phone number, and work mailing address), LAO, accruing LAO, or AO name, LAO, accruing LAO, or AO CTEP code, and previous role in the network (e.g., Data Manager, Coordinator, etc.).

- The individual's changed role in the network.
- Any revisions to the list of email groups that the individual should be included on, if known.
- Any revisions to the list of studies that the individual will be working on, as applicable.

4. RESPONSIBILITIES FOR THE DEPARTURE OF LAO, ACCRUING LAO, OR AO PERSONNEL

1. When personnel leave an institution or are no longer participating in CP-CTNet, the LAO Coordinator or designee must follow the steps outlined in Appendix II *Checklist for Departing Personnel at CP-CTNet LAOs, Accruing LAO, and AOs*. The completed checklist is for LAO use only and does not need to be submitted to DMASC.

5. RESPONSIBILITIES FOR A CHANGE OF AN LAO, ACCRUING LAO, OR AO PI

1. To officially change the PI of an LAO, accruing LAO, or AO, the LAO Coordinator or designee must complete the steps outlined in Appendix III *Checklist for Change of CP-CTNet LAO, Accruing LAO, or AO PI*. The completed checklist is for LAO use only and does not need to be submitted to DMASC.

6. EMAIL GROUP MEMBERSHIP

1. Requests for updates (addition or removal of members) to email groups should be sent to ContactAdmin_CP-CTNet@frontierscience.org for review and approval.
2. Requests for the creation of new email groups should be sent to ContactAdmin_CP-CTNet@frontierscience.org for review and approval. The request should include:
 - 2.1. The purpose of the email group.
 - 2.2. The list of members who should be included, with their respective email addresses.
 - 2.3. The duration of use.

New email group requests will be reviewed, and the requestor will be informed when the email group has been approved and created, or if the email group has been disapproved and the reason for the disapproval.

7. REVIEW OF CONTACT DIRECTORY AND EMAIL GROUPS

1. To maintain an updated Contact Directory on the CP-CTNet DMASC public website and updated email groups, the DMASC Administrative and Coordinating Unit performs updates as follows:
 - 1.1. In real-time when personnel changes are submitted to Admin_CP-CTNet@frontierscience.org.
 - 1.2. In conjunction with the annual I-SCORE meeting. The DMASC Administrative and Coordinating Unit conducts a detailed annual review of the Contact Directory on the CP-CTNet DMASC public website and email groups to determine if any member needs to be added or removed. As applicable, they also follow up with the LAO Coordinator at each LAO and CP-CTNet Leadership to ask for assistance with identifying any additional members who need to be added or removed.

8. ADDITIONAL INFORMATION

Please send questions and comments to DMASC at Documentation_CP-CTNet@frontierscience.org.

9. REFERENCES

Note: All CP-CTNet SOPs are included in the [CP-CTNet Manual of Standard Operating Procedures \(M-SOP\)](#), which is available on the [CP-CTNet DMASC public website](#).

Resource	ID	Location
CIRB SOPs	SOP	ncicirb.org
CP-CTNet DMASC Public Website	Website	cp-ctnet-dmasc.org
CP-CTNet Manual of Standard Operating Procedures (M-SOP)	SOP	Program Resources
DCP Delegation of Tasks Log	Reference	Program Resources
DCP Delegation of Tasks Log – Individual Staff	Reference	Program Resources
DCP Delegation of Tasks Log – Site Principal Investigator	Reference	Program Resources
Essential Records Submission for Sponsor's Trial Master File	SOP 01-01	Program Resources
Lead Academic Organization Oversight Activities	SOP 03-03	Program Resources
Public Website and Portal Gateway Overview and User Registration Guide	USRMAN02	Program Resources

10. APPENDICES

1. Appendix I - Checklist for New Personnel at CP-CTNet LAOs, Accruing LAOs, and AOs
2. Appendix II - Checklist for Departing Personnel at CP-CTNet LAOs, Accruing LAOs, and AOs
3. Appendix III - Checklist for Change of CP-CTNet LAO, Accruing LAO, or AO PI

Appendix I

Checklist for New Personnel at CP-CTNet LAOs, Accruing LAOs, and AOs

Requestor Name:

New Staff Member Name:

LAO, Accruing LAO, or AO Name:

- ☐ Email Admin_CP-CTNet@frontierscience.org to notify DMASC of the new staff member. Include the following:
 - The new individual's name, contact information (email address, work phone number, and work mailing address), LAO, accruing LAO, or AO name, and LAO, accruing LAO, or AO CTEP code.
 - The new individual's role in the network.
 - A list of email groups that the new individual should be added to, if known.
 - A list of studies that the new individual will be working on, as applicable.
- ☐ Proxy-request a [CP-CTNet DMASC Portal Gateway](#) account and associated study and systems access for the new staff member. See USRMAN02 *Public Website and Portal Gateway Overview and User Registration Guide* for more information.
- ☐ Ensure that the RCR is updated for the new staff member. The DCP Regulatory Contractor assures that new staff have completed their required documents in the RCR.
- ☐ Ensure that the DTL and any additional essential records are updated for the new staff member. Accruing LAOs and AOs submit the updated record(s) to the LAO. The LAO sends an email to regulatory@ccsainc.com with the updated DTL for their institution and their accruing LAOs and AOs to notify the DCP Regulatory Contractor about the new staff member. See SOP 01-01 *Essential Records Submission for Sponsor's Trial Master File* and SOP 03-03 *Lead Academic Organization Oversight Activities* for more information. Submit to the LAO, accruing LAO, or AO IRB(s), as needed.

Requestor Signature:

Date Completed:

Appendix II

Checklist for Departing Personnel at CP-CTNet LAOs, Accruing LAOs, and AOs

Requestor Name:

Departing Staff Member Name:

LAO, Accruing LAO, or AO Name:

☐ Email Admin_CP-CTNet@frontierscience.org to notify DMASC of the departing staff member. Include the following:

- The individual's name, contact information (email address, work phone number, and work mailing address), LAO, accruing LAO, or AO name, and LAO, accruing LAO, or AO CTEP code.
- The date that the individual is leaving CP-CTNet (e.g., retirement date, last date of employment for the CP-CTNet position, last date of employment with the institution, etc.).
- Years of service to CP-CTNet and follow-up contact information, if feasible/applicable, so that CP-CTNet Leadership can thank the individual for their contributions to CP-CTNet.
- A list of email groups that the departing individual should be removed from, if known.

Note: If this is an instance where an individual is not leaving the institution but will no longer be participating in CP-CTNet, please indicate this in the notification email.

☐ Proxy-request the removal of the [CP-CTNet DMASC Portal Gateway](#) account and associated study and systems access for the departing staff member. See USRMAN02 *Public Website and Portal Gateway Overview and User Registration Guide* for more information.

☐ Ensure that the RCR is updated (as needed) for the departing staff member prior to their departure. If requested by the LAO, the DCP Regulatory Contractor can confirm if any records are missing in the RCR for the departing staff member.

☐ Ensure that the DTL and any additional essential records are updated for the departing staff member. Accruing LAOs and AOs submit the updated record(s) to the LAO. The LAO sends an email to regulatory@ccsainc.com with the updated DTL for their institution and their accruing LAOs and AOs to notify the DCP Regulatory Contractor about the departing staff member. The DCP Regulatory Contractor deactivates the email reminders regarding expiring records. See SOP 01-01 *Essential Records Submission for Sponsor's Trial Master File* and SOP 03-03 *Lead Academic Organization Oversight Activities* for more information. Submit to the LAO, accruing LAO, or AO IRB(s), as needed.

Requestor Signature:

Date Completed:

Appendix III
Checklist for Change of CP-CTNet LAO, Accruing LAO, or AO PI

Requestor Name:

New LAO, Accruing LAO, or AO PI Name:

LAO, Accruing LAO, or AO Name:

☐ Email a request to change the LAO, accruing LAO, or AO PI to Don Johnsey, CP-CTNet Program Official at johnseyd@mail.nih.gov and Goli Samimi, CP-CTNet Program Director at goli.samimi@nih.gov. The email should include the following information and documentation:

☐ A formal letter, addressed to Goli Samimi, requesting the change:

Goli Samimi, PhD, MPH
CP-CTNet Program Director
Breast and Gynecologic Cancer Research Group
Division of Cancer Prevention
9609 Medical Center Drive
Rockville, MD 20850

☐ A copy of the CV/biosketch for the new LAO, accruing LAO, or AO PI.

☐ A revised budget/justification if any budget category will change by more than 25% of your total budget due to this change (LAOs only).

Once the change of LAO, accruing LAO, or AO PI has been approved by the CP-CTNet Program Director and notification of approval has been received:

☐ Email Admin_CP-CTNet@frontierscience.org to notify DMASC of the new PI. Include the following:

- The new LAO, accruing LAO, or AO PI's name, contact information (email address, work phone number, and work mailing address), LAO, accruing LAO, or AO name, and LAO, accruing LAO, or AO CTEP code.
- The departing LAO, accruing LAO, or AO PI's name and contact information (email address, work phone number, and work mailing address).

☐ Submit a protocol amendment to notify the CIRB about the LAO, accruing LAO, or AO PI change (see the *CIRB SOPs, section 8.5.2* for more information).

☐ Report this change to PIO with the accompanying protocol amendment that reflects this change.

☐ Follow the procedures for onboarding new personnel and the corresponding *Checklist for New Personnel at CP-CTNet LAOs, Accruing LAOs, and AOs* for the new LAO, accruing LAO, or AO PI.

☐ Follow the procedures for departure of personnel and the corresponding *Checklist for Departing Personnel at CP-CTNet LAOs, Accruing LAOs, and AOs* for the departing LAO, accruing LAO, or AO PI.

Requestor Signature:

Date Completed: