Title: Participant Recruitment, Retention and Adherence

Document ID: CP-CTNet SOP 02-04

Version: Interim 1.0

Version Date: April 27, 2020

Document Distribution: Distribution of this document to persons or organizations outside of CP-CTNet without consent is strictly prohibited.
## REVISION HISTORY (most recent first)

<table>
<thead>
<tr>
<th>Version</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim 1.0</td>
<td>XXX-XX-2020</td>
<td>Original version of document.</td>
</tr>
</tbody>
</table>
1. PURPOSE AND INTRODUCTION

The CP-CTNet Recruitment, Retention and Adherence SOP is based on the National Cancer Institute (NCI), Division of Cancer Prevention’s (DCP’s) Accrual Quality Improvement Program (AQuIP). The overall purpose of AQuIP is to foster efficient conduct of clinical trials through efficient participant accrual, to support NCI/DCP’s mission to conduct ethical clinical prevention research, to maintain proper stewardship of public funds, and to facilitate scientific progress.

AQuIP is a multi-component continuous quality improvement program that entails systematic protocol- and site-specific recruitment planning with data-driven accrual rate goals and detailed real-time reporting on accrual activity and actual rates. Frequent monitoring and analysis of these accrual data enables better understanding of performance factors and continuous identification of opportunities for modification of protocol characteristics and outreach modifications.

2. SCOPE

This document provides information for Investigators and Site Coordinators of Lead Academic Organizations (LAOs) and Affiliated Organizations (AOs) regarding formulating, implementing, monitoring and adjusting recruitment, retention and adherence plans.

3. AQuIP

AQuIP provides the LAOs and AOs with six complementary tools. All tools are available on the DMACC Portal Gateway:

1. Recruitment, Retention and Adherence (RRA) Plan Outline Template, a comprehensive fillable PDF planning template.
2. AQuIP Toolkit, a user-friendly library of recruitment resources including a recruitment instruction manual, recruitment materials and templates as well as an image library.
   - Recruitment materials include items designed to inform potential participants about a specific protocol (including but not limited to letters, brochures, telephone scripts, advertisements, websites, webpages, Facebook posts and Tweets).
   - Recruitment materials (i.e., content, mode of communication, and the final copy of the materials) that are for presentation to potential participants. The content must be approved by DCP and the Central Institutional Review Board (CIRB).
   - Recruitment materials are to be submitted to DCP for review via the Protocol Information Office (PIO).
     Note: Different types of recruitment materials for the same study may be submitted through the PIO simultaneously, or at different times. However, every effort should be made to consolidate submissions.
   - Once the materials are approved by DCP, the PIO will forward the materials to the CIRB for review.
   - Recruitment materials are not be included as part of the protocol document itself.
     - If the protocol document refers to recruitment materials, those materials must be submitted as a separate part of the same protocol submission for DCP and CIRB approval.
     - If the protocol document refers to recruitment materials that are not included in the submission, the CIRB will table those protocols until those materials are submitted. For more information about CIRB requirements for submission of recruitment materials, refer to the CIRB SOPs.
If recruitment materials are not referred to in the protocol document (as they are not a required component of the protocol submission), these materials may be submitted for DCP and then CIRB review after the protocol and other associated documents are submitted/approved.

3. **Training and Resources**, a library of recorded webinars as well as links to additional clinical trial resources and accrual support tools compiled to aid LAOs in their ongoing research staff training responsibilities or for use by AOs.

4. Systems to Record Accrual Information:
   - Stars, the system sites will use to generate participant records in the clinical database for the recruitment, screening, and enrollment process.
   - Rave, the electronic data capture (EDC) system that holds the clinical database and that sites will use to record Participant-level Recruitment information as well as study-wide or site-specific Recruitment Journaling information. The Recruitment Journaling information includes events, situations, conditions or efforts that may affect accrual at a particular site and/or the study as a whole as opposed to specific individuals.

5. AQuIP Accrual Tracking and Monitoring Reports, a set of data visualizations produced by the Data Management Auditing and Coordinating Center (DMACC) based on real-time accrual data entered into Stars and Rave by site staff, to facilitate prompt identification of improvement opportunities and provide guidance for responsive interventions to address shortfalls in accrual.

6. Think Tank, a group of CP-CTNet and DCP representatives with expertise in clinical trial management and coordination, assembled to facilitate discussion of real-world clinical trial implementation issues, and collaborative identification of knowledge and training gaps as well as to provide practical feedback for DCP leadership.

### 4. PLANNING RESPONSIBILITIES

Use the [Recruitment, Retention and Adherence (RRA) Plan Outline Template](#) to formulate and document protocol-specific recruitment and retention adherence plans. The plans should include strategies that will be implemented by the Investigators, Site Coordinators, and designees at each enrolling site. The assigned personnel will document which strategies are used to identify and contact each study candidate in order to track implementation and effectiveness of the strategies. Components of the planning requirement are outlined below:

1. The RRA Plan is to be inclusive of each AO plan (as developed in consultation with site Principal Investigator (PI) and Coordinator) and is to be included as part of the second protocol submission to DCP PIO for review. The RRA Plans are to be study- and site-specific.
2. The RRA Plan will be revised per DCP recommendation if needed.
3. The approved RRA Plan is to be distributed to each study AO by the LAOs.

### 5. AQuIP DOCUMENTATION, REPORTING AND OVERSIGHT MONITORING REQUIREMENTS

Data should be entered on a continual basis, and all data fields are required and should be completed.

1. AQuIP data are reviewed carefully by the DMACC, who will aggregate the data, perform data integrity checks, and send data queries back to the sites (LAOs and AOs) for their site’s own data.
2. Each site (LAO and AO) is responsible for resolving or overseeing resolution of data queries within 30 days from identification.
An escalation process is defined for data and or query responses that are overdue:

1. For AOs: If an AO has not responded to requests for overdue data/queries, the DMACC will escalate to the LAO. If there is no resolution, the LAO and DMACC will escalate to the DCP.
2. If a LAO has not responded to requests for overdue data/queries, the DMACC will escalate to the DCP.

The DCP, DMACC and LAOs (as applicable) will work with the sites to determine the reason for the delinquency, and create a plan to address the issue and prevent further issues.

DMACC will generate monthly Monitoring Reports.

1. The LAO will provide oversight of accrual and journal event documentation for their respective AOs to assure timely and accurate data entry.
2. The LAO must review and proactively evaluate the study specific Monitoring Reports and distribute to their AOs.
3. The LAO must assure that the recruitment impediments, strategic corrective actions as well as favorable factors are well documented via site and protocol-level Recruitment Journal Event entries.
4. DCP may require additional recruitment barrier analysis and a corrective action plan for review by the DCP Medical Monitor, Scientific Lead, and DCP Nurse Consultant and approval by the DCP leadership. Depending on the recruitment issues, interventions for improvement will be devised and/or study design modifications or discontinuation will be considered.

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

6. REFERENCES
   • None

7. APPENDICES
   • None