Title:	**Site Activation**
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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
Interim 1.0	XXX-XX-YYYY	Original version of document

1. INTRODUCTION AND PURPOSE

The purpose of this document is to provide site activation requirements for the Cancer Prevention Clinical Trials Network (CP-CTNet) studies. Lead Academic Organizations (LAOs) should follow the CP-CTNet Program Guidelines for protocol submissions, development, and review. All required regulatory documentation and approvals must be obtained prior to any site activating a study. LAOs are responsible for study oversight including conducting Study Initiation Meetings and assisting Affiliated Organizations (AOs) with meeting all regulatory and documentation requirements before activation at their site. An active site is defined as an institution or clinical site that, after having completed regulatory and DCP requirements for study initiation, has been initiated/activated in the Stars registration/randomization system by The Data Management Auditing and Coordinating Unit (DMACC), and is open to enroll/accrue patients. Stars is the web based enrollment system hosted at the DMACC to enter participant pre-screening and screening data (including some of the data items related to the Accrual Quality Improvement Program (AQuIP)), and to enroll participants to a study.

2. SCOPE

This document details the requirements and steps for LAOs, AOs, DMACC, DCP, and the DCP Regulatory Contractor that must be completed before activating a site to a study.

3. REQUIRED STEPS FOR SITE ACTIVATION

1. After the PIO has issued the "Approval on Hold" letter and the CIRB has approved the protocol, LAOs organize and conduct a Study Initiation Meeting internally at their site and with the AOs who are named as "Accrual Organizations" for the study. (Refer to SOP 01-02 Study Initiation Meeting).
2. The DCP regulatory contractor sends a protocol-specific Delegation of Tasks Log (DTL) in electronic format to the LAO when a protocol has received initial approval by DCP's CPC-CIRB. The regulatory contractor lists the protocol information as well as the site information, excluding the CTEP-Site ID. AOs provide information for the remaining sections in the DTL. The DCP Regulatory Contractor forwards the protocol-specific signed DTLs for each site to DMACC.
3. The LAO confirms that necessary sub-contracts are in place for each AO.
4. The LAO and AOs prepare required regulatory documents. The DCP Regulatory Contractor collects all necessary regulatory documents (refer to SOP 01-01 Regulatory Documents).
5. For each site, once all regulatory documents are in place:
   - If study drug is provided through the DCP repository, the DCP Regulatory Contractor notifies the site that drug shipment is authorized for that site and copies the PIO, the DCP study team (Medical Monitor, Scientific Lead, Nurse Consultant), and drug distributor (NCI repository contractor), LAO, and DMACC on this approval.
   - If the drug is from an outside source or there is no study drug, the DCP Regulatory Contractor sends an email to the PIO, the DCP study team (the Medical Monitor, Scientific Monitor, Nurse Consultant), LAO, and DMACC indicating that all regulatory documents for the site are in place.
6. The site orders study drug through MRI Global or other repository (if applicable) by completing an Investigational Agent Request.
7. Once study drug is received on site, the study pharmacy at the LAO or AO notifies MRI Global or other repository (if applicable), that they acknowledge receipt. AOs also copy LAOs.
8. The LAO confirms that all necessary site activation steps above have been completed. See Appendix I - Site Activation Checklist for LAOs. Once an accruing site has met all study activation requirements as outlined in Appendix 1, the LAO sends a confirmation email to DMACC, and the DCP study team (Medical Monitor, Scientific Lead, and Nurse Consultant).

NOTE: If there is no drug involved in the study intervention or if the drug is being prescribed locally, step 8 is done after step 4, once all regulatory documents are in place and confirmed by the DCP Regulatory Contractor.

9. DMACC activates the site in their Protocol Approval Utility (PAU). The PAU is a database at DMACC that tracks the site-specific activation dates to a study or amendment and allows site-specific access to Stars.
10. DMACC processes requests for logins/passwords for Stars and Rave for the sites (if not already done following the Study Initiation Meeting). LAOs submit login/password requests for the sites via the DMACC Gateway Portal. The User Support team at DMACC (UserSupport_CP-CTNet@frontierscience.org) is available to assist with any questions. DMACC also confirms access requests by checking the site-specific Delegation of Tasks Log.
11. DMACC sends a "Confirmation of Activation" email (copying PIO, LAO, AO (if applicable), regulatory contractor, and DCP study staff (Medical Monitor, Scientific Lead, and Nurse Consultant) to indicate the site is officially opened in Stars and the site may now begin pre-screening/screening activities). The LAO and AO file this email in their Investigator Site File for the study.
12. LAO completes and submits a "Protocol Status Update Form" to PIO to indicate that the study is active and open to accrual when the first site is activated.

4. SITE ACTIVATION OF STUDY AMENDMENTS

1. Once CIRB and DCP approval are given for a study amendment, the LAO needs to follow site institutional procedures and obtain notifications/approvals/acknowledgements (if applicable).
2. The LAO confirms that all necessary site activation requirements have been completed for the amendment. (See Appendix I Site Activation Checklist for LAOs.) Once an accruing site has met all study activation requirements, the LAO sends a confirmation email to DMACC and DCP.
3. DMACC activates the site to the Amendment in their Protocol Approval Utility (PAU) database. This is required before the site can use any updated eligibility checklists/enrollment screens in Stars or amended eCRFS in Rave or apply/enact any modifications included in the amendment.
4. DMACC sends a "Confirmation of Activation: Amendment" email (copying PIO, LAO, AO (if applicable)), regulatory contractor, and DCP study staff (Medical Monitor, Scientific Lead, and Nurse Consultant) to indicate the site is now activated to the amendment.

5. 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 DataManagement_CP-CTNet@frontierscience.org

6. REFERENCES

- None

7. APPENDICES

- Appendix 1 - Site Activation Checklist for LAOs

CP-CTNet Site Activation Checklist for LAOs

Once all requirements are met, inform DMACC (DataManagement_CP-CTNet@frontierscience.org) in order to initiate the activation of the Site in Stars. DMACC will send the Site and LAO a Confirmation of Activation email.

Study: Version:

LAO responsible for study:

Site Name: Site Code:

Site Principal Investigator:

Regulatory Approvals (enter approval dates and version (if applicable)

CIRB approval date: Version approved:

Informed consent approval date: Version Approved:

Local IRB approval date: Version approved:

Comments:

Contract in place

Confirmed by LAO or N/A (not applicable)

☐ Yes, date confirmed: ☐ Not applicable

Study Initiation Meeting (List of attendees and topics/agenda and materials should be on file in the TMF and Investigator File)

Date:

Comments:

Systems Access & Password Requests

Rave ☐ Yes ☐ No

Stars ☐ Yes ☐ No

DMACC Portal ☐ Yes ☐ No

Comments:

Regulatory Documents

LAO confirmed with the DCP Regulatory Contractor that all regulatory documents have been prepared and submitted (refer to Regulatory Documents SOP) ☐ Yes ☐ No

Comments:

Study Drugs

Drug Shipment Authorization (date the DCP Regulatory Contractor authorizes drug shipment) or N/A):

☐ Yes, date confirmed (date the DCP Regulatory Contractor authorizes drug shipment): ☐ Not applicable

Date Drug Shipment Acknowledgment of Receipt at AO:

Comments:

General Comments

Completed by Name: Date: