Title:	**Participant Recruitment, Retention, Adherence and Reporting Requirements**
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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
2.0	SEP-20-2021	This version of the RRA SOP includes updated information about CP-CTNet procedures, resources, and eCRFs used to collect AQuIP-related data. Proofing and formatting updates were applied throughout the SOP.
1.0	AUG-17-2020	Original version of document.

1. PURPOSE AND INTRODUCTION

The CP-CTNet Recruitment, Retention, Adherence and Reporting Requirements SOP pertains to the National Cancer Institute (NCI), Division of Cancer Prevention's (DCP's) Accrual Quality Improvement Program (AQuIP) and the required CP-CTNet Data Management, Auditing and Coordinating Center (DMACC) systems for recording accrual information. The overall purpose of AQuIP is to facilitate efficient implementation of clinical trials through well-planned, carefully monitored participant accrual. AQuIP supports 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 of 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 planning, implementing, monitoring, and adjusting recruitment, retention and adherence (RRA) strategies as well as documenting the recruitment-related information. AQuIP RRA planning covers the enrollment trajectory from study design to site selection to identification of potential participants (pre-screen phase) through first contact, consenting, screening, registration/randomization to starting the study intervention. Detailed instructions for completing the RRA Plan are embedded in the fillable PDF planning form. All activities should be consistent with Good Clinical Practice (GCP).

3. AQUIP TOOLS AND PROCEDURES

AQuIP provides LAOs and AOs with six complementary tools. ***All tools are available on the CP-CTNet DMACC Public Website and Portal Gateway***:

1. RRA Plan: a comprehensive fillable PDF planning form.
    1.1. Use the RRA Plan to formulate and document study- and site-specific plans for ensuring appropriate recruitment, retention and adherence for each protocol.
    1.2. Each protocol RRA Plan includes site-specific strategies for each enrolling site (as developed in consultation with the Site Principal Investigator (PI) and Coordinator for implementation by the local Investigators, Site Coordinators, and designees).
    1.3. RRA Plans are submitted with the first revision (e.g., version 2) of the protocol.
        1.3.1. The RRA Plan is revised per DCP recommendation if needed.
        1.3.2. The approved RRA Plan is distributed to each study AO by the LAO.
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.
    2.1. 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, social media announcements, etc.).

2.2. Recruitment materials (e.g., content and mode of communication) intended for presentation to potential participants must be approved by DCP and the Central Institutional Review Board (CIRB).

2.2.1. Recruitment materials* are submitted to DCP for review via the Protocol Information Office (PIO).

2.2.1.1. Once the materials are approved by DCP, the PIO forwards the materials to the CIRB for review.

2.3. Recruitment materials are not to be included as part of the protocol document itself.

2.3.1. 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.

2.3.2. If the protocol document refers to recruitment materials that are not included in the submission, the CIRB tables those protocols until those materials are submitted. For more information about CIRB requirements for submission of recruitment materials, refer to the CIRB SOPs.

2.3.2.1. Click the link to view and download the current version of the CIRB SOPs.

2.3.3. 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:

4.1. Stars is the system that sites use to obtain Participant ID assignments for Pre-Screening, Screening, and/or Enrollment (Registration/Randomization). The Stars system is also used to generate participant records in the Rave clinical database.

4.2. Rave is the electronic data capture (EDC) system that holds the clinical database that sites use to enter both participant-level and site-specific recruitment information.

4.2.1. Participant-level recruitment information includes:

4.2.1.1. Strategies used to identify and contact each study candidate – in order to track the implementation and effectiveness of recruitment strategies.

4.2.1.2. Reasons that individual study candidates do not proceed to the next stage of the enrollment process – in order to identify protocol components or recruitment strategies that may be modified to improve accrual.

4.2.1.3. Participant demographic data including race, ethnicity, gender, and age – in order to document the potential participant pool at each stage of the

enrollment process (e.g., pre-screening, screening, consent, registration/randomization and start of study intervention).

4.2.2. Study-wide and site-specific recruitment information, which is entered in the Recruitment Journal in Rave.

4.2.2.1. The Recruitment Journal includes eCRFs that are used to enter study 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 an individual participant).

4.2.2.2. Site-specific recruitment information impacts one site and is entered and maintained in the *CP-CTNet Recruitment Journal Form – Site-Specific Events* eCRF by the site where the event occurred.

4.2.2.3. Study-wide recruitment information impacts all sites and is entered and maintained in the *CP-CTNet Recruitment Journal Form – Study-Wide Events* eCRF by DMACC. Sites can view, but not edit, study-wide recruitment information.

4.2.3. Documentation and training materials for Stars and Rave can be found in the Stars and Rave sections of the CP-CTNet DMACC Portal Gateway.

5. AQuIP Accrual Tracking and Monitoring Reports: a set of data analytics visualizations produced by DMACC based on real-time accrual data entered into Stars and Rave by study 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 challenges and solutions, 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

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

1.1. Data are reviewed carefully by DMACC staff, who aggregate the data, perform data integrity checks, and send data queries back to the sites (LAOs and AOs) for their site's own data.

1.2. Each site (LAO and AO) is responsible for resolving or overseeing the resolution of data queries within 14 days from identification.

2. An escalation process is defined for data and/or query responses that are overdue:

2.1. For AOs: If an AO has not responded to requests for overdue data/queries, DMACC escalates to the LAO. If there is no resolution, the LAO escalates to DCP, keeping DMACC in copy.

2.2. If an LAO has not responded to requests for overdue data/queries, DMACC escalates to DCP.

3. DCP, DMACC and LAOs (as applicable) work with sites to determine the reason for the delinquency and create a plan to address the issue and prevent further issues.
4. DMACC generates monthly AQuIP Accrual Tracking and Monitoring Reports.
   4.1. The LAO provides oversight of accrual and Recruitment Journal event documentation for their respective AOs to assure timely and accurate data entry.
   4.2. The LAO must review and proactively evaluate the study-specific AQuIP Accrual Tracking and Monitoring Reports and distribute the reports to their AOs.
   4.3. The LAO must assure that the recruitment impediments, strategic corrective actions as well as favorable factors are well documented via site Recruitment Journal event entries.
   4.4. 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 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

Document	ID	Location
AQuIP Toolkit	Manual	CP-CTNet DMACC Program Resources page
RRA Plan	Form	CP-CTNet DMACC Program Resources page

6. APPENDICES

- None