

Title: Reviewing and Amending Standard Operating Procedures

Document ID: CP-CTNet SOP 02-05

Version: 1.0

Version Date: August 05, 2020

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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 Division of Cancer Prevention (DCP) CP-CTNet Standard Operating Procedures (SOPs) are written standard procedures that describe the responsibilities of the network's Lead Academic Organizations (LAOs) and Affiliate Organizations (AOs).

The DCP CP-CTNet SOPs are located on the [Data Management Auditing and Coordinating Center \(DMACC\) Portal Gateway](#).

2. SCOPE

This document details the responsibilities of the DCP, Data Management Auditing and Coordinating Center (DMACC), LAOs and AOs throughout the creation, review, amendment, and documentation process for CP-CTNet SOPs.

3. SOP CREATION AND REVIEW

- 3.1. The first iteration of the CP-CTNet SOPs will be written by DCP and the DMACC; then reviewed by the LAOs (each LAO will determine the reviewer); and then sent to the CP-CTNet Steering Committee for final approval.
- 3.2. The SOPs will become effective within five (5) business days after posting to the CP-CTNet website.
- 3.3. The SOPs require review by DCP and the DMACC annually, and ad hoc, with the latest version superseding earlier versions (annual review will be formally performed by DCP and the DMACC, with LAO and Steering review requested for major changes);
- 3.4. The LAOs will review the SOPs with the AOs annually, or as updated by DCP/DMACC, to ensure understanding.

4. AMENDING SOPS

- 4.1. CP-CTNet SOPs are to be adopted by the LAO and AO sites as written unless they are in direct conflict with local institutional policy. If this is the case, the LAO may amend the applicable SOPs only after obtaining approval from DCP.
- 4.2. If LAO and/or AO Principal Investigators (PIs) or Site Coordinators need to amend SOP(s) to comply with institutional policies, the LAO will:
 - 4.2.1. Collect all LAO and AO amendment requests and electronically submit them as a package to the DMACC (Audit_CP-CTNet@frontierscience.org). DMACC and DCP study staff will review the package.

The submission package will include:

- A cover letter requesting the changes to the SOPs including rationale for the requested changes;
- The 'clean' copy of the revised SOPs with a 'Site Version Date' in the footer;
- The 'tracked changes' copy of the revised SOPs with the 'Site Version Date' in the footer.

- 4.2.2. Communicate DCP's decision regarding the amended SOPs to all applicable LAO and AO staff.
- 4.2.3. Add the 'Effective Site Version Date' to the footer of the amended SOPs once approved by DCP.
- 4.2.4. Distribute the DCP-approved amended SOPs to all applicable LAO and AO staff for their use.

5. DOCUMENTATION REQUIREMENTS

The DMACC will distribute new and revised SOPs (including SOPs revised due to institutional policy) with a Sign-off Sheet. LAO and AO staff involved in trial conduct should read the SOPs and sign the sheet to confirm they have read them. Any new staff should also sign off on the SOPs. This sheet should be maintained at each site and will be reviewed during audit visits. The LAOs and AOs should maintain all approved CP-CTNet SOPs on file at each site. The SOPs that have been amended to meet institutional policies will not be posted on the CP-CTNet website.

6. ADDITIONAL INFORMATION

Refer to the [CP-CTNet Acronym List](#) to see the description of commonly used acronyms in this SOP.

Please send questions and comments to Audit_CP-CTNet@frontierscience.org.

7. REFERENCES

- None

8. APPENDICES

- None