Title: **National Cancer Institute/Division of Cancer Prevention**
Cancer Prevention Clinical Trials Network
Cross-Network Trials Guidelines

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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

This document provides the guideline for cross-network clinical trials for the Cancer Prevention Clinical Trials Network (CP-CTNet).

2. DEFINITION OF CROSS-NETWORK TRIALS AND RESTRICTED FUNDS

A CP-CTNet cross-network trial is a trial involving a collaboration between two or more LAOs whereby each LAO agrees to provide accrual and funding for accrual. Each LAO will receive credit for the participants accrued by its participating AOs and each LAO will be able to access the Rapid Response Restricted Funds. These funds are intended for use to support participant accrual to cross-network trials and/or novel biomarker development and analysis. Steering Committee approval is needed for access to Rapid Response Restricted Funds. Separate guidance will be provided on accessing Rapid Response Restricted Funds for biomarker projects.

2.1. Each LAO must plan to make a substantive contribution to accrual.
2.2. The accrual and biomarker analysis do not need to be divided equally between the LAOs.
2.3. Accrual targets and plans for biomarker analysis will be determined by the collaborating institutions.
2.4. Statistical support for all cross-network trials will be provided by the DMACC Statistical Center
2.5. The following constructs do not meet the definition of a cross-network trial:
- An AO affiliated with one LAO chooses to participate in a second LAO's trial and all accrual costs are provided from the second LAO's budget (the LAO with which the AO is affiliated does not provide funding for the trial).
- An investigator from one LAO's organization chooses to participate in a second LAO's trial and all accrual costs are provided by the second LAO (the LAO at the investigator's organization does not provide funding for the trial).

3. REVIEW OF CROSS-NETWORK TRIALS

Two proposed routes for cross-network trials are possible:

3.1. If two or more LAOs collaborate on concept development, the concept will be submitted to DCP for scientific review.
- Scientific Review of all trials will be provided by the DCP Concept Review Committee as per usual procedures.
- DCP-approved concepts will be reviewed by the Steering Committee for approval to access the Rapid Response Restricted Funds .
- The proposed project will be presented to the Steering Committee for approval by the appropriate LAO Investigator(s). The concept submitted to DCP will be shared with the Steering Committee.
- The budget for the use of Rapid Response Restricted Funds will be presented (e.g., how much of the $100,000/yr of the Funds is being requested by each LAO).
- In order to have a record of the vote, the vote will be done via a confidential electronic or paper process. A letter confirming the approval of the project and funds will be issued by DCP.

3.2. If a trial is already ongoing (and thereby has already undergone DCP scientific review) and there is a desire to convert it to a cross-network trial, the proposed project summary will be presented to the Steering Committee for approval as above. The LAO investigator will provide a short background document providing an overview of the trial, status update, and justification for converting to a cross-network trial.
- Since the trial is ongoing, the original statistician will remain the statistician of record, while DMACC Statistical Center may provide consultation as necessary.

- Conversion to a cross-network trial will allow access to the Rapid Response Restricted Funds.

4. DATA AND SAFETY MONITORING

Data and safety monitoring for cross-network trials will be provided by the Data and Safety Monitoring Committee established by the DMACC, and reporting to the DSMC will be prepared by the DMACC.