## SOP 6: Participant Recruitment, Retention and Adherence

### Overview:

The Consortia Recruitment, Retention and Adherence policy is based on 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 dynamic clinical trial accrual improvement program that is based on systematic planning, ongoing accrual activity reporting, evaluation and responsive actions that lead to measurable improvement in accrual.

AQuIP provides the CLOs and POs with 6 complementary tools accessible on [dcpaquip.com](http://www.dcpaquip.com/Default.aspx):

1. [Recruitment, Retention and Adherence (RRA) Plan Outline Template](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/Recruit-Retent-Adhere-Plan-Outline.pdf), a comprehensive fillable PDF planning template.
2. [AQuIP Toolkit](http://www.dcpaquip.com/Public/AQuIP_Toolkit.aspx), a user-friendly library of recruitment resources including a recruitment instruction manual, recruitment materials and templates as well as an image library available via dcpaquip.com.
* 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) are considered recruitment materials. Before potential participants receive recruitment materials, the content of the materials, the mode of communication, and the final copy of the materials must be approved by DCP and the CIRB.
* Recruitment materials\* should be submitted to DCP for review via the PIO.
* Once the materials are DCP approved, the PIO will forward the materials to the CIRB for review.
* The CIRB will not approve a study protocol that refers to recruitment materials within the protocol unless those materials are submitted at the same time as the protocol document. (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](https://ncicirb.org/about-cirb/sops).
* However, recruitment materials are not a required component of the protocol submission to DCP or to the CIRB if those materials are not referred to in the protocol document. As such, recruitment materials that are not mentioned in the protocol document may be submitted for DCP and then CIRB review 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.  Recruitment materials should not be included in the protocol.

1. [Training and Resources](http://www.dcpaquip.com/Public/AQuIP_TrainingandResources.aspx), a library of recorded webinars as well as links to additional clinical trial resources and accrual support tools compiled to aid CLOs in their ongoing research staff training responsibilities; available on dcpaquip.com.
2. [AQuIP On-line Accrual Reporting System (OARS)](http://www.dcpaquip.com/Login.aspx?ReturnUrl=%2fPrivate%2fAQuIP_Report.aspx), a system for recording, tracking, reporting, and monitoring accrual. The system includes a Protocol Information Page for study-level status, a Participant Accrual Page for study candidate/participant-level accrual data entry , and a Recruitment Journal Page to capture events, situations, conditions or efforts that may affect accrual at a particular site and/or the study as a whole See [AQuIP OARS User Guide](http://www.dcpaquip.com/Documents/Media/AQuIP%20OARS%20User%20Guide%20v%205.0.pdf) for instructional details.
3. AQuIP Zone Monitoring Report, a tool that provides a visualization of accrual progress based on a comparison of the actual current accrual rate with accrual rate benchmarks or milestones presented on a background of color-coded accrual performance zones. The report is updated monthly by DCP for each accruing trial to facilitate frequent monitoring and prompt identification of improvement opportunities. The zones provide guidance for corrective approaches to address shortfalls in accrual. The calculations are based on the ‘Target Enrollment: (Maximum #)’ and ‘Projected Monthly Accrual Rate’ specified by the CLO in the Protocol Submission Worksheet. Study-specific quarter milestones are included to assist CLO and DCP monitoring. Zones and interventions triggers are outlined below:
* **Green Zone** – indicates actual accrual rate that is greater than or equal to 90% of the projected accrual rate. DCP welcomes the opportunity to commend you on your success and encourage your insights on successful recruitment factors/strategies.
* **Orange Zone** – indicates actual accrual rate that is less than 90% but greater than or equal to 75% of the projected accrual rate. Interventions may include but are not limited to a required corrective action plan based on staff input and a review of the screening log is required. Monitoring frequency may increase to ensure that the investigators are implementing corrective actions to ensure full enrollment.
* **Yellow Zone** – indicates actual accrual rate that is less than 75% but greater than Red Zone accrual performance. Interventions may include but are not limited to a required analysis of recruitment barriers and a corrective action plan for review by the DCP. Medical/Scientific Monitor and Nurse Consultant and approval by the DCP leadership.
* **Red Zone**– indicates actual accrual rate that is less than 25% at the end of the 1st quarter, less than 25% at the end of the 2nd quarter and less than 50% at the end of the 3rd quarter. Interventions may include but are not limited to a corrective action plan, a site visit by DCP and CLO staff, a retreat to discuss protocol issues and consideration of study closure if continuation is not approved by DCP leadership.

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| **Green: ≥ 90 %** | DCP welcomes the opportunity to commend you on your success and encourage your insights on successful recruitment factors/strategies. |
| **Orange < 90% and ≥75%** | Interventions may include but are not limited to a required corrective action plan based on staff input and a review of the screening log is required. Monitoring frequency may increase to ensure that the investigators are implementing corrective actions to ensure full enrollment. |
| **Yellow: <75%, but still > Red Zone** | Interventions may include but are not limited to a required analysis of recruitment barriers and a corrective action plan for review by the DCP. |
| **Red: <25% at end of 1st quarter** **<25% at end of 2nd quarter** **<50% at end of 3rd quarter** | Interventions may include but are not limited to a corrective action plan, a site visit by DCP and CLO staff, a retreat to discuss protocol issues and consideration of study closure if continuation is not approved by DCP leadership. |

1. Think Tank, a group of Consortia 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.

### Planning Responsibilities:

Use the [Recruitment, Retention and Adherence (RRA) Plan Outline Template](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/Recruit-Retent-Adhere-Plan-Outline.pdf)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 PO plan (as developed in consultation with site PI and coordinator) and is to be included as part of the second protocol submission to DCP Protocol Information Office (PIO) for review.
2. The RRA Plan will be revised per DCP recommendation.
3. The approved RRA Plan is to be distributed to each study PO.

### CLO AQuIP Documentation and Reporting Requirements

The CLO will provide oversight of accrual and journal event documentation for their respective POs to assure timely and accurate data entry via AQuIP OARS. All data fields are required and should be completed as instructed in the [AQuIP OARS User Guide](http://www.dcpaquip.com/Documents/Media/AQuIP%20OARS%20User%20Guide%20v%205.0.pdf). The CLO Lead Coordinator (or designee) initiates AQuIP OARS account requests for applicable research staff members once a protocol has been approved by DCP. The CLO Lead Coordinator/designee must also notify the DCP Help Desk when a CLO or PO user no longer needs access to AQuIP OARS. See [AQuIP OARS User Guide](http://www.dcpaquip.com/Documents/Media/AQuIP%20OARS%20User%20Guide%20v%205.0.pdf) for account management details.

1. OARS data fields include Participant ID, First Contact Date, Recruitment Strategies, Consent Date/Status, Reasons Consent NOT Signed/Study Intervention NOT Started, Intervention Start Date, and Comments.
	1. AQuIP data are reviewed carefully by the DCP auditing and informatics support contractor. Inaccurate data or insufficient data specifications will result in data queries.
	2. The CLO is responsible for resolving or overseeing resolution of data queries within 30 days from identification.
2. CLOs are responsible for reviewing their POs’ monthly accrual and journal event data accuracy and submitting the AQuIP data via OARS **no later than the 10th of the following month.**
3. Discontinuation of monthly reporting is determined by DCP and contingent upon notification via the Study Status Update Form specifying accrual closure (non-temporary) and confirmation that all OARS data queries are resolved. The DCP Help Desk will send the CLO a confirmation of reporting discontinuation on behalf of DCP.

### CLO AQuIP Oversight Monitoring

The AQuIP Report data for each month is submitted on or before the 10th of the following month for review by the DCP auditing and informatics support contractor, who will aggregate the data, perform data integrity checks, send data queries back to the CLOs, and generate the AQuIP Zone Monitoring Reports (refer to Overview section A5). The reports support DCP and the CLO in early performance analysis and directs the responsive actions to be taken as per the color-coded AQuIP Zones to assure efficient conduct of clinical trials through efficient participant accrual.

1. The CLO must review and proactively evaluate the study specific AQuIP Zone Monitoring Reports and distribute to their POs.
2. The CLO must assure that the recruitment impediments, strategic corrective actions as well as favorable factors are well documented via [AQuIP OARS](http://www.dcpaquip.com/Login.aspx?ReturnUrl=%2fPrivate%2fAQuIP_Report.aspx) site and protocol-level Recruitment Journal Event entries.
3. DCP may require additional recruitment barrier analysis and a corrective action plan for review by the DCP Medical/Scientific Monitor and Nurse Consultant and approval by the DCP leadership. Depending on the applicable performance zone status, interventions for improvement will be devised and/or study design modifications or discontinuation will be considered.

**Please send questions and comments to the DCP Help Desk at:
1-844-901-4357 or** **dcphelpdesk@dcpais.com**