Title: **CP-CTNet Responsibilities for Personnel Changes**

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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
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 institution is expected to contact the Data Management, Auditing, and Coordinating Center (DMACC) to ensure that all appropriate permissions, directories, and email groups are set up or amended for that individual. Examples of personnel changes include, but are not limited to, a staff member being hired or leaving a Lead Academic Organization (LAO) or Affiliated Organization (AO), or a change in a Principal Investigator (PI). Sending appropriate and timely notifications of staffing changes to DMACC 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 or AO PI and are outlined below.

This policy also includes procedures for requesting updates to email groups, including adding or removing members, or creating a new email group. This reference guide applies to all CP-CTNet 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
DMACC	Data Management, Auditing, and Coordinating 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 OR AO PERSONNEL

1. When adding new personnel, the PI, Coordinator, or designee at the LAO or AO must:

    1.1. Send an email to Admin_CP-CTNet@frontierscience.org to notify DMACC. This email should include the following information:

    - The new individual's name, contact information (email address, work phone number, and work mailing address), LAO or AO name, and 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.

2. A member of the DMACC Administrative and Coordinating Unit sends the *Checklist for New Personnel at CP-CTNet LAOs and AOs* to the new individual's PI, Coordinator, and/or designee at the LAO or AO for completion (see Appendix I for more information).

2.1.   The new individual's Coordinator or designee at the LAO or AO should retain the completed checklist at their institution. The completed checklist does not need to be submitted to DMACC.

3.   DMACC follows their work instructions to document the new staff member and assists with their account setup once the steps in the *Checklist for New Personnel at CP-CTNet LAOs and AOs* are completed.

4.   When there is a change in roles for existing personnel (e.g., an AO Data Manager becoming a Coordinator, etc.), the PI, Coordinator, or designee at the LAO or AO must:

4.1.   Send an email to Admin_CP-CTNet@frontierscience.org to notify DMACC. This email should include the following information:

- The individual's name, contact information (email address, work phone number, and work mailing address), LAO or AO name, LAO or AO CTEP code, and previous role in the network (PI, Coordinator, Data Manager, etc.).

- The individual's new/changed role in the network.

- Any revisions to the list of email groups that the individual should be added to, 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 OR AO PERSONNEL

1.   When personnel leave an institution or are no longer participating in CP-CTNet, the PI, Coordinator, or designee at the LAO or AO must:

1.1.   Send an email to Admin_CP-CTNet@frontierscience.org to notify DMACC. This email should include the following information:

- The individual's name, contact information (email address, work phone number, and work mailing address), LAO or AO name, and 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.

- 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.

2.   A member of the DMACC Administrative and Coordinating Unit sends the *Checklist for Departing Personnel at CP-CTNet LAOs and AOs* to the departing individual's PI, Coordinator, and/or designee at the LAO or AO for completion (see Appendix II for more information).

2.1.   The departing individual's Coordinator or designee at the LAO or AO should retain the completed checklist at their institution. The completed checklist does not need to be submitted to DMACC.

3.   DMACC follows their work instructions to document the departing staff member and assists with their account deactivation once the steps in the *Checklist for Departing Personnel at CP-CTNet LAOs and AOs* are completed.

4.   The LAO providing oversight sends an email to regulatory@ccsainc.com with the updated DTL to notify the DCP Regulatory Contractor about the departing individual. The DCP Regulatory Contractor deactivates the email reminders regarding expiring documents.

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

1. To officially change the PI of an LAO or AO, the PI, Coordinator, or designee at the LAO or AO must complete the steps outlined in Appendix III. This change must be approved by the DCP Program Director.

2. Once the change has been approved by the CP-CTNet Program Director, notification will be sent to the LAO or AO by the CP-CTNet Program Official. Once this notification is received:

   2.1. The PI, Coordinator, or designee at the LAO or AO sends an email to Admin_CP-CTNet@frontierscience.org to notify DMACC. This email should include the following information:

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

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

   2.2. The LAO must submit a protocol amendment to notify the CIRB about the LAO or AO PI change (see the *CIRB SOPs, section 8.5.2* for more information).

3. A member of the DMACC Administrative and Coordinating Unit sends the person who provided notification of the LAO or AO PI change the *Checklist for New Personnel at CP-CTNet LAOs and AOs* to be completed for the new LAO or AO PI, as well as the *Checklist for Departing Personnel at CP-CTNet LAOs and AOs* to be completed for the departing LAO or AO PI. See Appendix I and Appendix II for more information.

   3.1. The completed checklists should be retained at the PI's institution. The completed checklists do not need to be submitted to DMACC.

4. DMACC follows their work instructions to implement these changes once the steps in each checklist are completed.

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.

3. New email group requests will be considered, and the requestor will be informed when the email group has been approved and created.

7. REVIEW OF CONTACT DIRECTORY AND EMAIL GROUPS

1. To maintain an updated Contact Directory on the CP-CTNet DMACC website and updated email groups, the DMACC 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 DMACC Administrative and Coordinating Unit conducts a detailed annual review of the Contact Directory on the CP-CTNet DMACC website and email groups to determine if any member needs to be added or removed. As applicable, they also follow

up with the 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 DMACC at Documentation_CP-CTNet@frontierscience.org.

9. REFERENCES

Note: All CP-CTNet SOPs are included in the *CP-CTNet M-SOP*, which is available on the CP-CTNet DMACC public website.

Resource	ID	Location
CIRB SOPs	SOP	ncicirb.org
CP-CTNet DMACC Public Website	Website	cp-ctnet-dmacc.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 Documents Submission for Sponsor's Record	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 and AOs

2. Appendix II - Checklist for Departing Personnel at CP-CTNet LAOs and AOs

3. Appendix III - Checklist for Change of CP-CTNet LAO or AO PI

Appendix I
Checklist for New Personnel at CP-CTNet LAOs and AOs

Requestor Name:
New Staff Member Name:
LAO or AO Name:

☐ Email Admin_CP-CTNet@frontierscience.org to notify DMACC 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 or AO name, and 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.

☐ The LAO Coordinator or designee proxy-requests a CP-CTNet DMACC 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.

☐ Update the RCR for the new staff member. The DCP Regulatory Contractor assures that new staff have completed their required documents in the RCR.

☐ Update the DTL and any additional essential documents. Accruing LAOs and AOs submit the updated document(s) to the LAO. LAOs providing oversight submit the DTL for their institution and their accruing LAOs and AOs to the DCP Regulatory Contractor as per SOP 01-01 *Essential Documents Submission for Sponsor's Record* and SOP 03-03 *Lead Academic Organization Oversight Activities*. Submit to the LAO or AO IRB(s), as needed.

Requestor Signature:
Date Completed:

Appendix II
Checklist for Departing Personnel at CP-CTNet LAOs and AOs

Requestor Name:
Departing Staff Member Name:
LAO or AO Name:

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

- The individual's name, contact information (email address, work phone number, and work mailing address), LAO or AO name, and 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.

- 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.

☐ The LAO Coordinator or designee proxy-requests the removal of the CP-CTNet DMACC 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 documents are missing in the RCR for the departing staff member.

☐ Update the DTL and any additional essential documents. Accruing LAOs and AOs submit the updated document(s) to the LAO. LAOs providing oversight submit the DTL for their institution and their accruing LAOs and AOs to the DCP Regulatory Contractor as per SOP 01-01 *Essential Documents Submission for Sponsor's Record* and SOP 03-03 *Lead Academic Organization Oversight Activities*. Submit to the LAO or AO IRB(s), as needed.

Requestor Signature:
Date Completed:

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

Requestor Name:
New LAO or AO PI Name:
LAO or AO:

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

    ☐ A formal letter, addressed to Eva Szabo, requesting the change:

        Eva Szabo, MD
        CP-CTNet Program Director; Head Medical Monitor
        Chief Lung and Upper Aerodigestive Cancer Research Group
        9609 Medical Center Drive
        Room 5E-102
        Bethesda, MD 20892

    ☐ A copy of the CV/biosketch for the new 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 or AO PI has been approved by the CP-CTNet Program Director:

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

☐ The LAO must report this change to PIO with the accompanying protocol amendment that reflects this change.

☐ The PI, Coordinator, or designee at the LAO or AO follows the procedures for onboarding new personnel and the corresponding *Checklist for New Personnel at CP-CTNet LAOs and AO*s for the new LAO or AO PI.

☐ The PI, Coordinator, or designee at the LAO or AO follows the procedures for departure of personnel and the corresponding *Checklist for Departing Personnel at CP-CTNet LAOs and AOs* for the departing LAO or AO PI.

Requestor Signature:
Date Completed: