This User Guide provides an introduction to the AQuIP On-line Accrual Reporting System (OARS) for the Division of Cancer Prevention (DCP) Consortia 2012 clinical trials. AQuIP OARS is a system for collecting and reporting study participant level accrual data to DCP on a monthly basis.

Please note: For questions, please contact the DCP Help Desk at dcphelpdesk@dcpais.com or 1-844-901-4357

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AQuIP OARS Process Overview

Accrual and recruitment journaling data entry is completed in real time at the accruing PO or CLO. By the 10th of every month, the affiliated CLO reviews and modifies (as necessary) the POs' accrual data from the prior month and submits the data to the DCP Help Desk. The DCP Help Desk aggregates the submitted data, performs data integrity checks, and creates data queries for CLO resolution with their respective POs as needed. These queries are now created, communicated, addressed, verified, and resolved within OARS. The DCP Help Desk also generates data visualizations comparing projected accrual rates to actual accrual rates in the AQuIP Zone Monitoring Report (ZMR). The ZMR accrual performance status allows DCP and CLOs to identify the need for strategic recruitment modifications. This cycle of reporting and evaluation occurs each month, providing a foundation for continuous improvement. Furthermore, all accrual outcomes data are collected, aggregated, mined, and analyzed to uncover "lessons learned" for future protocols and recruitment plans.
How to Request Access to AQuIP OARS:

AQuIP OARS Website Access Request:

- Complete the 20-minute AQuIP OARS Training Webinar and review the AQuIP OARS User Guide via dcpaquip.com.
- Submit a request online via the “Request Access” option available on the AQuIP OARS login page.

The DCP Help Desk will confirm the access request with the CLO representative.

AQuIP OARS credentials will be provided by the DCP Help Desk and the CLO will be notified within two (2) business days of access request receipt.

Changing/Resetting AQuIP OARS Password:

After receiving credentials, the AQuIP OARS password should be changed:

1. Select the “Password Reset” button on the AQuIP OARS login page.
2. Enter the email address associated with the AQuIP OARS account.
3. Select the “Password Reset” button.
4. AQuIP OARS will send a password reset link to the email provided.

(Please note: this email notification may be sent to your clutter/junk folders.)

Account Deactivation

- CLO representatives must notify the DCP Help Desk when user access should be deactivated.
- Account activity is reviewed by the DCP Help Desk every 90 days. Accounts with no activity over the past 90 days will be flagged for deactivation. The DCP Help Desk will then notify the account holder, copying the CLO representative, with instructions to log into AQuIP OARS within 30 days to maintain account activity, or request to confirm deactivation. If after the 30-day period, the account holder does not login or request deactivation, the account will be deactivated without further notice.
Accessing the AQuIP Online Accrual Reporting System

1. Once access is granted, select the Accrual Report tab.

2. Log into AQuIP OARS using your account credentials provided by the DCP Help Desk and select Log In.
Participating Organization (PO) Accrual Reporting

Participating Organizations (PO) are the DCP Consortia accrual sites affiliated with the CLOs. Please note, “Ima Researcher” is used as an example of a PO user to illustrate the AQuIP OARS process below.

1. Once logged in, the Assigned Protocol page appears. This page includes all protocol numbers* assigned to the end user. The following columns are displayed:
   - CLO Name
   - Study Status*
   - Target Enrollment*
   - Total Number of Participants Started Study Intervention*
   Please note: *These columns are sortable in ascending/descending order by clicking the column header.

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>CLO Name</th>
<th>Study Status</th>
<th>Target Enrollment</th>
<th>Total Number of Participants Started Study Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLO2016-02-01</td>
<td>Consortia Lead Organization</td>
<td>Active</td>
<td>120</td>
<td>7</td>
</tr>
<tr>
<td>CLO2016-04-01</td>
<td>Consortia Lead Organization</td>
<td>Active</td>
<td>80</td>
<td>3</td>
</tr>
</tbody>
</table>

2. To continue, select Protocol CLO2016-02-01.
3. Next, the information for Protocol CLO2016-02-01 appears along with the following tabs to enter additional data:
   a. **Protocol Information**: Displays the current status for Protocol CLO2016-02-01 including Approved Participating Organizations. A specification indicating that an Approved Participating Organization has been closed will be listed as PO Name (closed).

   ![Protocol Information](image)

   **Current Reporting Month**: December 2018  
   **Protocol Title**: Randomized Placebo X Trial of Agent B in High-Risk Individuals  
   **Protocol Number**: CLO2016-02-01  
   **Targeted Enrollment**: 50  
   **Total Number of Participating Study Interventions**: 5  
   **Projected Accrual Per Month**: 8  
   **Projected Completion Date**: June 12, 2019  
   **Study Status**: Active  
   **Study Status Date**: March 27, 2017  
   **Accrual Duration (months)**: 12  
   **Approved Participating Organizations**:  
   - University of Chemoprevention  
   - Health Institute (closed)  
   **Date of First Contact**: January 20, 2017

   ![Participant Accrual](image)

   b. **Participant Accrual**: Next, select the Participant Accrual tab to view, edit, or delete participant information.

   The Participant Accrual page opens. On this page, you can view/edit the following columns:

   - Participant ID*  
   - First Contact Date*  
   - Recruitment Strategies  
   - Consent Date/Status*  
   - Reasons Consent NOT Signed/Study Intervention NOT Started  
   - Intervention Start Date*  
   - Comments

   **Please note**: *These columns are sortable in ascending/descending order by clicking the column header.

   ![Participant Accrual](image)

   - **Status Marker**: Each participant accrual record includes a Status Marker reflecting the accrual progression status as either Contacted, Consented, Not on Study or On Study. **Please note**: the status marker may not be edited.
When an Accrual Record remains in a pending status for >90 days from the First Contact Date or Consent Date/Status, a pop-up reminder will appear on the Participant Accrual page. Select the Continue button to proceed.

The record(s) highlighted below have been in a pending status for greater that 90 days. Please open the highlighted records below and update the Consent Date/Status, Intervention Start Date and/or the Reason(s) Consent NOT Signed/Study Intervention NOT Started fields as applicable to complete the identified recruitment record(s).

The pending Accrual Record can be located by searching for an entry highlighted in red, as shown below. If screening is ongoing, please select “Screening on-going” via the edit function. Please note: after 90 days from selecting “Screening is on-going”, the pop-up reminder re-appears prompting the end user to revisit and update the highlighted record.
i. **How to Add a New Participant**
Step 1: Select **+Add New Participant** on the Participant Accrual page.

![Participant Accrual](image)

Step 2: The **Add Participant Accrual Information** page appears.

![Add Participant Accrual Information](image)

Step 3: Next, enter the **Participant ID**.

![Add Participant Accrual Information](image)

For quality assurance, the **AQuIP OARS System does not allow for duplicate or blank, placeholders and/or participant IDs.** In the event a CLO does not have a standard screening (or placeholder ID) procedure, we offer the below numbering convention until participants receive a unique ID. Enter these screening/placeholders in the Participant ID # field (PID) and replace them with the accruing site PID upon study enrollment. As this is a recommendation, CLOs are welcome to follow this process or apply the necessary institutional conventions to avoid blank or duplicate IDs.

<table>
<thead>
<tr>
<th>Participant Entered into AQuIP OARS</th>
<th>Participant ID #</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Participant Entered by DCP Institution</td>
<td>DCP Institution Code-01</td>
</tr>
<tr>
<td>Second Participant Entered by DCP Institution</td>
<td>DCP Institution Code-02</td>
</tr>
<tr>
<td>Third Participant Entered by DCP Institution</td>
<td>DCP Institution Code-03</td>
</tr>
<tr>
<td>Example: First Participant Entered by The University of Arizona Medical Center-University Campus</td>
<td>Example: UAZ017-01</td>
</tr>
<tr>
<td>Example: Second Participant Entered by The University of Arizona Medical Center-University Campus</td>
<td>Example: UAZ017-02</td>
</tr>
</tbody>
</table>

Contact the DCP Help Desk at [dcphelpdesk@dcpai.org](mailto:dcphelpdesk@dcpai.org) or by calling 1-844-901-4357 if CLO or PO DCP Institution Code is unknown.
Step 4: Enter the **First Contact Date** manually or by selecting the calendar button. **Please note:** data validation prohibits entering future dates in this field.

Please note: First Contact Date field is required once the Participant ID (PID) is entered.

Step 5: Next, select the +Add/Edit button to enter the Recruitment Strategies used to contact this participant.

Step 6: The Recruitment Strategies page appears.
- Include multiple staff when applicable; specify the staff name or enter “not available” if the name is unknown/not available.
- Select ALL applicable strategies used to contact this participant and complete ALL applicable “specify here” text boxes.

For this example, under the **Protocol Staff Recruitment** drop down list, we checked the **Investigator** and **Site Coordinator** options and completed the applicable “specify here” text boxes. Under the **Existing Database** drop down list, we checked the **Clinic Schedules** option (See Appendix A - AQuIP OARS Recruitment Strategies).
Select the Protocol Staff Involved in Recruitment

Please note: To view the full list of recruitment strategies select Expand All (see Appendix A - AQuIP OARS Recruitment Strategies). Select the applicable recruitment strategy(ies) and provide specifics in the Specify here field where provided.

Step 7: Select Save to submit your data and return to the Add Participant Accrual Information page.

Step 8: Check the appropriate checkbox under [Signed, Pending, or Not Signed] and enter the date [if applicable] under Consent Date/Status. For this example, since participant ABC signed the Consent Form on 10/09/2017, the “Signed” option was selected.
Step 9: Next, if the Participant starts study intervention, enter the **Intervention Start Date** and update the **Participant ID (PID)** to reflect the **Study Participant ID (PID)** number issued upon study enrollment:

Please note: “External Participant ID (PID)” is a system generated number. This field may not be edited.

Step 10: If Participant does not sign consent or does not start study intervention, enter ALL reasons in the **Reason(s) Consent NOT Signed/Study Intervention NOT Started** field by clicking on the **+Add/Edit** button to proceed (see Appendix B - AQuIP OARS Reason(s) Consent NOT Signed/Study Intervention NOT Started).
Step 11: The **Reason Consent NOT Signed or Study Intervention NOT Started Table** page appears.

- From the list, select ALL the reasons the individual did not sign consent or did not start study intervention. **Please note:** definitions are available by hovering over each **Reason Consent NOT Signed or Study Intervention NOT Started** option.
- Complete ALL “specify here” text boxes for the option(s) selected.

For this example, under the **Eligibility Criteria Not Met** drop down list, we selected **Prohibited Concomitant Medication** and completed the applicable required “specify here” text box (See Appendix B - AQuIP OARS Reason(s) Consent NOT Signed/Study Intervention NOT Started).

![Reason Consent NOT Signed or Study Intervention NOT Started Table](image)

Step 12: Select **Save** to submit your data and return to the **Add Participant Accrual Information** page.

![Reason Consent NOT Signed or Study Intervention NOT Started Table](image)

Step 13: Select **Submit** and a message appears indicating the participant was successfully added. Select **OK** to return to the **Participant Accrual** page.

![Success](image)
### ii. How to Edit Information

Step 1: To update or edit information for existing participants, select the **Edit** button and the **Edit Participant Accrual Information** page will appear. Then update or edit the entry accordingly by following **Steps 1 to 12** in Section 3.b.i (above).

<table>
<thead>
<tr>
<th>Status Marker</th>
<th>Participant ID</th>
<th>First Contact Date</th>
<th>Recruitment Strategies</th>
<th>Consent Date/Status</th>
<th>Reason(s) Consent NOT Signed/Study Intervention NOT Started</th>
<th>Intervention Start Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DGDP</td>
<td>November 09, 2018</td>
<td>Principal Investigator (Dr. Chemoprevention) Site Coordinator (Not Available) Clinic Schedules</td>
<td>November 09, 2018/Signed</td>
<td>Prohibited Concomitant Medication (Patient unable to stop taking aspirin and nitrates)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Please note:** ‘External Participant ID (PID)’ is a system generated number. This field may not be edited.

### iii. How to Delete Information

Step 1: Select the **Delete** button corresponding to the participant information you wish to remove from the list.

<table>
<thead>
<tr>
<th>Status Marker</th>
<th>Participant ID</th>
<th>First Contact Date</th>
<th>Recruitment Strategies</th>
<th>Consent Date/Status</th>
<th>Reason(s) Consent NOT Signed/Study Intervention NOT Started</th>
<th>Intervention Start Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>E</td>
<td>March 08, 2017</td>
<td>Mailing List</td>
<td>No</td>
<td>Known History of Non-Compliance,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>March</td>
<td>Mailing List</td>
<td>March 22</td>
<td>Scheduling Conflict,</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Step 2: A message appears. To continue, select Yes, delete it!

![Yes, delete it! message]

Step 3: A message appears indicating participant accrual was successfully deleted. Select OK to return to the Participant Accrual page.

![Participant Accrual successfully deleted message]

c. **Recruitment Journal:** This page is used to document activities, events or other factors that may positively or negatively influence study accrual trends. Examples might include: changes in staffing, changes in clinic hours, institution-wide events, or a change in eligibility criteria. This information will provide insights into accrual patterns and may be useful for future planning.

Step 1: Select the Recruitment Journal tab to view and enter Study Event data.

![Recruitment Journal tab]

The Recruitment Journal page appears. On this page, you can view/edit the following columns:

- Study Event Start Date*
- Study Event End Date*
- Study Event
- Event Description

Please note: *These columns are sortable in ascending/descending order by clicking the column header.
i. **How to Add a New Study Event**

   Step 1: Select **Add New Study Event** on the **Recruitment Journal** page.

   ![Recruitment Journal](image1)

   Step 2: The **Add Study Event** page appears.

   ![Add Study Event](image2)

   Step 3: Enter the start date and enter an end date *(if applicable)*. Select the **Study Event** from the pull-down menu. For this example, we selected **Protocol Amendment Approval: Eligibility**.

   ![Edit Study Event](image3)
Please note: The following **Study Events** require **Study Event Descriptions**:

- **A0** – Change in Monthly Accrual Rate (Provide new monthly accrual rate in the Event Description)
- **A3** – Site Open (Provide Date in the Event Type Description)
- **A9** – Accrual Hold: Specify in the Event Type Description
- **A23** – New recruitment strategy started (Specify in the Event Type Description)
- **A28** – Other (Specify in the Event Type Description)

**Step 4:** Select **Submit** to save your changes.

**Step 5:** A message appears indicating the recruitment journal entry was successfully added. Select **OK** to return to the **Recruitment Journal** page.

ii. **How to Edit Information**

**Step 1:** Select the **Edit** button to update or edit information for existing Study Events.
Step 2: The Edit Study Event page appears. Enter or update the required information and select Submit to save your changes.

Step 3: A message appears indicating the recruitment journal entry was successfully updated. Select OK to return to the Recruitment Journal page.

iii. How to Delete Information
Step 1: Select the Delete button corresponding to the study event you wish to remove from the list.

Step 2: A message to confirm deletion appears. To continue select Yes, delete it!

Step 3: A second and final message appears indicating the Recruitment Journal entry was successfully deleted. Select OK to return to the Recruitment Journal page.
d. **Query List**: Accrual data queries are now created, communicated, addressed, verified, and resolved within OARS. The CLOs submit the monthly report by the 10th of each month. The DCP Help Desk then performs data integrity checks and creates data queries for CLO/PO resolution as needed. The CLOs will be asked to visit OARS to review/address queries with their respective POs as needed. This communication is included in the AQuIP Zone Monitoring Report distribution.

The **Query List** is a place to view Participant Accrual and Recruitment Journal queries. Queries might include requests to revise recruitment strategies or reasons not category selections, provide more information regarding a study event, or provide a reason for lack of contacts at a site. The Participant Accrual Queries tab and Recruitment Journal Queries tab will contain a list of requested corrections. The CLO/PO corrections will be reviewed/resolved the following month by the OARS administrator.

**Step 1**: Select the **Query List** tab to view Participant Accrual and Recruitment Journal Queries.

**Step 2**: Select the **Participant Accrual Queries** to view Participant Accrual Queries:

**Step 3**: Identify the Participant ID and Query.
Step 4: Select the **Participant Accrual** tab and use Ctrl+F for each PID to locate the corresponding record. Make the necessary update(s) and save the record prior to the 10th of each month. The queries will be reviewed for resolution after the 15th of each month.

Step 5: Select the **Recruitment Journal Queries** on the **Query List** tab to view Recruitment Journal Queries:

![Query List Tab](image)

Step 6: Identify the **Study Event Start Date** and **Query**.

![Recruitment Journal Queries](image)

Step 7: Select the **Recruitment Journal** tab again and use Ctrl+F for each **Study Event Start Date** to locate the corresponding record, make necessary update(s) and save the record prior to the 10th of each month. The queries will be reviewed for resolution after the 15th each month.
Consortia Lead Organization (CLO) Accrual Reporting

Consortia Lead Organizations (CLOs) are the five main DCP Consortia clinical trial institutions which include Mayo Clinic, MD Anderson Cancer Center, Northwestern University, University of Arizona, and University of Wisconsin. Please note: “Ima Researcher” at Consortia Lead Organization is used as an example of a CLO user to illustrate the AQuIP OARS process below.

1. Log into the AQuIP OARS using your account credentials provided by the DCP Help Desk and select Log In. If you do not have an account, please reference the steps under How to Request AQuIP OARS Access.

2. Once logged in, the Assigned Protocol page appears, listing all protocol numbers assigned to each of Ima Researcher’s Participating Organizations. The following columns are displayed:
   - Study Status
   - Target Enrollment
   - Total Number of Participants Started Study Intervention
   Please note: All columns are sortable in ascending/descending order by clicking the column header.

3. To continue, select a Protocol CLO2016-02-01.
4. Once you select Protocol CL02016-02-01, a reminder appears indicating when the Monthly Report is due. Please note: these reminders appear from the 1st to the 15th of each month until the report is submitted. Select Continue to proceed.

5. Another reminder may appear indicating that queries are ready for review. Choose Query List to go to those queries or Continue to proceed to the Protocol Information page.

Accrual data corrections or requests for information are documented, addressed, and resolved within AQuIP OARS. The Query List is a place to view Participant Accrual and Recruitment Journal queries. Examples might include requests to revise recruitment strategies or reasons not category selections, provide more information regarding a study event, or provide a reason for lack of contacts at a site. The Query List will be updated after the 15th of each month.

6. The information for Protocol CLO2016-02-01 appears along with the following tabs to enter additional data:

   a. Protocol Information: Displays the current status for Protocol CL02016-02-01 including Approved Participating Organizations. A specification indicating that an Approved Participating Organization has been closed will be listed as PO name (closed).
b. **Participant Accrual:**

Step 1: Select the **Participant Accrual** tab to view, edit, or delete participant information.

Step 2: The **Participant Accrual** page opens and displays all POs assigned to CLO coordinator “Ima Researcher”, the First Contact Date, and the Total Number of Participants Started Study Intervention Per Site.

<table>
<thead>
<tr>
<th>Approved PO Name</th>
<th>First Contact Date</th>
<th>Total Number of Participants Started Study Intervention Per Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Chemoprevention</td>
<td>March 08, 2017</td>
<td>4</td>
</tr>
<tr>
<td>Chemoprevention Institute</td>
<td>March 09, 2017</td>
<td>3</td>
</tr>
</tbody>
</table>

Step 3: To continue, select a PO **University of Chemoprevention**.

The **Participant Accrual** page for PO **University of Chemoprevention** opens. On this page, you can view/edit the following columns:

- Participant ID*
- First Contact Date*
- Recruitment Strategies
- Consent Date/Status*
- Reason(s) Consent NOT Signed/Study Intervention NOT Started
- Intervention Start Date*
- Comments

Please note: *These columns are sortable in ascending/descending order by clicking the column header.

- Status Marker: Each participant accrual record includes a **Status Marker** reflecting the accrual progression status as either Contacted, Consented, Not on Study or On Study. **Please note:** this column may not be edited.
When a pending Accrual Record remains in a pending status for >90 days from the First Contact Date or Consent Date/Status, a pop-up reminder will appear on the Participant Accrual page. Select the Continue button to proceed.

The record(s) highlighted below have been in a pending status for greater than 90 days. Please open the highlighted records below and update the Consent Date/Status, Intervention Start Date and/or the Reason(s) Consent NOT Signed/Study Intervention NOT Started fields as applicable to complete the identified recruitment record(s).

The pending Accrual Record can be located by searching for an entry highlighted in red, as shown below. Select the Edit button to update the record or select “Screening is on-going” if applicable. Please note: after 90 days from selecting “Screening is on-going”, the pop-up reminder re-appears prompting the end user to revisit and update the highlighted record.
i. **How to Add a New Participant**

   Step 1: Select **Add New Participant** in the **Participant Accrual** page.

### Participant Accrual

**PO: University of Chemoprevention**

- Contacted
- Consented
- Not on Study (Consent Not Signed, Ineligible, etc.)
- On Study Intervention

**+ Add New Participant**

---

**Step 2:** The **Add Participant Accrual Information** page appears.

<table>
<thead>
<tr>
<th>Add Participant Accrual Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant ID (PID):</td>
</tr>
<tr>
<td>First Contact Date:</td>
</tr>
<tr>
<td>Recruitment Strategies:</td>
</tr>
<tr>
<td>Consent Date/Status:</td>
</tr>
<tr>
<td>Intervention Start Date:</td>
</tr>
<tr>
<td>Reason(s) Consent NOT Signed/Study Intervention NOT Started:</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
</tbody>
</table>

---

**Step 3:** Next, enter the **Participant ID**.

---

For quality assurance, the **AQuIP OARS System does not allow for duplicate or blank, placeholders and/or participant IDs**. In the event a CLO does not have a standard screening (or placeholder ID) procedure, we offer the below numbering convention until participants receive a unique ID. Enter these screening/placeholders in the Participant ID # field (PID) and replace them with the accruing site PID upon study enrollment. As this is a recommendation, CLOs are welcome to follow this process or apply the necessary institutional conventions to avoid blank or duplicate IDs.

<table>
<thead>
<tr>
<th>Participant Entered into AQuIP OARS</th>
<th>Participant ID #</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Participant Entered by DCP Institution</td>
<td>DCP Institution Code-01</td>
</tr>
<tr>
<td>Second Participant Entered by DCP Institution</td>
<td>DCP Institution Code-02</td>
</tr>
<tr>
<td>Third Participant Entered by DCP Institution</td>
<td>DCP Institution Code-03</td>
</tr>
<tr>
<td>Example: First Participant Entered by The University of Arizona Medical Center-University Campus</td>
<td>Example: UAZ017-01</td>
</tr>
<tr>
<td>Example: Second Participant Entered by The University of Arizona Medical Center-University Campus</td>
<td>Example: UAZ017-02</td>
</tr>
</tbody>
</table>

Contact the DCP Help Desk at [dcphelpdesk@dcpais.com](mailto:dcphelpdesk@dcpais.com) or by calling 1-844-901-4357 if CLO or PO DCP Institution Code is unknown.
Step 4: Enter the **First Contact Date** manually or by selecting the calendar button. **Please note:** data validation prohibits entering future dates in this field.

**Add Participant Accrual Information**

- **Participant ID (PID):** ABC
- **First Contact Date:**
- **Recruitment Strategies:**

**First Contact Date:**

> **First Contact Date**
> *First Contact Date is required!*

**Please note:** First Contact Date field is required once the Participant ID (PID) is entered.

Step 5: Next, select the **+Add/Edit** button to enter the **Recruitment Strategies** used to contact this participant.

**Add Participant Accrual Information**

- **Participant ID (PID):** ABC
- **First Contact Date:** 10/02/2017
- **Recruitment Strategies:**

**Step 6:** The **Recruitment Strategies** page appears.

- Include multiple staff when applicable, please specify the appropriate name or enter “not available” if the name is unknown/not available.
- Select ALL applicable strategy(ies) used to contact this participant and complete ALL applicable “specify here” text boxes.

For this example, under the **Protocol Staff Recruitment** drop down list, we checked the **Investigator** and **Site Coordinator** options and completed the applicable “specify here” text boxes. Under the **Existing Database** drop down list, we checked the **Clinic Schedules** option (See Appendix A - AQuIP OARS Recruitment Strategies).

**Select the Protocol Staff Involved in Recruitment**

**Indicate all Recruitment Strategies**
Please note: To view the full list recruitment strategies select Expand All (see Appendix A - AQuIP OARS Recruitment Strategies). Select the applicable recruitment strategy(ies) and provide specifics in the Specify here field where provided.

Step 7: Select Save to submit your changes and to return to the Add Participant Accrual Information page.

Step 8: Check the appropriate checkbox under [Signed, Pending, or Not Signed] and enter the date [if applicable] under Consent Date/Status. For this example, since participant ABC signed the Consent Form on 10/09/2017, the “Signed” option was selected.

Step 9: Next, if the Participant will continue to start intervention, enter the Intervention Start Date and update the Participant ID (PID) to reflect the Study Participant ID (PID) number issued upon study enrollment:

Please note: “External Participant ID (PID)” is a system generated number. This field may not be edited.
Step 10: If Participant does not sign consent or does not start study intervention, enter ALL reasons in the **Reason(s) Consent NOT Signed/Study Intervention NOT Started** field by clicking on the +Add/Edit button to proceed (see Appendix B - AQuIP OARS Reason(s) Consent NOT Signed/Study Intervention NOT Started).

Step 11: The **Reason Consent NOT Signed or Study Intervention NOT Started Table** page appears.
- From the list, select ALL the reasons the individual did not sign consent or did not start study intervention. **Please note**: definitions are available by hovering over each **Reason Consent NOT Signed or Study Intervention NOT Started** option.
- Complete ALL “specify here” text boxes for the option(s) selected.
For this example, under the **Eligibility Criteria Not Met** drop down list, we selected **Prohibited Concomitant Medication** and completed the applicable required “Specify here” text box.(See Appendix B - AQuIP OARS Reason(s) Consent NOT Signed/Study Intervention NOT Started).
Step 12: Select **Save** to submit your changes.

![Image](image.png)

Step 13: Select **Submit** and a message appears indicating the participant was successfully added. Select **OK** to return to the **Participant Accrual Information** page.

![Image](image.png)

ii. **How to Edit Information**
Step 1: To update or edit information, select the **Edit** button and follow **Steps 1 to 12** in section i.

<table>
<thead>
<tr>
<th>Status Marker</th>
<th>Participant ID</th>
<th>First Contact Date</th>
<th>Recruitment Strategies</th>
<th>Consent Date/Status</th>
<th>Reason(s) Consent NOT Signed/Study Intervention NOT Started</th>
<th>Intervention Start Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ABC</td>
<td>April 03, 2017</td>
<td>Script Call,</td>
<td>No</td>
<td>Scheduling Conflicts,</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

iii. **How to Delete Information**
Step 1: Select the **Delete** button corresponding to the participant you wish to remove from the list.

<table>
<thead>
<tr>
<th>Status Marker</th>
<th>Participant ID</th>
<th>First Contact Date</th>
<th>Recruitment Strategies</th>
<th>Consent Date/Status</th>
<th>Reason(s) Consent NOT Signed/Study Intervention NOT Started</th>
<th>Intervention Start Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>March 16, 2017</td>
<td>Study Website,</td>
<td>March 17, 2017/Yes</td>
<td></td>
<td>March 20, 2017</td>
<td></td>
</tr>
</tbody>
</table>
Step 2: A message appears. To continue, select **Yes, delete it!**

![Alert message](image)

Step 3: A second message appears indicating participant accrual was successfully deleted. Select **OK** to return to the **Participant Accrual** page.

![Success message](image)
c. **Recruitment Journal**: This page is used to document activities, events or other factors that may have an effect on study accrual trends (either positive or negative). Examples might include: changes in staffing, changes in clinic hours, institution-wide events or a change in eligibility criteria. This information will provide insights into accrual patterns and may be useful for future planning.

   **Step 1:** Select the **Recruitment Journal** tab to view and enter study event data.

![Recruitment Journal page](image)

The **Recruitment Journal** page opens. On this page, you can view/edit the following columns:

- Study Event Start Date*
- Study Event End Date*
- Study Event
- Event Description
- POs Affected

*Please note: *These columns are sortable in ascending/descending order by clicking the column header.
i. **How to Add New Study Event**

   Step 1: Select **Add New Study Event** in the **Recruitment Journal** page.

   ![Recruitment Journal](image1)

   **Step 2:** The **Add Study Event** page appears. **Please note:** CLOs will be able to view all POs under **POs Affected** and closed POs are designated as (closed) and are unable to be selected.

   ![Add Study Event](image2)

   **Step 3:** Enter the start date and enter an end date (**if applicable**). Select the **Study Event** from the pull-down menu. For this example, we **Accrual on Hold: Interim Analysis Per Protocol** and all POs are checked (Closed POs will be greyed out and are not selectable).
Please Note: The following Study Events require Study Event Descriptions:

- A0 – Change in Monthly Accrual Rate (Provide new monthly accrual rate in the Event Description)
- A3 – Site Open (Provide Date in the Event Type Description)
- A9 – Accrual Hold: Specify in the Event Type Description
- A23 – New recruitment strategy started (Specify in the Event Type Description)
- A28 – Other (Specify in the Event Type Description)

Study Event Description: [Blank]

*Study Event Description is required!

Step 4: Select Submit to save your changes.

Step 5: A message appears indicating the recruitment journal entry was successfully updated. Select OK to return to the Recruitment Journal page.
ii. How to Edit Information
   Step 1: Select the Edit button to update or edit information to existing Study Events.

   Step 2: The Edit Study Event page appears. Enter the required information and select Submit to save your changes.

   Step 3: A message appears indicating the recruitment journal was successfully updated. Select OK to return to the Recruitment Journal page.
iii. **How to Delete Information**

   **Step 1:** Select the **Delete** button corresponding to the study event you wish to remove from the list.

   | March 08, 2017 | AB - Accrual on Hold: FDA Clinical Hold | Study is now on hold. | University of Chemoprevention | Edit | Delete |
   | March 20, 2017 | A2 - Site Issues: Drug Shipment Authorization | | University of Chemoprevention | Edit | Delete |

   **Step 2:** A message to confirm deletion appears. To continue, select **Yes, delete it!**

   ![Yes, delete it!](image)

   **Step 3:** A second message appears indicating recruitment journal was successfully deleted. Select **OK** to return to the **Recruitment Journal** page.

   ![Success](image)

   **a. Query List:** Accrual data queries are now created, communicated, addressed, verified, and resolved within OARS. The CLOs submit the monthly report by the 10th of each month. The DCP Help Desk then performs data integrity checks and creates data queries for CLO/PO resolution as needed. The CLOs will be asked to visit OARS to review/address queries with their respective POs as needed. This communication is included in the AQuIP Zone Monitoring Report distribution.

   The **Query List** is a place to view **Participant Accrual** and **Recruitment Journal** queries. Queries might include requests to revise recruitment strategies or reasons not category selections, provide more information regarding a study event, or provide a reason for lack of contacts at a site. The **Participant Accrual Queries** tab and **Recruitment Journal Queries** tab will contain a list of requested corrections. The CLO/PO corrections will be reviewed/resolved the following month by the OARS administrator.

   **Step 1:** Select the **Query List** tab to view **Participant Accrual** and **Recruitment Journal** Queries.
Step 2: Select the **Participant Accrual Queries** to view **Participant Accrual Queries**:

![Participant Accrual Queries](image)

Step 3: Identify the **Participant ID** and **Query**. **Please note:** the CLO will have access to all Participating Organizations (POs) queries.

![Participant Accrual Queries Table](image)

- **University of Chemoprevention**
  - **DSGP**
    - **Query:** Please select the Participant Accrual tab, edit the specified record, and revise "Reason Consent NOT Signed/Study Intervention NOT Started" from "Other" to "Passive Decline" to match the content in the "Other, specify here" field.
    - **Open Date:** 11/12/2018
  - **0421**
    - **Query:** Please select the Participant Accrual tab, edit the specified record, and revise the "Reason Consent NOT Signed/Study Intervention NOT Started" to match the content in the "specify" field by selecting "Too many procedures".
    - **Open Date:** 11/8/2018

- **Chemo prevention Institute**
  - **111**
    - **Query:** Please select the Participant Accrual tab, edit the specified record, and revise the "Reason Consent NOT Signed/Study Intervention NOT Started" from "Other" to "Passive Decline" to match the content in the "Other, specify here" field.
    - **Open Date:** 11/12/2018

**Please note:** You may quickly switch between Participant Accrual and Recruitment Journal Queries by clicking here from either query page.

Step 4: Select the **Participant Accrual** tab again and the applicable PO and use Ctrl+F for each PID to locate the corresponding record. Make the necessary update(s) and save the record prior to the 10th of each month. The queries will be reviewed for resolution after the 15th of each month.
Step 5: Select the **Recruitment Journal Queries** on the **Query List** tab to view Recruitment Journal Queries:

![Query List Tab](image)

Step 6: Identify the **Study Event Start Date** and **Query**. **Please note**: the CLO will have access to all Participating Organizations (POs) queries.

![Recruitment Journal Queries](image)

Step 7: Select the **Recruitment Journal** tab again and use Ctrl+F for each **Study Event Start Date** to locate the corresponding record. Make the necessary update(s) and save the record prior to the 10th of each month. The queries will be reviewed for resolution after the 15th of each month.
How to Submit the Monthly Accrual Report

CLO users receive daily reminders from the 1st to the 15th of the month until the report is submitted. Please note: CLO users cannot submit reports after the 15th of each month.

1. Once all the required information is updated or added, select Submit Monthly Report on the Protocol Information page.

![Protocol Information Screenshot](image)
2. If records have been in a pending status for greater than 90 days, users will receive a notice to update the applicable records before continuing to submit. Updates for pending records must be completed prior to submitting the report. If the user clicks **Continue to Submit Report**, a message appears indicating the monthly report was successfully submitted. Select **OK** to return to the **Protocol Information** page.

3. The **Protocol Information** page appears. If finished, select **Log out**. Please follow the same process for additional Monthly Report submissions.

We welcome your feedback on this Quick Start Guide. Please send your comments to dcphelpdesk@dcpais.com
Frequently Asked Questions

1. **Q**: Who will edit study-specific PO statuses in AQuIP OARS?
   
   o **A**: PO and CLO users submit PO changes as Study Events including the Study Event Dates, Type, and Description on the “Recruitment Journal” tab. The DCP Help Desk will edit the list of POs accordingly.

2. **Q**: Will AQuIP OARS collect pre-contacted data (i.e., data before participant was contacted)?
   
   o **A**: Pre-screening data will be piloted for several DCP-selected protocols in OARS starting in January 2018.

3. **Q**: Where can I find total participants that started study intervention per PO and protocol?
   
   o **A**: The total number of participants that started study intervention per PO and protocol can be viewed on the “Participant Accrual” page next to each site within each protocol.

4. **Q**: How are pending accrual records handled in AQuIP OARS (i.e., participants that have been contacted without consent dates, or consented participants that have not started intervention)?
   
   o **A**: Accrual records are considered pending when the individual was contacted but has not yet signed consent or started intervention. In these instances, the “Date Consent Signed Date” and/or the “Date Started Study Intervention” are left blank and the “First Contact Date” and “Recruitment Strategy” fields are populated.

5. **Q**: If a participant is identified through a participant registry, but the Principal Investigator (PI) had a key role in the enrolling process, should the PI also be added as a recruitment strategy?
   
   o **A**: Yes, DCP recommends listing all recruitment strategies used to enroll participants.
## Appendix A – AQuIP OARS Recruitment Strategies

Include multiple staff when applicable and select the applicable strategy(ies) used. When selecting a protocol staff member as a Recruitment Strategy, please specify the applicable name, if possible, or enter ‘not available’ if the name is unknown/not available.

<table>
<thead>
<tr>
<th>Protocol Staff Recruitment (Protocol Staff member involved in recruitment of individual participant)</th>
<th>Non-Digital Mass Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Investigator (specify name or enter “not available” if the name is unknown/not available)</td>
<td>□ Newspaper Advertisement</td>
</tr>
<tr>
<td>□ Recruitment Designee (specify name or enter “not available” if the name is unknown/not available)</td>
<td>□ TV Advertisement</td>
</tr>
<tr>
<td>□ Site Coordinator (specify name or enter “not available” if the name is unknown/not available)</td>
<td>□ Radio Advertisement</td>
</tr>
<tr>
<td>□ Research Nurse (specify name or enter “not available” if the name is unknown/not available)</td>
<td>□ Flyer</td>
</tr>
<tr>
<td></td>
<td>□ Poster</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Existing Data</th>
<th>Social/Digital Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Participant Registries</td>
<td>□ Study Website</td>
</tr>
<tr>
<td>□ Clinic Schedules</td>
<td>□ Institutional Website</td>
</tr>
<tr>
<td>□ O.R. Schedules</td>
<td>□ Site Website</td>
</tr>
<tr>
<td>□ Pathology Reports</td>
<td>□ Craig’s List</td>
</tr>
<tr>
<td>□ Contact From Previous Study</td>
<td>□ Facebook</td>
</tr>
<tr>
<td></td>
<td>□ Clinicaltrials.gov</td>
</tr>
<tr>
<td></td>
<td>□ Participant/Disease Group</td>
</tr>
<tr>
<td></td>
<td>□ YouTube</td>
</tr>
<tr>
<td></td>
<td>□ Video (specify source or website)</td>
</tr>
<tr>
<td></td>
<td>□ Text message (Please select applicable protocol staff member under Recruitment Staff)</td>
</tr>
<tr>
<td></td>
<td>□ Twitter</td>
</tr>
<tr>
<td></td>
<td>□ Other Website (specify website)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>U.S. Postal Service or Email</th>
<th>Community Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Introductory Letter to Prior Study Participant</td>
<td>□ Advocacy Group</td>
</tr>
<tr>
<td>□ Introductory Letter to Family Member</td>
<td>□ Church Group</td>
</tr>
<tr>
<td>□ Mailing List</td>
<td>□ Community Leader</td>
</tr>
<tr>
<td>□ Newsletter</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Telephone Calls</th>
<th>Patient Issues/Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Returned Call</td>
<td>□ Use Participant Education Materials to Allay Any Specific Concerns</td>
</tr>
<tr>
<td>□ Script Call</td>
<td>□ Compensation/Reimbursement</td>
</tr>
<tr>
<td></td>
<td>□ Time Commitment</td>
</tr>
<tr>
<td></td>
<td>□ Arrange Transportation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Referral</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Community HCP (specify specialty)</td>
<td>□ Other (specify here)</td>
</tr>
<tr>
<td>□ Within Institution, Non-Study Staff (specify specialty)</td>
<td></td>
</tr>
<tr>
<td>□ Another Study Participant</td>
<td></td>
</tr>
<tr>
<td>□ Pathology/Any Regular Case Review Meetings</td>
<td></td>
</tr>
<tr>
<td>□ Physician</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix B – AQuIP OARS Reason(s) Consent NOT Signed/Study Intervention NOT Started

<table>
<thead>
<tr>
<th>Reason(s) Consent NOT Signed/Study Intervention NOT Started</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eligibility Criteria Not Met</strong></td>
<td></td>
</tr>
<tr>
<td>□ Lab Values <em>(specify in comments)</em></td>
<td>Lab values that fall outside of range specified per protocol.</td>
</tr>
<tr>
<td>□ Prior Cancer</td>
<td>History of cancer (type &amp;/or diagnosis timing) as specified in protocol exclusion criteria.</td>
</tr>
<tr>
<td>□ Age</td>
<td>Age falling outside of range specified per protocol.</td>
</tr>
<tr>
<td>□ Pregnancy-Related Issue</td>
<td>Includes issues pertaining to willingness to adhere to birth control as specified per protocol.</td>
</tr>
<tr>
<td>□ Allergy to Related Drugs <em>(specify here)</em></td>
<td>History of allergy to study related drug, drug class or those specified in protocol.</td>
</tr>
<tr>
<td>□ Prohibited Concomitant Medication <em>(specify here)</em></td>
<td>Taking protocol-prohibited medications and unwilling to discontinue, or discontinuation is not medically advised.</td>
</tr>
<tr>
<td>□ Comorbidity/Medical History <em>(specify here)</em></td>
<td>Any concurrent illness or disorder reported or as documented in the patient record that is excluded in the protocol eligibility criteria.</td>
</tr>
<tr>
<td>□ Eligibility Procedure Timing <em>(specify here)</em></td>
<td>Protocol required schedule of events do not align with Standard of Care (SOC) guidelines, medical indication, or insurance requirements. <em>Note: for non-timing related insurance denials please select “Insurance”</em>.</td>
</tr>
<tr>
<td>□ Surgery Timing</td>
<td>Unwilling to delay procedures/surgery or delay is not medically indicated.</td>
</tr>
<tr>
<td>□ Lack of targeted disease, pathology or biomarker <em>(specify here)</em></td>
<td>Does not have the targeted disease, condition, or severity of condition. Usually determined after screening procedure(s).</td>
</tr>
<tr>
<td>□ PI decision <em>(specify here)</em></td>
<td>Participation not advised per PI.</td>
</tr>
<tr>
<td>□ Protocol Eligibility Criterion NOT Listed Above <em>(specify here)</em></td>
<td>Any eligibility criterion not specified in the other “Reasons Not” options listed.</td>
</tr>
<tr>
<td>**Logistics <em>(if not listed below, specify in comments)</em></td>
<td></td>
</tr>
<tr>
<td>□ Non-Medical Scheduling Issues</td>
<td>Non-medical scheduling issue such as personal vacations, work schedules, clinic hours.</td>
</tr>
<tr>
<td>□ Transportation/Commute/Parking</td>
<td>Local transportation, commute or parking specified as problematic.</td>
</tr>
<tr>
<td>□ Insurance <em>(specify here)</em></td>
<td>Insurance coverage denial of clinical trial participation or of research related complications.</td>
</tr>
<tr>
<td>□ Compensation/Reimbursement</td>
<td>Refers to declined participation specifically due to study compensation/reimbursement.</td>
</tr>
<tr>
<td>□ Lives Out of Area/Patient Not Local</td>
<td>Individual lives non-locally (out of town/state).</td>
</tr>
<tr>
<td>**Study Related Issues <em>(if not listed below, specify in comments)</em></td>
<td></td>
</tr>
<tr>
<td>□ Route, Frequency or Duration of Study Agent Administration</td>
<td>Concerns pertaining to the frequency, duration or route of study agent administration.</td>
</tr>
<tr>
<td>□ Agent Toxicity</td>
<td>Concerns pertaining to side effects of study agent.</td>
</tr>
<tr>
<td>□ Too Many Visits or Length of Appointments</td>
<td>Concerns pertaining to number of study visits or visit length.</td>
</tr>
<tr>
<td>□ Too Many Procedures or invasiveness of Procedures</td>
<td>Concerns pertaining to number of procedures, or invasiveness of procedures.</td>
</tr>
<tr>
<td>□ Randomization/Placebo</td>
<td>Concerns pertaining to possibility of receiving placebo or being randomized.</td>
</tr>
<tr>
<td>**Participant Attitude and Concern <em>(if not listed below, specify in comments)</em></td>
<td></td>
</tr>
<tr>
<td>□ Confidentiality Concerns</td>
<td>Concerns regarding confidentiality.</td>
</tr>
<tr>
<td>□ Family’s Concerns</td>
<td>Family or friend concern about participation.</td>
</tr>
<tr>
<td>□ Personal Past Experiences</td>
<td>Concerns due to past research experience.</td>
</tr>
<tr>
<td>□ Medical Research Attitudes</td>
<td>Concern regarding “experimental” aspects of research or cultural beliefs.</td>
</tr>
<tr>
<td>□ Known History of Non-Adherence</td>
<td>Non-adherence to medical advice such as not keeping appointments or not taking prescribed medications.</td>
</tr>
<tr>
<td>□ Verbalized Minimal Concern of Cancer Risk</td>
<td>Conveyed minimal concern regarding their cancer risk.</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
</tr>
<tr>
<td>□ Overwhelmed with recent diagnosis</td>
<td>Too overwhelmed with recent health findings to discuss study participation.</td>
</tr>
<tr>
<td>□ Pursuing Alternative Treatment Option</td>
<td>Stated alternative treatment as reason for participation decline.</td>
</tr>
<tr>
<td>□ Site Study Accrual Complete</td>
<td>Accrual stopped due to site/study accrual target completion.</td>
</tr>
<tr>
<td>□ Subcontract Issue</td>
<td>Accrual stopped due to site subcontract issues.</td>
</tr>
<tr>
<td>Reason(s) Consent NOT Signed/Study Intervention NOT Started:</td>
<td>Definitions</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>□ Decline</td>
<td>Declined without specified reason. <em>Note: when reasons for decline are known please use applicable category.</em></td>
</tr>
<tr>
<td>□ Passive decline</td>
<td>Did not respond to attempts at further contact (did not return calls, did not return for screening appointments).</td>
</tr>
<tr>
<td>□ Other <em>(specify here)</em></td>
<td>Reasons NOT specified in other “Reasons Not” categories provided.</td>
</tr>
</tbody>
</table>