Title: Participant Recruitment, Retention and Adherence

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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. 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 efficient implementation of clinical trials through well-planned, carefully monitored participant accrual in support of NCI/DCP's mission to lead, conduct, and support cancer research across the nation, to advance scientific knowledge and help all people to live longer, healthier lives, while ensuring proper stewardship of public funds.

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 recruitment rates. Frequent monitoring and analysis of accrual data enables a better understanding of performance factors and continuous identification of opportunities for modification of protocol characteristics and outreach methods.

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 Tools and Procedures

AQuIP provides the LAOs and AOs with six complementary tools. ***All tools are available on the Data Management Auditing and Coordinating Center (DMACC Portal Gateway***:

1. Recruitment, Retention and Adherence (RRA) Plan Template, a comprehensive fillable PDF planning template.
    - Use the Recruitment, Retention and Adherence (RRA) Plan Template to formulate and document the recruitment, retention and adherence plans for each protocol.
    - Each protocol RRA Plan will include site-specific strategies for each enrolling site (as developed in consultation with the Site PI and Coordinator) for implementation by the local Investigators, Site Coordinators, and designees.
    - RRA Plans are to be submitted with the first revision (i.e., version 2) of the protocol.
        - The RRA Plan will be revised per DCP recommendation if needed.
        - The approved RRA Plan is to be distributed to each study AO by the LAOs.
2. AQuIP Toolkit, a user-friendly library of recruitment resources including a recruitment instruction manual, templates for recruitment materials, media templates, (and an image library that may be used by recruitment staff.
    - Recruitment materials include items designed to inform potential participants or referral sources 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 and mode of communication) intended for presentation to potential participants 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).

        - Once the materials are approved by DCP, the PIO will forward the materials to the CIRB for review.
    - Recruitment materials are not to 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 referenced 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 any time after the protocol and other associated documents are submitted/approved.

          * 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.

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

4. Systems to Record Accrual Information:
    - Stars is the system that sites will use to obtain assignments of Pre-Screening, Screening, and/or Registration/Randomization IDs for participants, and to generate participant records in the Rave clinical database.
    - Rave is the electronic data capture (EDC) system that holds the clinical database that sites will use to record both participant-level and study-wide or site-specific recruitment information.
        - Participant-level recruitment information includes:
            i. Strategies that were used to identify and contact each study candidate in order to track implementation and effectiveness of the strategies wi
            ii. Reasons for the non-enrollment of each study candidate who does not ultimately start study drug
        - Study-wide or site-specific recruitment information
            i. Events, situations, conditions or efforts that may affect accrual (either positively or negatively) at a particular site and/or all sites as opposed to those that affect one individual participant will be recorded in the Recruitment Journal.

          Note: Details regarding Stars and Rave can be found in the *Stars and Rave User Manual (currently in development).*

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. AQuIP 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. 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. 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 will escalate to the DCP, keeping the DMACC in copy.
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

5. REFERENCES

- None

6. APPENDICES

- None