

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](mailto:dcphelpdesk@dcpais.com) or 1-844-901-4357

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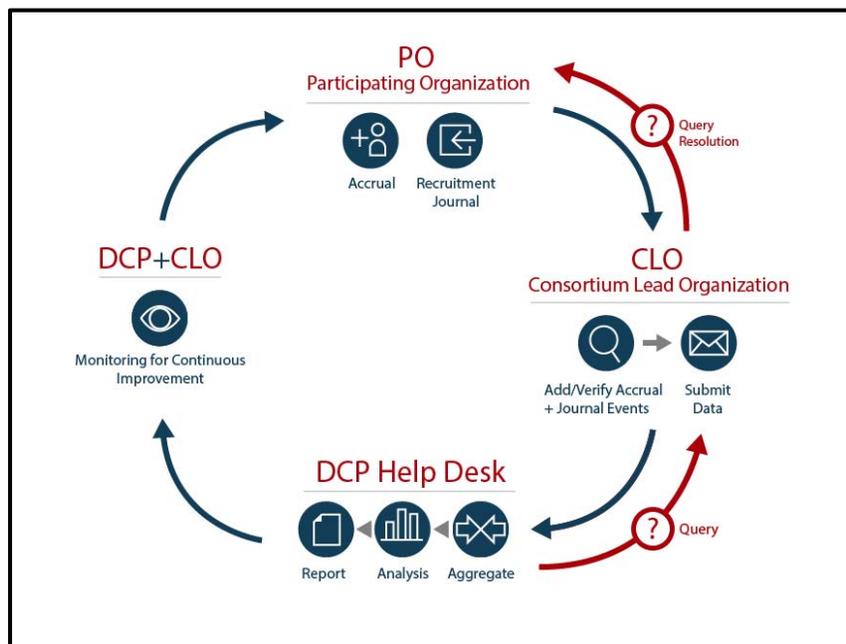
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**AQuIP OARS Process Overview**

Accrual and recruitment journaling data entry is done in real time at the accruing PO or CLO. By the 10th of every month the affiliated CLO reviews the POs' accrual data from the prior month, clarifies and/or modifies as necessary and then submits the data to the DCP Help Desk at TRI. The DCP Help Desk then aggregates the data, performs data integrity checks and sends data queries back to the CLOs for resolution with their respective POs as needed. TRI then generates the AQuIP Zone Monitoring Reports which show how actual accrual rates compare to the projected accrual rate. This accrual performance status helps DCP and CLOs identify the need for strategic modifications. This cycle of reporting and ongoing evaluation occurs each month and is the basis for continuous improvement. Furthermore, all accrual outcomes data are being collected, aggregated, analyzed and mined to find "lessons learned" to apply when developing future protocols and recruitment plans.



## How to Request Access to AQuIP OARS

AQuIP OARS accounts may be requested when a protocol has been approved by DCP. A request for AQuIP OARS access is initiated by the CLO since CLOs may differ in how they manage accrual tracking and reporting per [DCP SOP 6](#): Participant Recruitment, Retention and Adherence.

Please contact your CLO Lead Coordinator to submit an access request on your behalf following the instructions below:

1. CLO Lead Coordinator/designee sends an AQuIP OARS access request to the [DCP Help Desk](#) confirming the [20 minute AQuIP OARS training webinar and user guide](#) have been reviewed by the individual specified, and therefore has completed the AQuIP OARS training. Please send your requests using the following table format and include all requested information:

DCP Protocol Number/Agent/Organ (list each)	First/Last Name	Site Designation (CLO or PO)	Site Name	Confirmation of webinar training (complete)	Confirmation of user guide training (complete)	Email address	Phone Number

2. DCP Help Desk submits the CLO's request to DCP for approval.
3. An AQuIP OARS account is created and credentials are provided within two (2) business days from receipt of DCP's approval.
  - a. The password may be reset by selecting the "Password Reset" button on the "Accrual Report" login page and entering your email address. Next, select the "Password Reset" button to prompt an email notification, which includes a link to change your current password. Please note: this email notification may be sent to your clutter/junk folders.

**Please note:** Account activity will be reviewed by the DCP auditing and informatics support contractor at Technical Resources International (TRI), Inc. Account holders that have not logged into the system for more than 90 days (approximately 3 months) will be identified as candidates for inactivation. An email will be sent requesting the account holder to login into the system and thereby confirm the account is still needed. Upon confirmation that the account is no longer needed or if no response is received within 30 calendar days of the request for confirmation, the account will be deactivated without further notification. The CLO Lead Coordinator/designee must notify the [DCP Help Desk](#) when a CLO or PO user no longer needs access to AQuIP OARS.

4. Once access is granted, select the **Accrual Report** tab.

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Division of Cancer Prevention

## Accrual Quality Improvement Program (AQIP)

Home Recruitment Planning Toolkit **Accrual Report** Training and Resources DCP Helpdesk

### About the Accrual Quality Improvement Program (AQIP)

AQIP is a dynamic clinical trial accrual improvement program that will leverage sponsor, study staff, and participant input. AQIP consists of systematic planning, ongoing evaluation and responsive actions that lead to measurable improvement.

**AQIP Goals**

- Ethical conduct of early phase clinical chemoprevention research
- Proper stewardship of public funds
- Scientific progress

**AQIP Strategies**

- Monitor and improve recruitment early and often - together
- Determine realistic recruitment rate projections - by consensus
- Use enhanced screening reports
- Apply accrual zones for early intervention

**Quick Links**

- Planning**
  - SOP 6: Participant Recruitment, Retention and Adherence
  - Recruitment, Retention and Adherence Plan Outline
- Toolkit**
  - Manual
  - Media Templates
  - Image Library
- Accrual Report**
  - Report Form Template
  - Report Completion Demonstration
- Training & Resources**
  - Webinars
  - Resources

[Click here to visit the C2012 Clinical Trial Management Website](#)

This website is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services. NIH...Turning Discovery Into Health<sup>®</sup>

5. Log into AQIP OARS using your account credentials provided by the DCP Help Desk and select **Log In**.

## AQIP Online Accrual Reporting System

Please log in

Registered User Email Address

Password

**Log In**

[Request Access](#) | [Password Reset](#)

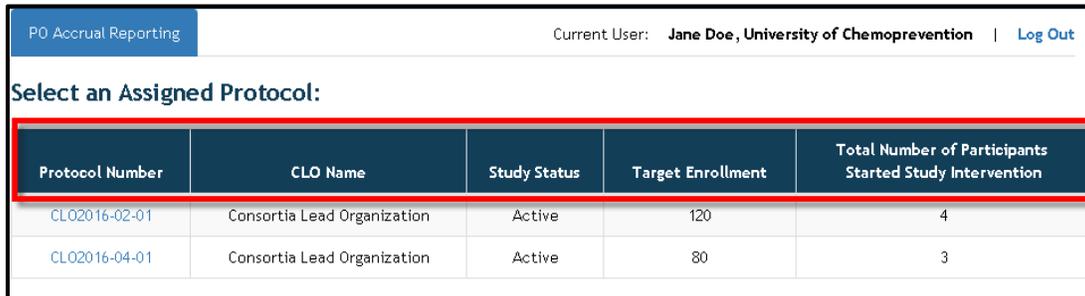
## Participating Organization (PO) Accrual Reporting

Participating Organizations (PO) are the DCP Consortia accrual sites affiliated with the CLOs. Please note: Jane Doe 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, listing all protocol numbers assigned to Jane Doe at University of Chemoprevention. In addition, the following columns are displayed:

- CLO Name
- Study Status
- Target Enrollment
- Total Number of Participants Started Study Intervention

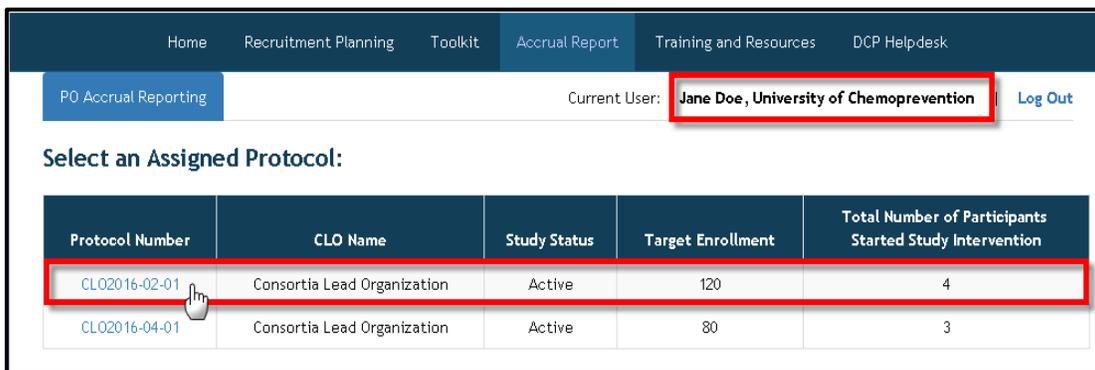
**Please note:** All columns, with the exception of the CLO Name, can be sorted in ascending/descending order by clicking on the column header.



The screenshot shows the 'PO Accrual Reporting' page. At the top right, it says 'Current User: Jane Doe, University of Chemoprevention | Log Out'. Below this is a heading 'Select an Assigned Protocol:' followed by a table with the following data:

Protocol Number	CLO Name	Study Status	Target Enrollment	Total Number of Participants Started Study Intervention
CL02016-02-01	Consortia Lead Organization	Active	120	4
CL02016-04-01	Consortia Lead Organization	Active	80	3

2. To continue, select Protocol **CL020 16-02-01**.



This screenshot is similar to the previous one but includes a navigation bar at the top with links: Home, Recruitment Planning, Toolkit, Accrual Report, Training and Resources, and DCP Helpdesk. The 'Current User' information is also present. A red box highlights the 'Current User' text. A mouse cursor is shown clicking on the 'CL02016-02-01' protocol number in the table below:

Protocol Number	CLO Name	Study Status	Target Enrollment	Total Number of Participants Started Study Intervention
CL02016-02-01	Consortia Lead Organization	Active	120	4
CL02016-04-01	Consortia Lead Organization	Active	80	3

3. Next, the information for **Protocol CL02016-02-01** appears along with the following tabs to enter additional data:
- a. **Protocol Information:** Displays the current status for **Protocol CL020 16-02-01**.

PO Accrual Reporting

Current User: **Jane Doe, University of Chemoprevention** | [Log Out](#)

**Protocol Number: CL02016-02-01**

Protocol Information | Participant Accrual | Recruitment Journal | Close

### Protocol Information

Current Reporting Month:	April 2017
Protocol Title:	Randomized Phase X Trial of Agent B in High-Risk Individuals
Protocol Number:	CL02016-02-01
Targeted Enrollment:	120
Total Number of Participants Started Study Intervention:	4
Projected Accrual Per Month:	8.00
Projected Completion Date:	June 12, 2018
Study Status:	Active
Study Status Date:	March 27, 2017
Accrual Duration (Months):	15
Approved Participating Organizations:	University of Chemoprevention Chemoprevention Institute
Date of First Contact:	March 08, 2017

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

Current User: **Jane Doe, University of Chemoprevention** | [Log Out](#)

Protocol Information | **Participant Accrual** | Recruitment Journal | Close

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

- 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.
- 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 can be sorted in ascending/descending order by clicking on the column header.

PO Accrual Reporting | Current User: Jane Doe, University of Chemoprevention | Log Out

Protocol Number: CLO2016-02-01 | Protocol Information | Participant Accrual | Recruitment Journal | Close

**Participant Accrual** | + Add New Participant

◆ Co: Contacted | ◆ C: Consented | ◆ NS: Not on Study (Consent Not Signed, Ineligible, etc.) | ◆ OS: On Study

Status Marker	Participant ID	First Contact Date	Recruitment Strategies	Consent Date/Status	Reason(s) Consent NOT Signed/Study Intervention NOT Started	Intervention Start Date	Comments
◆	D	March 29, 2017	Principal Investigator (specify name[]) Returned Call, Community HCP* (specify specialty),				

Edit | Delete

i. How to Add a New Participant

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

**Participant Accrual**

◆ Co: Contacted | ◆ C: Consented | ◆ NS: Not on Study (Consent Not Signed, Ineligible, etc.) | ◆ OS: On Study

+ Add New Participant

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

**Add Participant Accrual Information** | Submit | Close

**Participant ID (PID):** Participant ID (PID)

**First Contact Date:** First Contact Date [X] [Calendar]

**Recruitment Strategies:** Recruitment Strategies [Add/Edit]

**Consent Date/Status:** Consent Date/Status [X] [Calendar]  Consent NOT Signed

**Intervention Start Date:** Intervention Start Date [X] [Calendar]  Not On Study Intervention (ineligible, dropped out before screening, etc.)

**Reason(s) Consent NOT Signed/Study Intervention NOT Started:** Reason(s) Consent NOT Signed/Study Intervention NOT Started [Add/Edit]

**Comments:** Comments

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

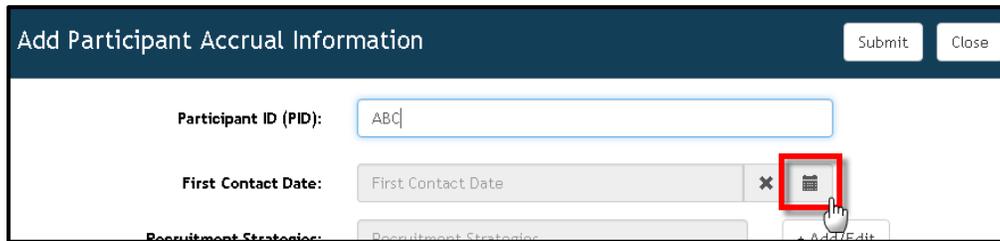
The screenshot shows a web form titled "Add Participant Accrual Information". The "Participant ID (PID)" field is highlighted with a red box and contains the text "ABC". Other fields include "First Contact Date", "Recruitment Strategies", "Consent Date/Status", "Intervention Start Date", "Reason(s) Consent NOT Signed/Study Intervention NOT Started", and "Comments". There are also "Submit" and "Close" buttons in the top right corner.

**Please note:** For quality assurance purposes, 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 following screening/placeholder ID numbering convention until participants receive a unique ID. The Participant ID # field (PID) should be populated with this screening/placeholder and replaced with the PID upon study enrollment [by the accruing site]. As this is a recommendation, CLOs are welcome to follow this process or apply the necessary institutional conventions to avoid blank or duplicate IDs.

Participant Entered into AQuIP OARS	Participant ID #
First Participant Entered by DCP Institution	DCP Institution Code-01
Second Participant Entered by DCP Institution	DCP Institution Code-02
Third Participant Entered by DCP Institution	DCP Institution Code-03
Example: First Participant Entered by The University of Arizona Medical Center-University Campus	Example: AZ017-01
Example: Second Participant Entered by The University of Arizona Medical Center-University Campus	Example: AZ017-02

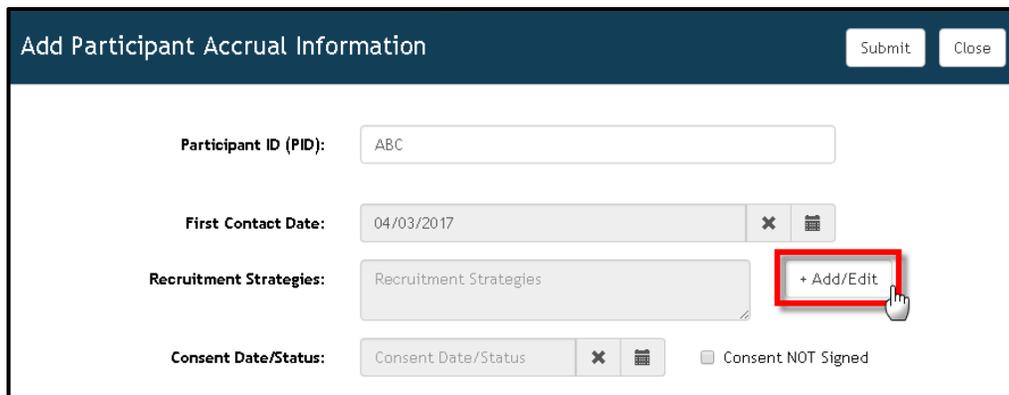
Contact the DCP Help Desk at [dcphelpdesk@dcpais.com](mailto:dcphelpdesk@dcpais.com) or by calling 1-844-901-4357 if CLO or PO DCP Institution Code is unknown.

Step 4: If this participant has already been contacted, enter the date by selecting the calendar button.



The screenshot shows the 'Add Participant Accrual Information' form. The 'Participant ID (PID)' field contains 'ABC'. The 'First Contact Date' field is empty, and a red box highlights the calendar icon to its right. Below it, the 'Recruitment Strategies' field is also empty, with a '+ Add/Edit' button to its right.

Step 5: Next, select the **+Add/Edit** button to indicate the recruitment strategy used for this participant.

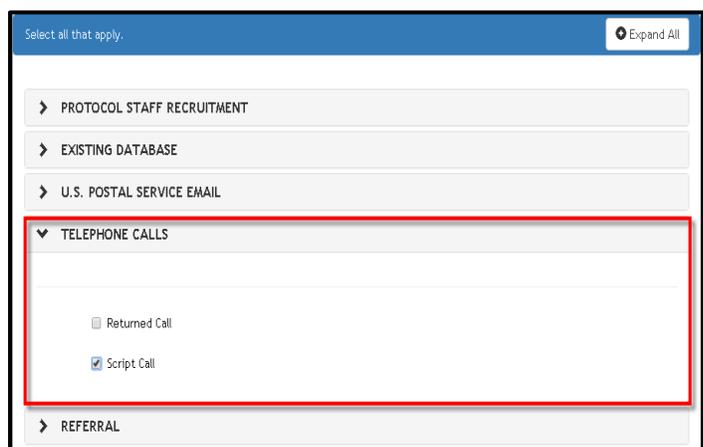


The screenshot shows the 'Add Participant Accrual Information' form. The 'Participant ID (PID)' field contains 'ABC'. The 'First Contact Date' field is now filled with '04/03/2017'. The 'Recruitment Strategies' field is empty, and a red box highlights the '+ Add/Edit' button to its right. Below it, the 'Consent Date/Status' field is empty, and a checkbox labeled 'Consent NOT Signed' is present.

Step 6: The **Recruitment Strategies** page appears. Select the recruitment strategy used to contact the participant and fill out/check the displayed options [as needed] for each of the strategies selected. For this example, we selected **Telephone Calls** and checked the **Script Call** option.

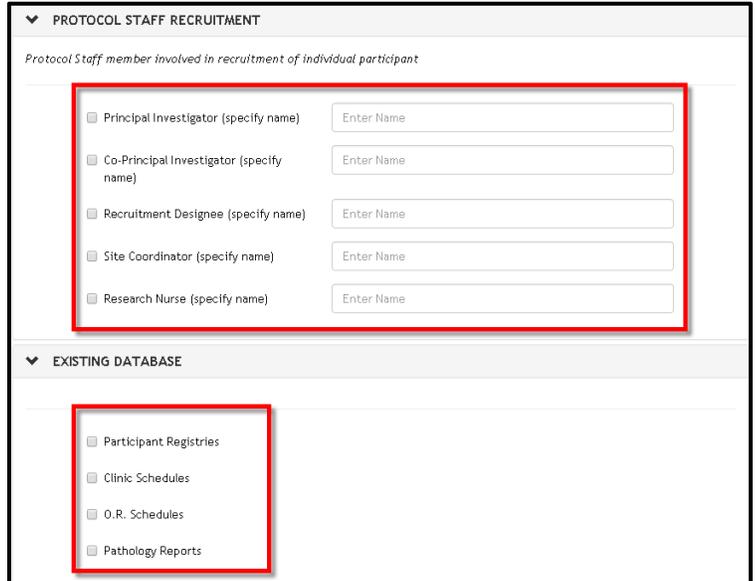


The screenshot shows the 'Recruitment Strategies' page. A list of strategies is displayed, including 'PROTOCOL STAFF RECRUITMENT', 'EXISTING DATABASE', 'U.S. POSTAL SERVICE EMAIL', 'TELEPHONE CALLS', 'REFERRAL', 'NON-DIGITAL MASS MEDIA', 'DIGITAL MEDIA', 'COMMUNITY CONTACTS', 'PATIENT ISSUES/CONCERNS', and 'Other'. The 'TELEPHONE CALLS' option is highlighted with a red box.

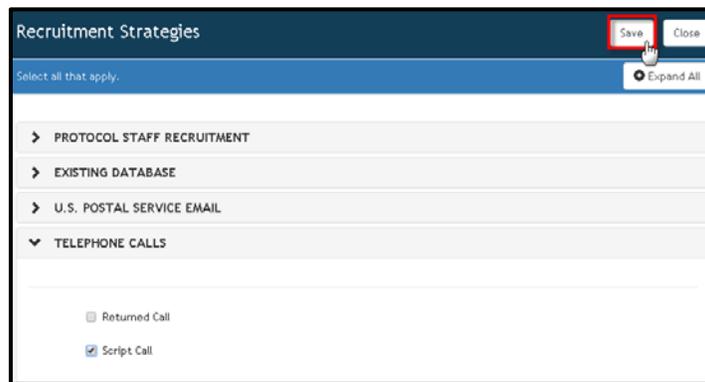


The screenshot shows the 'Recruitment Strategies' page with the 'TELEPHONE CALLS' strategy expanded. The expanded view shows two options: 'Returned Call' (unchecked) and 'Script Call' (checked). The 'Script Call' option is highlighted with a red box.

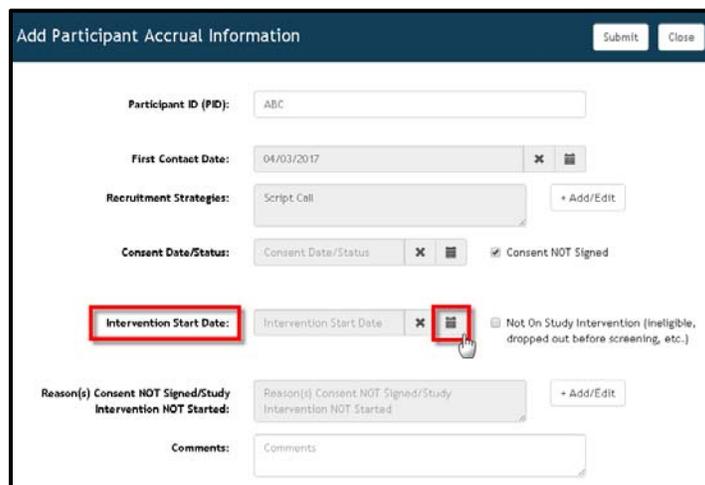
**Please note:** each strategy has its own options or fields to check/fill out. To view these options or fields for all Strategies, select **Expand All**.



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



Step 8: If the Study Intervention Date is available, select the calendar button and enter a date. **Please note** users can later enter this information to document any changes.



Step 9: Enter the additional information required [i.e. if a Consent Form has been signed]. If it has not been signed, check the **Consent NOT Signed** box and select the **+Add/Edit** button.

The screenshot shows a form titled "Add Participant Accrual Information" with fields for Participant ID (PID), First Contact Date (04/03/2017), Recruitment Strategies (Script Call), Consent Date/Status (with a checked "Consent NOT Signed" box), Intervention Start Date, and Reason(s) Consent NOT Signed/Study Intervention NOT Started (with an "+ Add/Edit" button). A "Comments" field is at the bottom.

Step 10: The **Reason Consent NOT Signed or Study Intervention NOT Started Table** page appears. From the list, select the reason this participant did not sign a consent form and enter the required information. For this example, we selected **Logistics** and checked **Scheduling Conflicts**.

The screenshot shows a table with categories: ELIGIBILITY CRITERIA NOT MET, LOGISTICS, STUDY RELATED ISSUES, PARTICIPANT ATTITUDE AND CONCERN, and Other. The LOGISTICS row is highlighted with a red box.

The screenshot shows the "LOGISTICS" section expanded, listing options: Scheduling Conflicts (checked), Transportation/Commute, Transportation/Parking, Insurance, and Compensation/ Reimbursement. The "Scheduling Conflicts" checkbox is highlighted with a red box.

Step 11: Select **Save** to submit your changes.

Reason Consent NOT Signed or Study Intervention NOT Started Table

Select all that apply. Expand All

ELIGIBILITY CRITERIA NOT MET

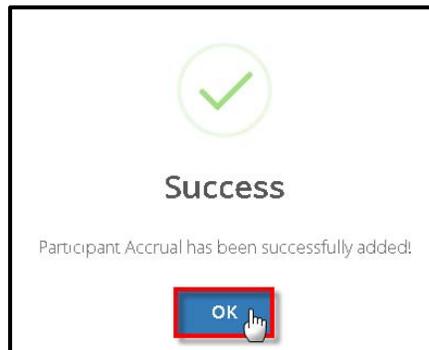
LOGISTICS

(if not listed below, specify in comments)

- Scheduling Conflicts
- Transportation/Commute
- Transportation/Parking
- Insurance
- Compensation/ Reimbursement

STUDY RELATED ISSUES

Step 12: A message appears indicating the participant was successfully added. Select **OK** to return to the **Participant Accrual Information Page**.



ii. How to Edit Information

Step 1: To update or edit information for existing participants, select the **Edit** button and follow **Steps 1 to 12** in section i.

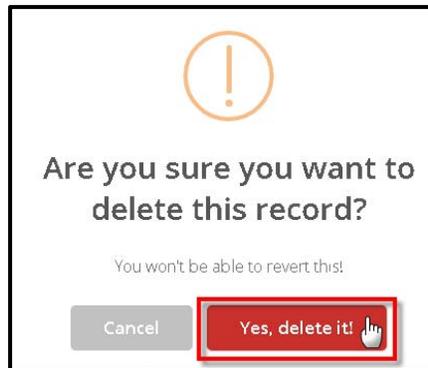
Status Marker	Participant ID	First Contact Date	Recruitment Strategies	Consent Date/Status	Reason(s) Consent NOT Signed/Study Intervention NOT Started	Intervention Start Date	Comments	
◆	B	March 08, 2017	Mailing List,	No	Known History of Non-Compliance,			<div style="border: 1px solid gray; padding: 2px;"> <span>Edit</span>  <span>Delete</span> </div>

iii. How to Delete Information

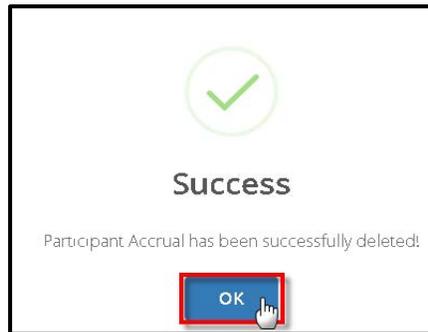
Step1: Select the **Delete** button corresponding to the participant information you wish to remove from the list.

Status Marker	Participant ID	First Contact Date	Recruitment Strategies	Consent Date/Status	Reason(s) Consent NOT Signed/Study Intervention NOT Started	Intervention Start Date	Comments
◆	B	March 08, 2017	Mailing List,	No	Known History of Non-Compliance,		<input type="button" value="Edit"/> <input type="button" value="Delete"/>
	C	March	Mailing List	March 23	Scheduling Conflicts		

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



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



- c. **Recruitment Journal:** This is a place to document activities, events or other factors that may have an effect on study accrual trends (either positive or negative) rather than on a specific participant. 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: Once the **Participant Accrual** page appears, select the **Recruitment Journal** tab to view and enter Study Event data.



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

**Please note:** \* These columns can be sorted in ascending/descending order by clicking on the column header.

Protocol Number: **CLO2016-02-01**    Protocol Information    Participant Accrual    **Recruitment Journal**    Close

### Recruitment Journal

+ Add New Study Event

Study Event Start Date	Study Event End Date	Study Event	Event Description	
March 08, 2017		A8 - Accrual on Hold: FDA Clinical Hold	Study is now on hold.	Edit    Delete

i. How to Add a New Study Event

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

### Recruitment Journal

+ Add New Study Event

Study Event Start Date	Study Event End Date	Study Event	Event Description	
March 08, 2017		A1 - Study Active		Edit    Delete

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

### Add Study Event

Submit    Close

**Study Event Start Date:**

**Study Event End Date: (if applicable)**

**Study Event:**

**Study Event Description:**

Step 3: Enter the start date and select the **Study Event** from the pull-down menu. For this example, we selected **Protocol Amendment Approval: Eligibility**.

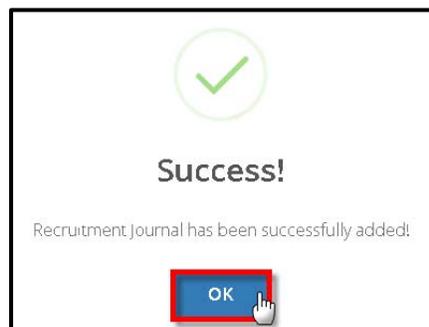
The screenshot shows the 'Add Study Event' form. The 'Study Event Start Date' field is highlighted with a red box and contains '04/03/2017'. The 'Study Event' dropdown menu is open, showing a list of event types. The option 'A5 - Protocol Amendment Approval: Eligibility' is highlighted with a blue background and a mouse cursor. Below the dropdown is a table with columns 'Event Start Date', 'Study Event End Date', and 'Study Event Description'. The table contains three rows of data.

Event Start Date	Study Event End Date	Study Event Description
ch 08, 2017		A8 - Accrual Clinical
ch 28, 2017		A5 - Protocol Approval
ch 29, 2017		A4 - Protocol Submitt

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

The screenshot shows the 'Add Study Event' form with the 'Submit' button highlighted with a red box and a mouse cursor. The form fields are filled with the same data as in the previous screenshot.

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.

Recruitment Journal				
Study Event Start Date	Study Event End Date	Study Event	Event Description	
March 08, 2017		A1 - Study Active		<input type="button" value="Edit"/> <input type="button" value="Delete"/>

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

### Edit Study Event

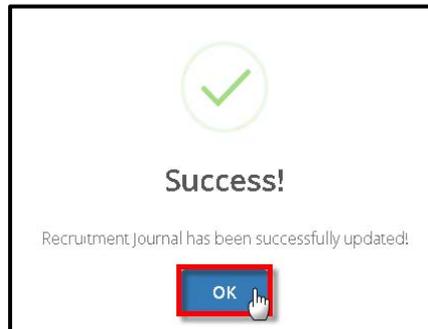
**Study Event Start Date:**

**Study Event End Date: (if applicable)**

**Study Event:**

**Study Event Description:**

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

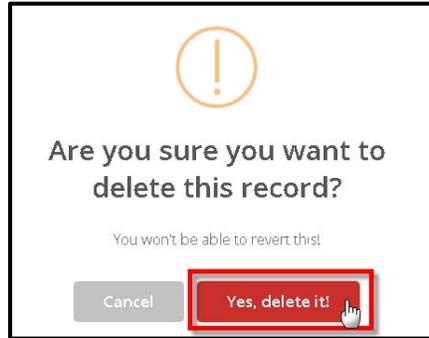


iii. How to Delete Information

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

March 29, 2017		A4 - Protocol Amendment Submitted to DCP		<input type="button" value="Edit"/> <input type="button" value="Delete"/>
April 03, 2017		A18 - PI Issues: Availability/ Change in PI		<input type="button" value="Edit"/> <input type="button" value="Delete"/>

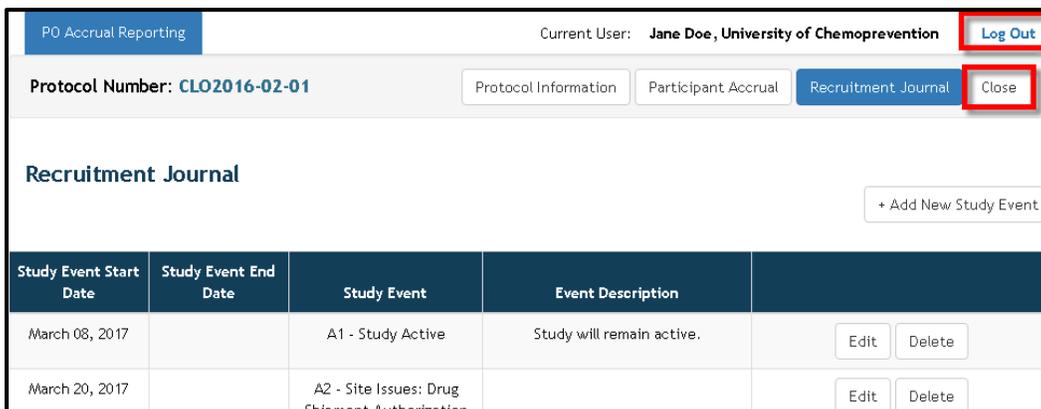
Step 2: A message to confirm deletion appears. To continue select **Yes, delete it!**



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.



Step 4: The **Recruitment Journal** page appears. If you wish to add or update another protocol, select **Close** to return to the **Assigned Protocol** page or select **Log Out** to end this session.



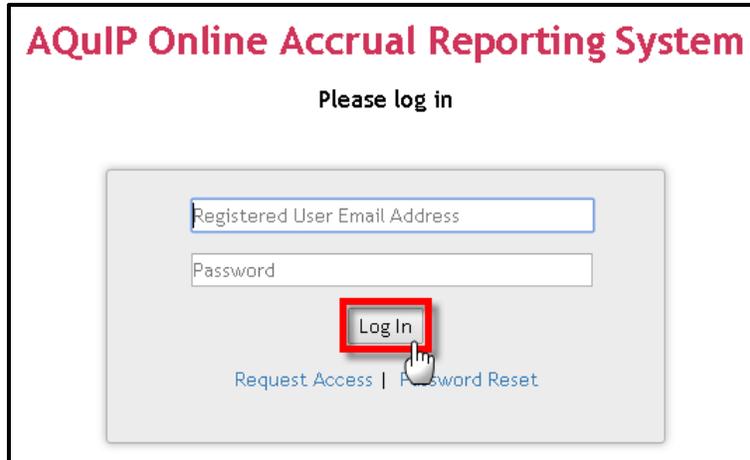
The screenshot shows the "Recruitment Journal" page in a web application. At the top, there is a navigation bar with "PO Accrual Reporting" on the left and "Current User: Jane Doe, University of Chemoprevention" on the right, with a "Log Out" button. Below the navigation bar, the "Protocol Number: CLO2016-02-01" is displayed. There are three tabs: "Protocol Information", "Participant Accrual", and "Recruitment Journal", with the "Recruitment Journal" tab selected. A "Close" button is visible next to the "Recruitment Journal" tab. Below the tabs, there is a section titled "Recruitment Journal" with a "+ Add New Study Event" button. A table with the following columns is shown: "Study Event Start Date", "Study Event End Date", "Study Event", "Event Description", and "Action". The table contains two rows of data.

Study Event Start Date	Study Event End Date	Study Event	Event Description	Action
March 08, 2017		A1 - Study Active	Study will remain active.	Edit Delete
March 20, 2017		A2 - Site Issues: Drug Shipment Authorization		Edit Delete

## 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 of Arizona, and University of Wisconsin. Please note, Jane Doe 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 steps 1-5 under **How to Request AQUiP OARS** Access section.



**AQUiP Online Accrual Reporting System**

Please log in

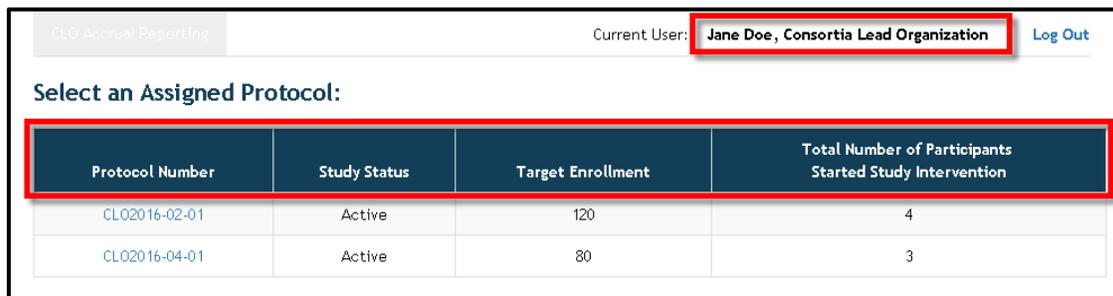
Registered User Email Address

Password

Log In

[Request Access](#) | [Password Reset](#)

2. Once logged in, the **Assigned Protocol** page appears, listing all protocol numbers assigned to each of Jane Doe's Participating Organizations. In addition, the following columns are displayed:
  - Study Status
  - Target Enrollment
  - Total Number of Participants Started Study Intervention**Please note:** All columns can be sorted in ascending/descending order by clicking on the column header.



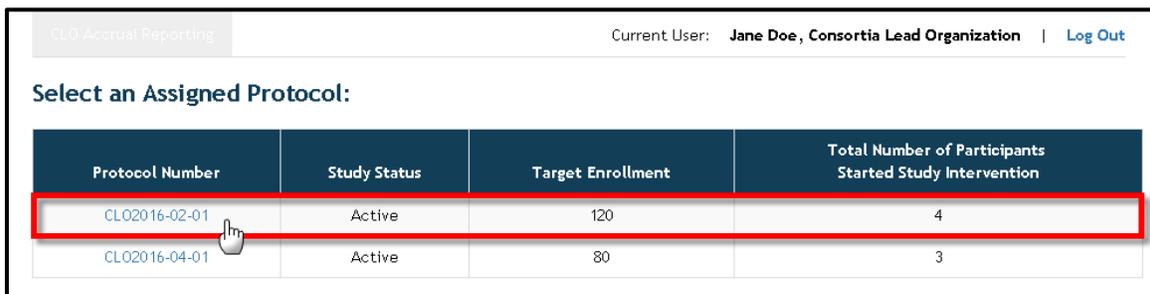
CLO Accrual Reporting

Current User: **Jane Doe, Consortia Lead Organization** [Log Out](#)

Select an Assigned Protocol:

Protocol Number	Study Status	Target Enrollment	Total Number of Participants Started Study Intervention
<a href="#">CLO2016-02-01</a>	Active	120	4
<a href="#">CLO2016-04-01</a>	Active	80	3

3. To continue, select **CL02016-02-01**.



CLO Accrual Reporting

Current User: **Jane Doe, Consortia Lead Organization** | [Log Out](#)

Select an Assigned Protocol:

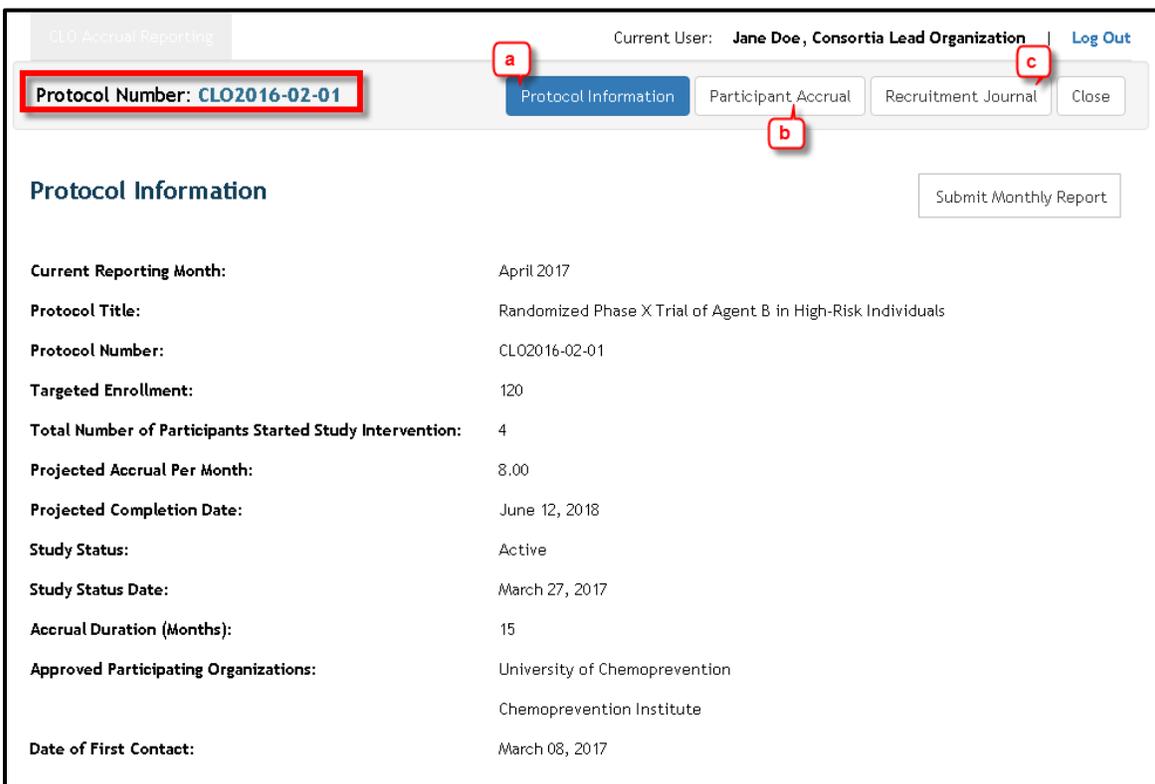
Protocol Number	Study Status	Target Enrollment	Total Number of Participants Started Study Intervention
<a href="#">CLO2016-02-01</a>	Active	120	4
<a href="#">CLO2016-04-01</a>	Active	80	3

4. Once you select **Protocol CL02016-02-01**, a reminder appears indicating when the Monthly Report is due. Select **Continue** to proceed to the **Protocol Information** page.



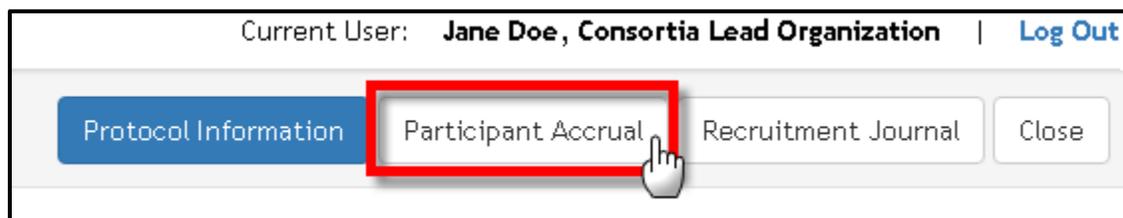
**Please note:** Daily reminders for Monthly Report submission appear from the 1st to the 15th of the month.

5. Next, the information for **Protocol CL02016-02-01** appears along with the following tabs to enter additional data:
- Protocol Information:** Displays the current status for **Protocol CL020 16-02-01**.



b. **Participant Accrual:**

Step 1: Next, 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 Jane Doe and the First Contact Date.

CLO Accrual Reporting | Current User: Jane Doe, Consortia Lead Organization | Log Out

Protocol Number: CLO2016-02-01 | Protocol Information | Participant Accrual | Recruitment Journal | Close

### Participant Accrual

Select a Participating Organization Assigned to this Protocol.

Approved PO Name	First Contact Date
University of Chemoprevention	March 08, 2017
Chemoprevention Institute	March 09, 2017

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

CLO Accrual Reporting | Current User: Jane Doe, Consortia Lead Organization | Log Out

Protocol Number: CLO2016-02-01 | Protocol Information | Participant Accrual | Recruitment Journal | Close

### Participant Accrual

Select a Participating Organization Assigned to this Protocol.

Approved PO Name	First Contact Date
University of Chemoprevention	March 08, 2017
Chemoprevention Institute	March 09, 2017

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

- 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.
- 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 can be sorted in ascending/descending order by clicking on the column header.

CLO Accrual Reporting | Current User: Jane Doe, Consortia Lead Organization | Log Out

Protocol Number: CLO2016-02-01 | Protocol Information | Participant Accrual | Recruitment Journal | Close

### Participant Accrual

PO: University of Chemoprevention | + Add New Participant

◆ Co: Contacted 
 ◆ C: Consented 
 ◆ NS: Not on Study (Consent Not Signed, Ineligible, etc.) 
 ◆ OS: On Study

Status Marker	Participant ID	First Contact Date	Recruitment Strategies	Consent Date/Status	Reason(s) Consent NOT Signed/Study Intervention NOT Started	Intervention Start Date	Comments
<span style="color: gold;">◆</span>	D	March 29, 2017	Principal Investigator (specify name)() Returned Call, Community HCP* (specify specialty),				

Edit | Delete

i. How to Add a New Participant

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

**Participant Accrual**

PO: **University of Chemoprevention**

◆ Co: Contacted   ◆ C: Consented   ◆ NS: Not on Study (Consent Not Signed, Ineligible, etc.)   ◆ OS: On Study

**+ Add New Participant**

Status Marker	Participant ID	First Contact Date	Recruitment Strategies	Consent Date/Status	Reason(s) Consent NOT Signed/Study Intervention NOT Started	Intervention Start Date	Comments
◆	D	March 29, 2017	Principal Investigator (specify name)() Returned Call, Community HCP* (specify specialty),				<input type="button" value="Edit"/> <input type="button" value="Delete"/>

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

**Add Participant Accrual Information**

**Participant ID (PID):**

**First Contact Date:**

**Recruitment Strategies:**

**Consent Date/Status:**     Consent NOT Signed

**Intervention Start Date:**     Not On Study Intervention (ineligible, dropped out before screening, etc.)

**Reason(s) Consent NOT Signed/Study Intervention NOT Started:**

**Comments:**

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

**Add Participant Accrual Information**

**Participant ID (PID):**

**First Contact Date:**

**Recruitment Strategies:**

**Consent Date/Status:**     Consent NOT Signed

**Intervention Start Date:**     Not On Study Intervention (ineligible, dropped out before screening, etc.)

**Reason(s) Consent NOT Signed/Study Intervention NOT Started:**

**Comments:**

**Please note:** For quality assurance purposes, the **AQuIP OARS System does not allow for duplicate or blank, placeholders and/or participant IDs.** In the event that a CLO does not have a standard screening (or placeholder ID) procedure, we offer the following screening/placeholder ID numbering convention until participants receive a unique ID. The Participant ID # field should be populated with this screening/placeholder and replaced with the PID upon study enrollment [by the accruing site]. As this is a recommendation, CLOs are welcome to follow this process or apply the necessary institutional conventions to avoid blank or duplicate IDs.

Participant Entered into AQuIP OARS	Participant ID #
First Participant Entered by DCP Institution	DCP Institution Code-01
Second Participant Entered by DCP Institution	DCP Institution Code-02
Third Participant Entered by DCP Institution	DCP Institution Code-03
Example: First Participant Entered by The University of Arizona Medical Center-University Campus	Example: AZ017-01
Example: Second Participant Entered by The University of Arizona Medical Center-University Campus	Example: AZ017-02

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: If this participant was already contacted, enter the date by selecting the calendar button.

Step 5: Next, select the **+Add/Edit button** to indicate the recruitment strategy used on this participant.

Step 6: The **Recruitment Strategies** page appears. Select the recruitment strategy used to contact the participant and fill out/check the displayed options [as needed] for each of the strategies selected. For this example, we selected **Telephone Calls** and checked the **Script Call** option.

Recruitment Strategies

Select all that apply. Expand All

- > PROTOCOL STAFF RECRUITMENT
- > EXISTING DATABASE
- > U.S. POSTAL SERVICE EMAIL
- > TELEPHONE CALLS**
- > REFERRAL
- > NON-DIGITAL MASS MEDIA
- > DIGITAL MEDIA
- > COMMUNITY CONTACTS
- > PATIENT ISSUES/CONCERNS
- > Other

Select all that apply. Expand All

- > PROTOCOL STAFF RECRUITMENT
- > EXISTING DATABASE
- > U.S. POSTAL SERVICE EMAIL
- ▼ TELEPHONE CALLS**
  - Returned Call
  - Script Call
- > REFERRAL

**Please note:** each strategy has its own options or fields to check/fill out. To view these options or fields for all strategies, select **Expand All**.

Save Close

**Expand All**

▼ PROTOCOL STAFF RECRUITMENT

Protocol Staff member involved in recruitment of individual participant.

- Principal Investigator (specify name) Enter Name
- Co-Principal Investigator (specify name) Enter Name
- Recruitment Designee (specify name) Enter Name
- Site Coordinator (specify name) Enter Name
- Research Nurse (specify name) Enter Name

▼ EXISTING DATABASE

- Participant Registries
- Clinic Schedules
- O.R. Schedules
- Pathology Reports

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

Recruitment Strategies

Select all that apply. Expand All

- > PROTOCOL STAFF RECRUITMENT
- > EXISTING DATABASE
- > U.S. POSTAL SERVICE EMAIL
- ▼ TELEPHONE CALLS
  - Returned Call
  - Script Call

Save Close

Step 8: If the Study Intervention Date is available, select the calendar button and enter a date. **Please note** users can later enter this information to document any changes.

The screenshot shows the 'Add Participant Accrual Information' form. The 'Intervention Start Date' field is highlighted with a red box, and a calendar icon next to it is also highlighted with a red box and a mouse cursor. Other fields include Participant ID (ABC), First Contact Date (04/03/2017), Recruitment Strategies (Script Call), Consent Date/Status (Consent Date/Status), and Reason(s) Consent NOT Signed/Study Intervention NOT Started.

Step 9: Enter the additional information required [i.e. if a Consent Form has been signed]. If it has not been signed, select the **+Add/Edit** button.

The screenshot shows the 'Add Participant Accrual Information' form. The 'Consent NOT Signed' checkbox is checked and highlighted with a red box. The '+ Add/Edit' button next to the Reason(s) Consent NOT Signed/Study Intervention NOT Started field is also highlighted with a red box and a mouse cursor.

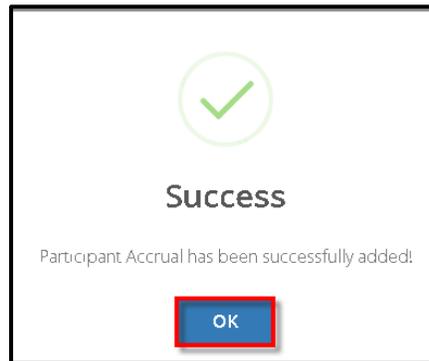
Step 10: The **Reason Consent NOT Signed or Study Intervention NOT Started Table** page appears. From the list, select the reason this participant did not sign a Consent Form and enter the required information. For this example, we selected **Logistics** and checked **Scheduling Conflicts**.

The screenshot shows the 'Reason Consent NOT Signed or Study Intervention NOT Started Table' page. The 'LOGISTICS' option is selected and highlighted with a red box.

The screenshot shows the 'Reason Consent NOT Signed or Study Intervention NOT Started Table' page. The 'LOGISTICS' section is expanded, and the 'Scheduling Conflicts' checkbox is checked and highlighted with a red box.

Step 11: Select **Save** to submit your changes.

Step 12: A message appears indicating the participant was successfully added. Select **OK** to return to the **Participant Accrual Information** page.



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.

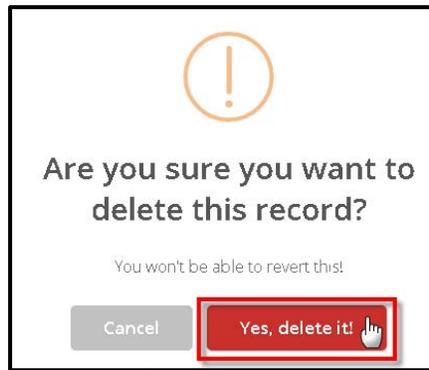
Status Marker	Participant ID	First Contact Date	Recruitment Strategies	Consent Date/Status	Reason(s) Consent NOT Signed/Study Intervention NOT Started	Intervention Start Date	Comments	
◆	ABC	April 03, 2017	Script Call,	No	Scheduling Conflicts,			<div style="border: 1px solid red; padding: 2px;">Edit</div> Delete

iii. How to Delete Information

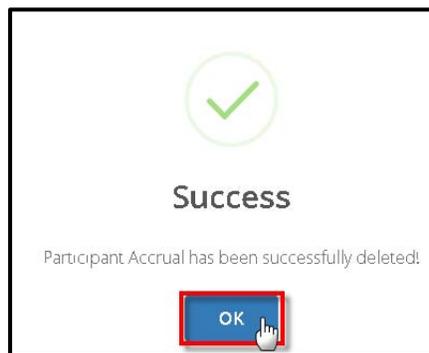
Step 1: Select the **Delete** button corresponding to the participant you wish to remove from the list.

Status Marker	Participant ID	First Contact Date	Recruitment Strategies	Consent Date/Status	Reason(s) Consent NOT Signed/Study Intervention NOT Started	Intervention Start Date	Comments	
◆	A	March 16, 2017	Study Website, Institutional Website,	March 17, 2017/Yes		March 20, 2017		Edit <div style="border: 1px solid red; padding: 2px;">Delete</div>

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



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



c. **Recruitment Journal:** Once the **Participant Accrual** page appears, select the **Recruitment Journal** tab to view and enter study event data.



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 can be sorted in ascending/descending order by clicking on the column header.

The screenshot shows the 'Recruitment Journal' page for protocol CLO2016-02-01. The current user is Jane Doe, Consortia Lead Organization. The page has tabs for Protocol Information, Participant Accrual, and Recruitment Journal (selected). A '+ Add New Study Event' button is in the top right. Below is a table with the following data:

Study Event Start Date	Study Event End Date	Study Event	Event Description	POs Affected	
March 08, 2017		A1 - Study Active	Study will remain active.	University of Chemoprevention	Edit Delete

i. How to Add New Study Event

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

This screenshot is identical to the previous one, but the '+ Add New Study Event' button is highlighted with a red rectangular box, and a mouse cursor is pointing at it.

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

The 'Add Study Event' form contains the following fields:

- Study Event Start Date:
- Study Event End Date: (if applicable)
- Study Event:
- Study Event Description:
- POs Affected:  University of Chemoprevention  
 Chemoprevention Institute

Buttons: Submit, Close

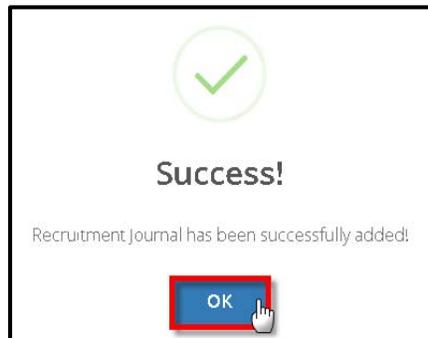
Step 3: Enter the start date and select the **Study Event** from the pull-down menu. For this example, we selected **Accrual on Hold: Interim Analysis Per Protocol** and all POs are checked.

The image shows two screenshots of the 'Add Study Event' form. In the first screenshot, the 'Study Event Start Date' is set to 04/03/2017. The 'Study Event' dropdown menu is open, showing a list of options. 'A9 - Accrual on Hold: Interim Analysis Per Protocol' is highlighted. In the second screenshot, the 'Study Event' is set to 'A9 - Accrual on Hold: Interim Analysis Per Protocol'. The 'POs Affected' list is shown with two items checked: 'University of Chemoprevention' and 'Chemoprevention Institute'.

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

The image shows the 'Add Study Event' form with the 'Submit' button highlighted. The form fields are filled with the same information as in the previous screenshots: 'Study Event Start Date' is 04/03/2017, 'Study Event' is 'A9 - Accrual on Hold: Interim Analysis Per Protocol', and 'POs Affected' includes 'University of Chemoprevention' and 'Chemoprevention Institute'.

Step 5: A message appears indicating the recruitment journal 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 to existing study events.

Recruitment Journal					
+ Add New Study Event					
Study Event Start Date	Study Event End Date	Study Event	Event Description	POs Affected	
March 08, 2017		A1 - Study Active	Study will remain active.	University of Chemoprevention	<div style="border: 2px solid red; padding: 2px;">Edit</div> <div style="border: 1px solid gray; padding: 2px;">Delete</div>

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

Edit Study Event

Submit

Close

Study Event Start Date:  ✕ 📅

Study Event End Date: (if applicable)  ✕ 📅

Study Event:

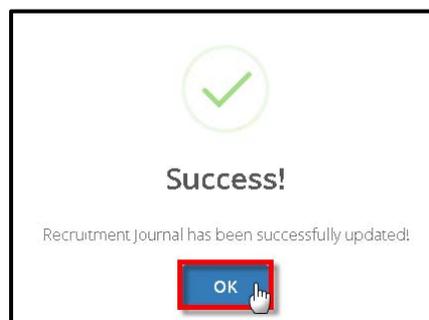
Study Event Description:

POs Affected:

- University of Chemoprevention
- Chemoprevention Institute

All POs

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

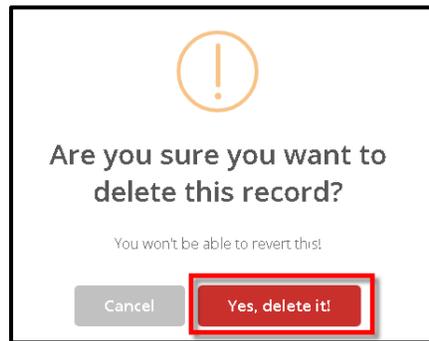


iii. How to Delete Information

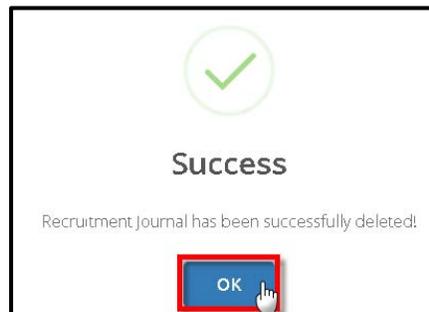
Step 1: Select the **Delete** button corresponding to the study event you wish to remove from the list.

March 08, 2017		A8 - Accrual on Hold: FDA Clinical Hold	Study is now on hold.	University of Chemoprevention	<input type="button" value="Edit"/> <input type="button" value="Delete"/> <input type="button" value="Edit"/> <input type="button" value="Delete"/>
March 20, 2017		A2 - Site Issues: Drug Shipment Authorization		University of Chemoprevention	<input type="button" value="Edit"/> <input type="button" value="Delete"/>

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

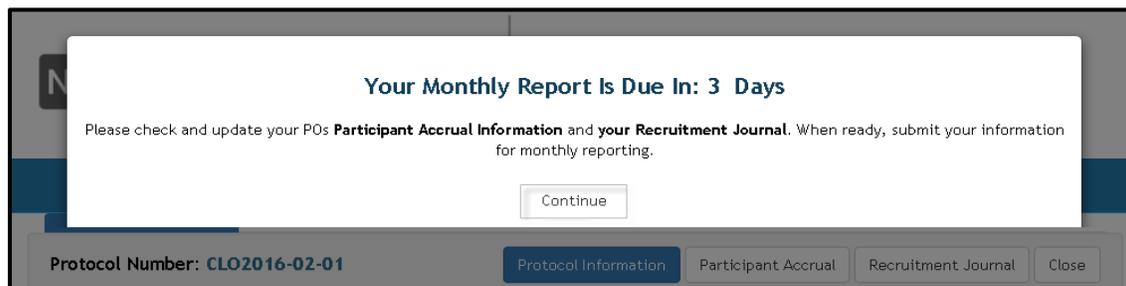


Step 3: A second message appears indicating recruitment journal was successfully deleted. Select **OK** to return to the **Recruitment Journal** page.



### How to Submit the Monthly Accrual Report

**CLO users receive daily reminders** from the 1<sup>st</sup> to the 15<sup>th</sup> of the month. **Please Note:** CLO users cannot submit reports after the 15<sup>th</sup> of each month.



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

CLO Accrual Reporting | Current User: Jane Doe, Consortia Lead Organization | Log Out

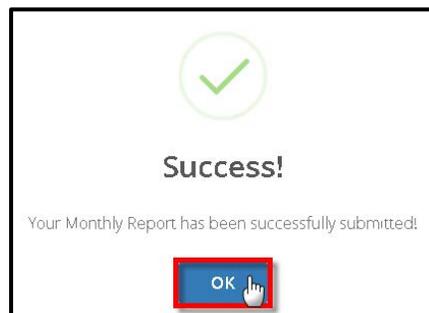
Protocol Number: CLO2016-02-01 | Protocol Information | Participant Accrual | Recruitment Journal | Close

### Protocol Information

**Submit Monthly Report**

Current Reporting Month:	May 2017
Protocol Title:	Randomized Phase X Trial of Agent B in High-Risk Individuals
Protocol Number:	CLO2016-02-01
Targeted Enrollment:	120
Total Number of Participants Started Study Intervention:	3
Projected Accrual Per Month:	8.00
Projected Completion Date:	June 12, 2018
Study Status:	Active
Study Status Date:	March 27, 2017
Accrual Duration (Months):	15
Approved Participating Organizations:	University of Chemoprevention Chemoprevention Institute
Date of First Contact:	March 08, 2017

2. 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**.

Home | Recruitment Planning | Toolkit | Accrual Report | Training and Resources | DCP Helpdesk

CLO Accrual Reporting | Current User: Jane Doe, Consortia Lead Organization | Log Out

Protocol Number: CLO2016-02-01 | Protocol Information | Participant Accrual | Recruitment Journal | Close

### Protocol Information

Submit Monthly Report

We welcome your feedback on this Quick Start Guide. Please send your comments to [dcpdesktop@dcpais.com](mailto:dcpdesktop@dcpais.com)

## Frequently Asked Questions

1. **Q:** Who will add/delete POs from AQuIP OARS?
  - **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)?
  - **A:** No, this information is outside the scope of AQuIP OARS data collection, beginning at “First Contact Date” and ending with “Intervention Start Date” or “Reason(s) Consent NOT Signed/Study Intervention NOT Started”
3. **Q:** Where can I find total participants that started study intervention per PO and protocol?
  - **A:** The total number of participants that started study intervention per PO and protocol is not available in the current AQuIP OARS; however, it is under consideration for the next AQuIP OARS iteration.
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)?
  - **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. **Please note:** The DCP Help Desk will query participants that have been pending for more than six (6) months.
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?
  - **A:** Yes, DCP recommends listing all recruitment strategies used to enroll participants.