

Manual of Operations (MOP) for the Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts Trial

Executive Summary

The Data Coordinating Center (DCC) for the ECP Registry is the Electronic Radiology Laboratory (ERL) at the Mallinckrodt Institute of Radiology (MIR) at Washington University School of Medicine in St. Louis. The team is led by Fred Prior, Ph.D., Professor of Radiology and Director of the ERL. The DCC's primary functions are to centrally coordinate the management of study data and to maintain the ECP Registry's secure website.

This manual of operations provides the staff at the study enrollment sites with the procedures for using the ECP Registry. The following directions will assist the user in completing the case report forms for the ECP Registry.

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1.0 User Account and Password

1.1 Requesting a User Account

- Complete the ECP Delegation of Authority (DOA) Log noting the appropriate responsibility codes for subject enrollment, data entry, data query, and SAE reporting. Forward the log to the Clinical Coordinating Center (CCC.)
- The Clinical Coordinating Center (CCC) will forward the DOA log to the DCC requesting an account to be created for the ECP site team member noted on the log.
- A user name and password will be sent to the research team member by the DCC. Initial Coordinator training will be completed at the site initiation visit (SIV). Once the SIV is complete, the PI and new coordinators will be sent instruction to complete training along with the username and password.
- Once the site staff member has completed the training module(s), sign and date the Attestation form. Keep the original signed Attestation in the site regulatory binder. Forward a copy to the CCC.
- **Password Change and Reset - For problems with your account and/or password, contact:**

- Joan Moulton moultonj@mir.wustl.edu 314-362-7185
- Mary Wolfsberger wolfsbergerm@mir.wustl.edu 314-362-7194

2.0 System Requirements

2.1 Acceptable Operating Systems

- Windows 8
- Windows 7
- Windows XP
- MAC

2.2 Acceptable Browsers

- Internet Explorer 8
- Internet Explorer 9
- Google Chrome

3.0 ECP Treatment Trial Resources Login

- 3.1 Open your browser and type the ECP Registry address listed below.

<http://ecpregistry.wustl.edu>

- 3.2 The ECP home page is displayed. Select the **Site Resource Login** button, *Figure 1*.



Figure 1

- 3.3 The ECP-Trial Site Resources Login page displays. Login using the username and password you were given, *Figure 2*.

Figure 2

4.0 Site Resources Page

- 4.1** Following login, there are three top-level menu buttons (Home, Check Enrollment/Arm Eligibility, and Registry) and two additional menu items (Investigator Resources and Help), *Figure 3* .

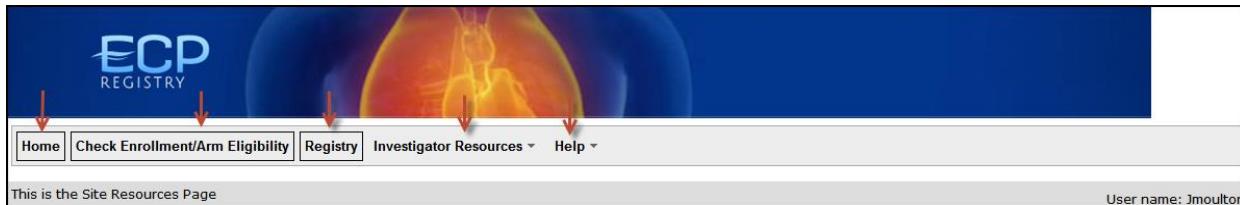


Figure 3

- The **Home** button directs you back to the ECP home page, *Figure 1*.
- The **Check Enrollment/Arm Eligibility** button directs you to the **Enrollment Assessment and Study Arm Eligibility** form. This form is used to determine enrollment eligibility and study arm assignment for all new participants. For more information, see Section 11.0 Enrollment Eligibility and Study Arm Determination
- The **Registry** button directs you to the **Site Summary** page that lists all enrolled site participants and that tracks the following data for each participant:
 - Participant ID
 - Enrolled Date
 - Study Arm – ECP Treatment Arm or Observation Arm
 - Participant Status – Enrolled, Completed, or Withdrawn
 - The number of case report forms (CRFs) in these categories: New, Started, Submitted, CRF Query, DCC Verified, PI Approved and Not Required. See Section 5.0 for detailed information.
- The **Investigator Resources** menu item contains a drop down box with links to valuable site documents: Key Contacts, Protocol, Manual of Operations, Training Modules, Case Report Forms, Site Start Up, and Source Document Labels, Training Modules (see *Figure 4*), Case Report Forms (see *Figure 5*), and Site Start Up (see *Figure 6*).
- Help – The help menu item contains a drop down box with links to the helpdesk support staff and ECP Registry personnel at the Clinical Coordinating Center and the Data Coordinating Center, hours of operation, holiday schedule, and information about the ECP Registry software.

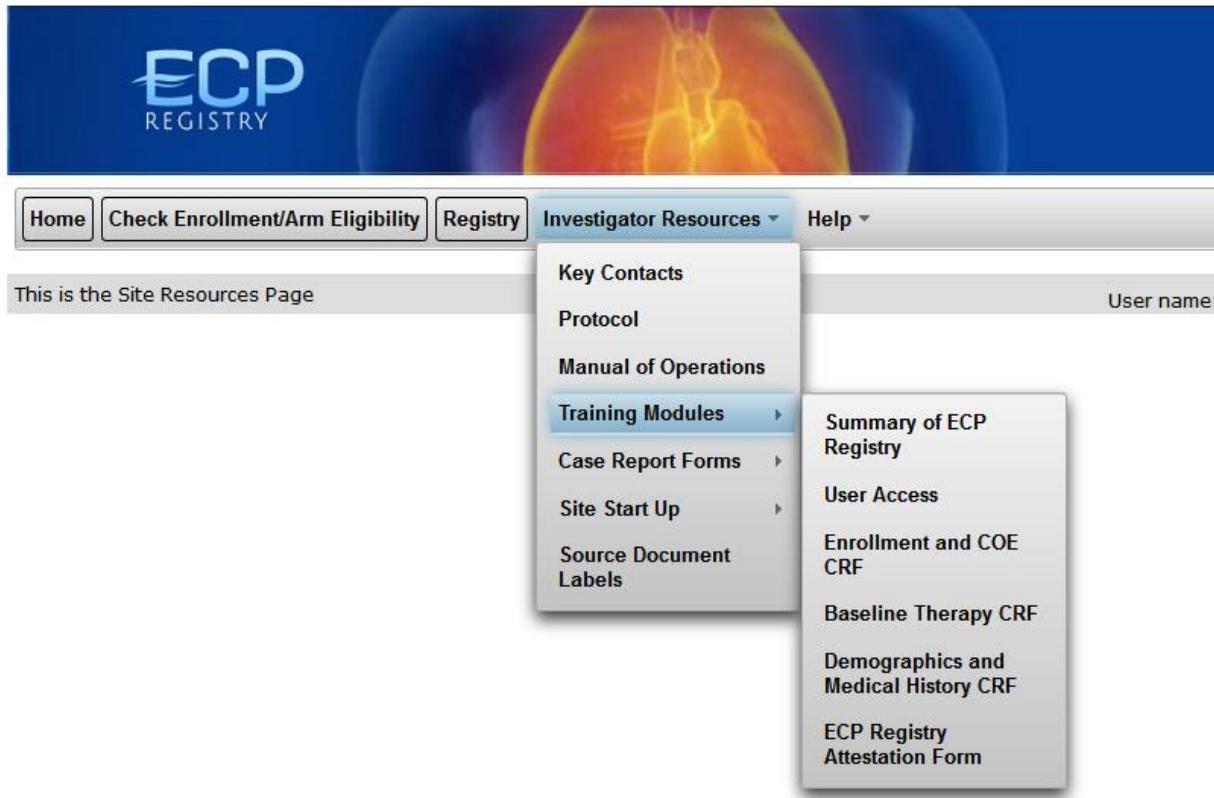


Figure 4

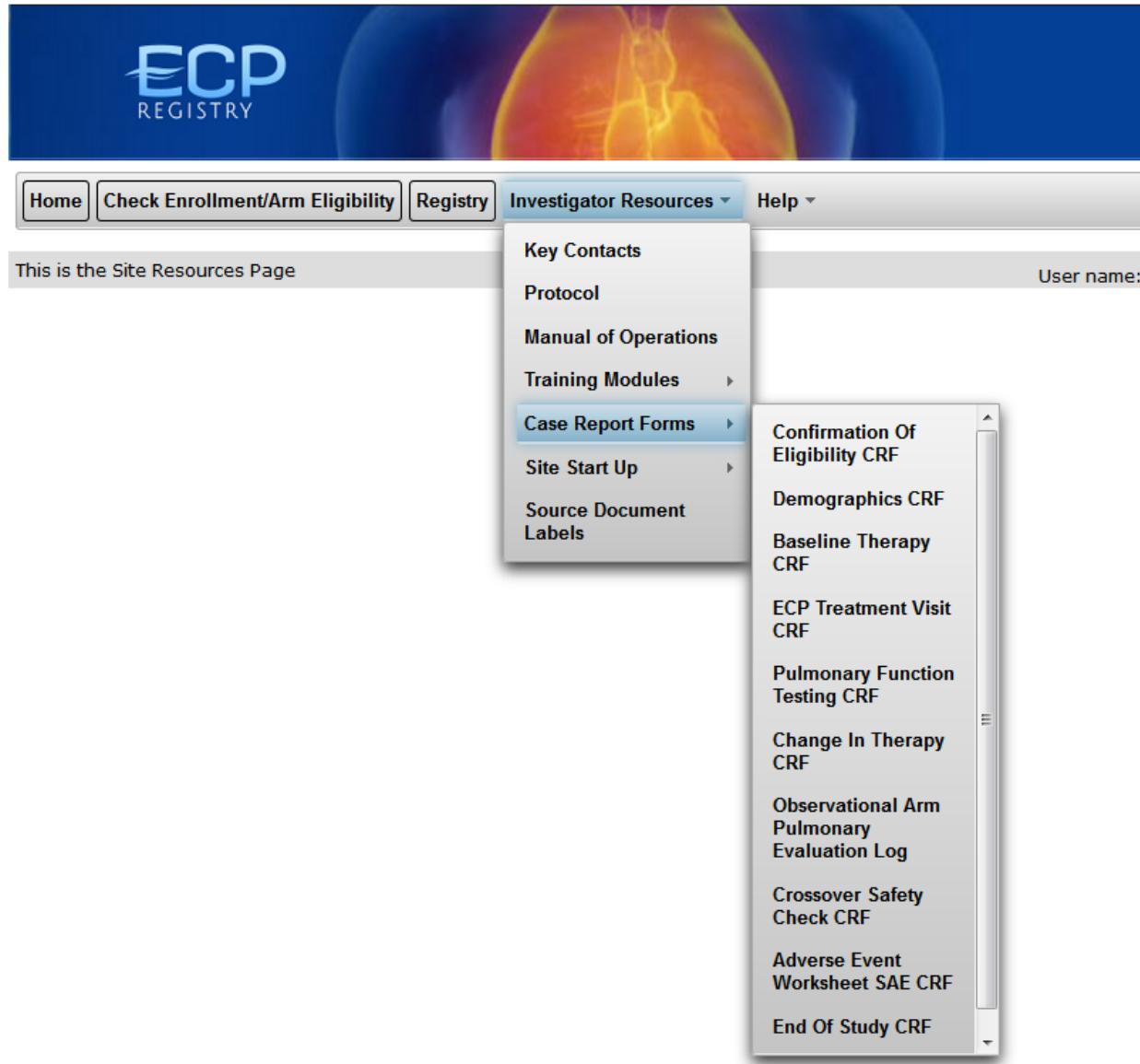


Figure 5

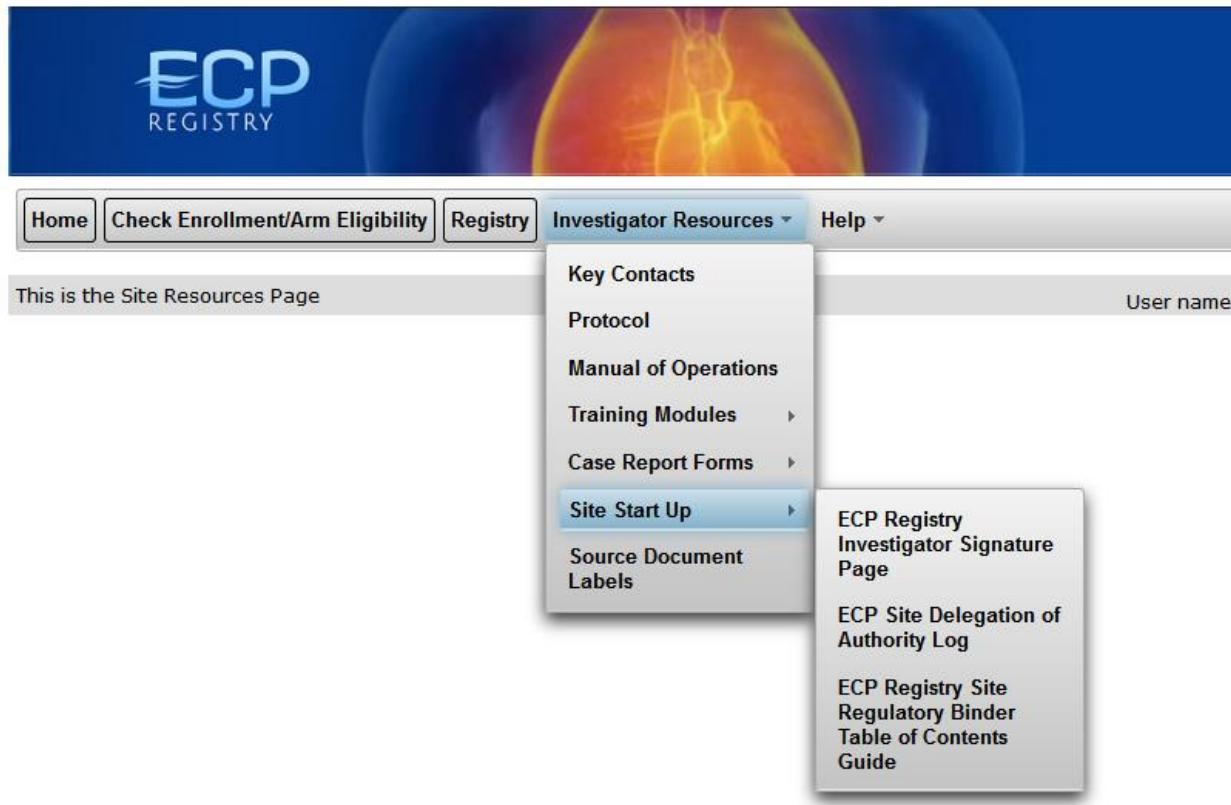


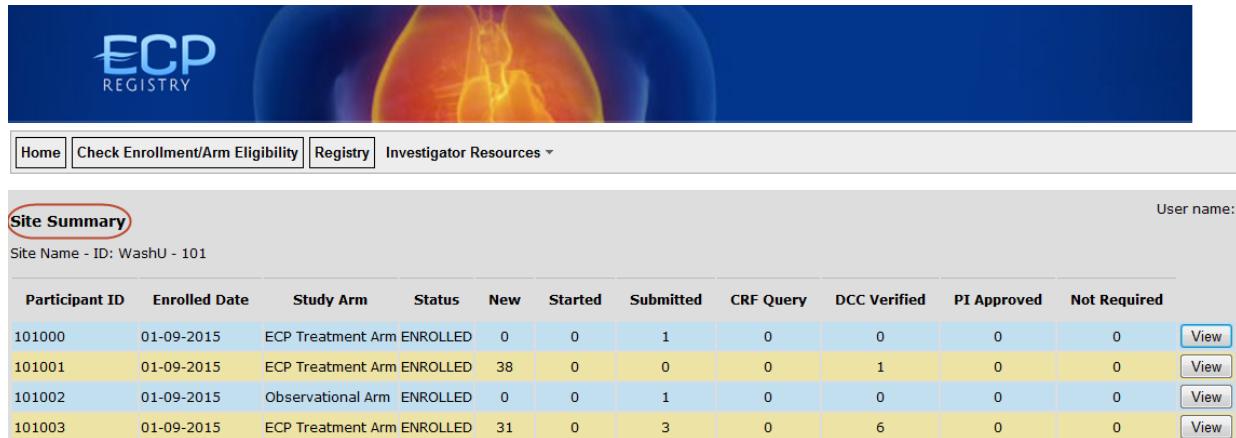
Figure 6

5.0 Site Summary Page

5.1 The **Site Summary** page displays all enrolled participants for the site. In the example in *Figure 7*, the site currently has four participants enrolled. The following columns appear on the Site Summary page:

- Participant ID – Assigned at time of enrollment
- Enrolled date – The date the patient was assigned a Participant ID number and treatment arm by the online system
- Study Arm – Either ECP Treatment Arm or Observation Arm
- Status of participant
 - Enrolled – Currently active participant
 - Completed – End of Study reached after one year of participation or death of participant.
 - Withdrawn – Subject withdrawn either by PI, or the participant withdraws self.
- New – The number of CRFs created but without data entry
- Started – The number of CRFs started but not submitted

- Submitted – The number of CRFs submitted but not DCC verified
- CRF Query – The number of CRFs that have gone through data verification by DCC staff and currently require correction or addition of source documents by the site staff. See Section 9.0
- DCC Verified – The number of CRFs verified and approved by the DCC based on supporting source documents
- PI Approved? – The number of CRFs with site PI approval following DCC verification
- Not Required – The number of CRFs which will not be completed because of participant withdrawal or missed visit.



Participant ID	Enrolled Date	Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	
101000	01-09-2015	ECP Treatment Arm	ENROLLED	0	0	1	0	0	0	0	View
101001	01-09-2015	ECP Treatment Arm	ENROLLED	38	0	0	0	1	0	0	View
101002	01-09-2015	Observational Arm	ENROLLED	0	0	1	0	0	0	0	View
101003	01-09-2015	ECP Treatment Arm	ENROLLED	31	0	3	0	6	0	0	View

Figure 7

6.0 Participant Summary Page

6.1 The Participant Summary page is found by clicking the view button that is associated with the participant ID in the Site Summary page. The participant summary page displays the status of all Events for a participant (Figure 8). The list of Events depends upon whether the participant is in the ECP Treatment Arm (Figure 8) or the Observation Arm (Figure 9).

6.2 For the Observation Arm the following Events and worksheets will appear on the Participant Summary page:

- Confirmation of Eligibility
- Demographics / Medical History
- Baseline Therapy
- Observation Pulmonary Evaluation Log

For the Observation Arm the following events and worksheets may be selected by adding a new event:

- Pulmonary Evaluation
- Change in Therapy

- Adverse Event Worksheet
- End of Study

6.3 For the ECP Treatment Arm the following Events and worksheets will appear on the Participant Summary page:

- Confirmation of Eligibility
- Demographics / Medical History
- Baseline
- ECP Treatment
- Pulmonary Evaluation

For the ECP Treatment Arm the following events and worksheet may be selected by adding a new event:

- Change in Therapy
- Adverse Event Worksheet
- End of Study
- Pulmonary Evaluation – for exams not mandated by the protocol
- ECP Treatment – for additional ongoing maintenance treatments beyond 6 months

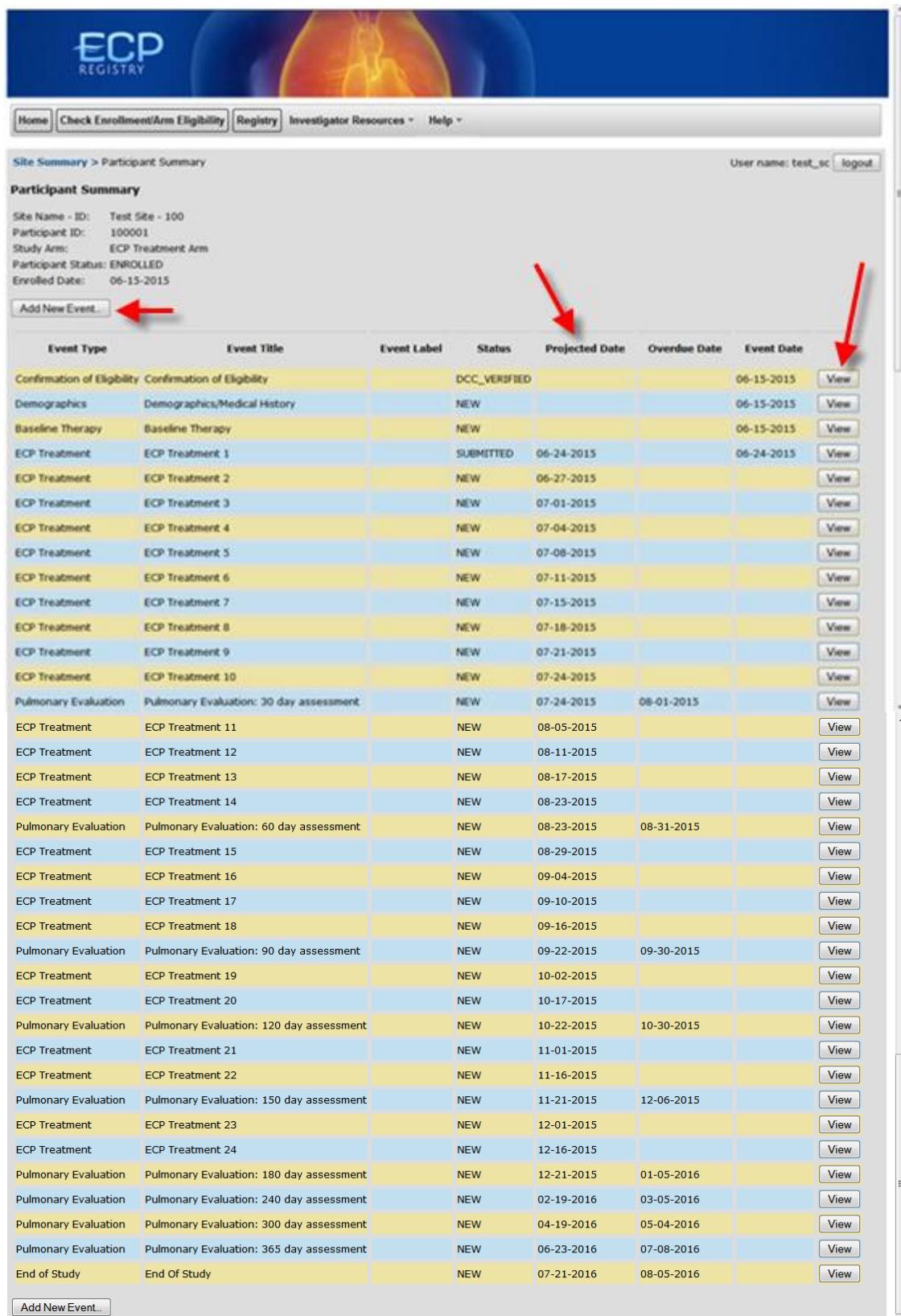
The Events Type and Event Title in both arms are populated following the DCC verification of the Confirmation of Eligibility Form. The CRF status becomes DCC_Verified.

6.4 The **Participant Summary** page also includes an **Add New Event** button, found in the upper left corner. See *Figure 8*.

- For an **Observation** Arm participant, the **Add New Event** button is used to create the forms for four possible unscheduled events:
 - Pulmonary Evaluation – See [section 13.5](#)
 - End of Study – See [section 13.7](#)
 - Change in Therapy – See [section 13.6](#)
 - Adverse Event Worksheet – See [section 14.0](#)
- For an **ECP Treatment** Arm participant, the **Add New Event** button is used to create the forms for four possible unscheduled events:
 - ECP Treatment - See [section 12.4](#)
 - Pulmonary Evaluation – See [section 12.5](#)
 - Change in Therapy – See [section 12.6](#)
 - Adverse Event Worksheet - See [section 14.0](#)

6.5 Selecting the **View** button to the right of a particular event directs the user to the **Event Summary** page.

Manual of Procedures



Site Summary > Participant Summary

User name: test_sc logout

Participant Summary

Site Name - ID: Test Site - 100
 Participant ID: 100001
 Study Arm: ECP Treatment Arm
 Participant Status: ENROLLED
 Enrolled Date: 06-15-2015

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	View
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED	06-15-2015			<input type="button" value="View"/>
Demographics	Demographics/Medical History		NEW	06-15-2015			<input type="button" value="View"/>
Baseline Therapy	Baseline Therapy		NEW	06-15-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 1		SUBMITTED	06-24-2015	06-24-2015		<input type="button" value="View"/>
ECP Treatment	ECP Treatment 2		NEW	06-27-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 3		NEW	07-01-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 4		NEW	07-04-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 5		NEW	07-08-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 6		NEW	07-11-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 7		NEW	07-15-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 8		NEW	07-18-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 9		NEW	07-21-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 10		NEW	07-24-2015			<input type="button" value="View"/>
Pulmonary Evaluation	Pulmonary Evaluation: 30 day assessment		NEW	07-24-2015	08-01-2015		<input type="button" value="View"/>
ECP Treatment	ECP Treatment 11		NEW	08-05-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 12		NEW	08-11-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 13		NEW	08-17-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 14		NEW	08-23-2015			<input type="button" value="View"/>
Pulmonary Evaluation	Pulmonary Evaluation: 60 day assessment		NEW	08-23-2015	08-31-2015		<input type="button" value="View"/>
ECP Treatment	ECP Treatment 15		NEW	08-29-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 16		NEW	09-04-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 17		NEW	09-10-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 18		NEW	09-16-2015			<input type="button" value="View"/>
Pulmonary Evaluation	Pulmonary Evaluation: 90 day assessment		NEW	09-22-2015	09-30-2015		<input type="button" value="View"/>
ECP Treatment	ECP Treatment 19		NEW	10-02-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 20		NEW	10-17-2015			<input type="button" value="View"/>
Pulmonary Evaluation	Pulmonary Evaluation: 120 day assessment		NEW	10-22-2015	10-30-2015		<input type="button" value="View"/>
ECP Treatment	ECP Treatment 21		NEW	11-01-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 22		NEW	11-16-2015			<input type="button" value="View"/>
Pulmonary Evaluation	Pulmonary Evaluation: 150 day assessment		NEW	11-21-2015	12-06-2015		<input type="button" value="View"/>
ECP Treatment	ECP Treatment 23		NEW	12-01-2015			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 24		NEW	12-16-2015			<input type="button" value="View"/>
Pulmonary Evaluation	Pulmonary Evaluation: 180 day assessment		NEW	12-21-2015	01-05-2016		<input type="button" value="View"/>
Pulmonary Evaluation	Pulmonary Evaluation: 240 day assessment		NEW	02-19-2016	03-05-2016		<input type="button" value="View"/>
Pulmonary Evaluation	Pulmonary Evaluation: 300 day assessment		NEW	04-19-2016	05-04-2016		<input type="button" value="View"/>
Pulmonary Evaluation	Pulmonary Evaluation: 365 day assessment		NEW	06-23-2016	07-08-2016		<input type="button" value="View"/>
End of Study	End Of Study		NEW	07-21-2016	08-05-2016		<input type="button" value="View"/>

Add New Event...

Figure 8



Site Summary > Participant Summary

User name: test_

Participant Summary

Site Name - ID: Test Site - 100
Participant ID: 100003
Study Arm: Observational Arm
Participant Status: ENROLLED
Enrolled Date: 04-20-2015

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility	DCC_VERIFIED		04-20-2015		View
Demographics	Demographics/Medical History	NEW		04-20-2015		View
Baseline Therapy	Baseline Therapy	NEW		04-20-2015		View
Observation Pulmonary Evaluation Log	Observation Pulmonary Evaluation Log	NEW		04-20-2015		View

Add New Event...

Figure 9

7.0 Event Summary Page

- 7.1 The **Event Summary** page displays the Site Name, Participant ID, Assigned Study Arm, Participant Status, Enrolled Date, Event Type, Event Title, Event Status, and the Event Date.
- 7.2 The **Event Summary** page, *Figure 9*, also displays the Form Type and the Form Title for the particular event selected and tracks the status of the Forms, the Form Creation Date, and Form Last Submitted Date.
- 7.3 Select **View** on the **Event Summary** page to be directed to the CRF.

8.0 CRF Data Entry and Navigation

- 8.1 The Electronic Data Capture system will log a user out two hours after the user has not had interaction with the website server, such as saving or submitting a form or changing to a different page. This period of time does not include typing words or mouse clicks. If the ECP Registry logs a user out, any unsaved data will not be saved. Be sure to regularly save data.
- 8.2 When adding data to a CRF, always **Save** before leaving a page. It is good practice to Save a CRF every 10 – 15 minutes.
- 8.3 To enter a date, click either the calendar icon, , next to the date field and select the date, or manually enter the date in the format MM/DD/YYYY.

- 8.4** To navigate from one data field to the next, use Tab or use the mouse to select a field.
- 8.5** To navigate to a field that requires a selection with a small round circle in front to it (i.e.  **YES**) such as  **YES**, the user can either manually click the selection with the mouse or tab to a radio button selection and use the space bar to select the radio button.
- 8.6** Do not use the **Backspace** key or click a back arrow on a screen to try to return to a previous page. Moving backward in a website application is not recommended as general normal practice. The website application is designed to navigate between pages using controls and buttons within the website application. See section 8.8
- 8.7** If you submit a CRF and the screen does not return to the **Participant Summary** page, scroll through the CRF screen looking for error messages in red. Usually a data field has been left blank or an amount is outside the allowable range
- 8.8** Note the line of text near the top of each page, circled in *Figure 9* below. This is a breadcrumb trail that allows a user to navigate back to previous pages. Click on a breadcrumb to return to a previous page. The rightmost breadcrumb, in black, is always the page that is currently displayed. In this example there are two bread crumbs, shown in blue: Site Summary and Participant Summary. Event Summary is the current page. Always save your work before clicking on a bread crumb from a CRF.



Event Summary

Site Name - ID:	Test Site - 100	Event Type:	Baseline Therapy
Participant ID:	100001	Event Title:	Baseline Therapy
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	06-15-2015	Event Date:	06-15-2015

Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date
Baseline Therapy	Baseline Therapy Form	NEW	06-15-2015	06-22-2015

Figure 9

9.0 CRF Data Verification

- 9.1** The Data Coordinating Center (DCC) is responsible for validating CRF data after each CRF has been submitted. When the status of a CRF becomes **SUBMITTED**, a technical coordinator from the DCC will examine the data values and compare to the uploaded source documentation.
- 9.2** For each data field evaluated, the technical coordinator will make one of three possible determinations.
- Verified – The data on the CRF match the corresponding data in the source document.
 - CRF Query – The data on the CRF do not match the corresponding data in the source document.
 - Source Missing – There is no source document to compare to the data on the CRF
- 9.3** If all data fields on a CRF are marked Verified and submitted by the technical coordinator, the Event Status of the CRF changes to DCC_Verified on the Participant Summary page. See *Figure 9*. After verification, all of the data fields are grayed out (*Figure 10 - Verification status of data values marked Verified by DCC. Note that the fields are grayed out and no changes can be made.*).

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED		02-05-2015	View

Figure 9

3. PULMONARY EVALUATIONS - Up to 15 pulmonary evaluations were entered to determine study arm eligibility:							
A. Date	11/03/2014	FEV1	3.2	liters	FVC	6.0	liters
B. Date	11/24/2014	FEV1	3.1	liters	FVC	5.9	liters
C. Date	12/08/2014	FEV1	3.0	liters	FVC	5.8	liters
D. Date	12/22/2014	FEV1	2.5	liters	FVC	5.5	liters
E. Date	02/02/2015	FEV1	2.4	liters	FVC	5.4	liters

Figure 10 - Verification status of data values marked Verified by DCC. Note that the fields are grayed out and no changes can be made.

- 9.4 A data field that is marked CRF Query may also have a comment explaining the nature of the discrepancy. See *Figure 11*.



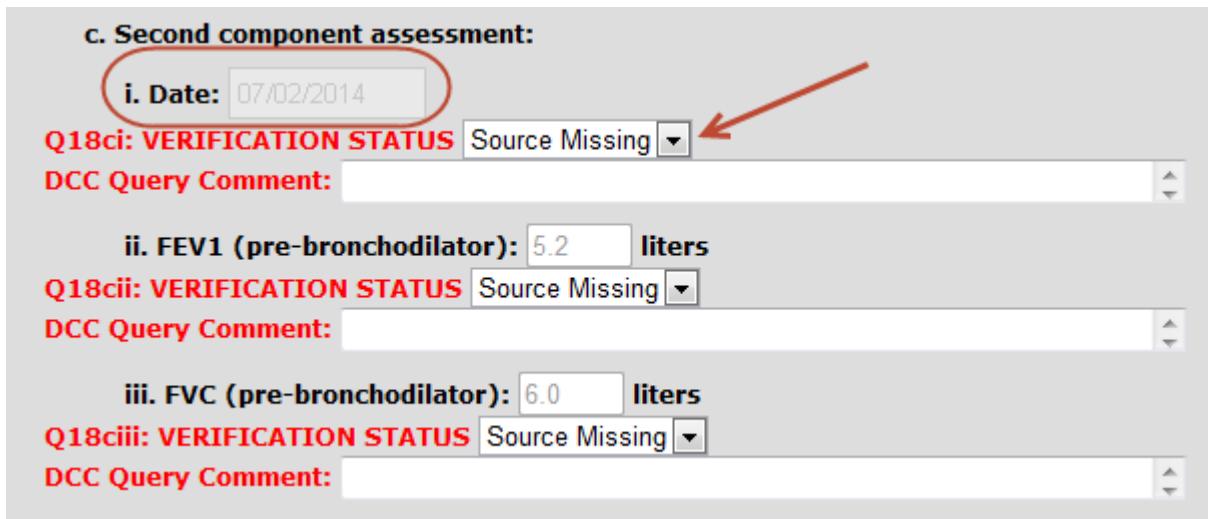
2. Gender: Male Female

Q2: VERIFICATION STATUS CRF Query

DCC Query Comment: Notes report participant as female

Figure 11 - Verification status of data values marked CRF Query by DCC

- 9.5 If a data field is marked Source Missing, the CRF does not have the necessary uploaded source document to confirm the value in that field. See *Figure 12* and *Figure 13* -.



c. Second component assessment:

i. Date: 07/02/2014

Q18ci: VERIFICATION STATUS Source Missing

DCC Query Comment:

ii. FEV1 (pre-bronchodilator): 5.2 liters

Q18cii: VERIFICATION STATUS Source Missing

DCC Query Comment:

iii. FVC (pre-bronchodilator): 6.0 liters

Q18ciii: VERIFICATION STATUS Source Missing

DCC Query Comment:

Figure 12

Source Document Type	Document Name	Submission Date	
History and Physical or Consultation Note	HX_101001_01062015.pdf	2015-01-12	<input type="button" value="View"/>
Operative Report of Transplant Procedure	ORTP_101001_05132014.pdf	2015-01-12	<input type="button" value="View"/>
Pulmonary Function Test Reports (for each FEV-1 submitted)	PFT_101001_06112014.pdf	2015-01-12	<input type="button" value="View"/>
Select Source Document Type <input type="button" value="History and Physical or Consultation Note"/>			

Figure 13 - Verification status of data values marked Source Missing by DCC

- 9.6 The Status of an event changes from SUBMITTED to CRF_QUERY when the DCC marks one or more data fields either CRF Query or Source Missing, *Figure 14*.

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		CRF_QUERY			02-03-2015 View

Figure 14

- 9.7** Site coordinators should monitor the status of the site's CRFs on the **Site Summary** page. For every CRF with a status of CRF Query:

- Open that **Participant's Summary** page by clicking **VIEW** button associated with the correct participant ID.
- Open the CRF that has a status of CRF Query by clicking **VIEW** button corresponding with the CRF query.
- Review the queries and make the required changes or additions. Look at *Figure 15*. When reviewing queries, the location and reference of each query must be carefully noted.

3. PULMONARY EVALUATIONS - Up to 15 pulmonary evaluations were entered to determine study arm eligibility:

A. Date 03/26/2015 View	FEV1 2.0 liters	FVC 3.0 liters
A. Date: VERIFICATION STATUS CRF Query		
DCC Query Comment: Source doc date reads 3/25/15		
B. Date 04/02/2015 View	FEV1 2.0 liters	FVC 3.0 liters
B. Date: VERIFICATION STATUS Source Missing		
DCC Query Comment: Source doc not uploaded		
B. FEV1: VERIFICATION STATUS Source Missing		
DCC Query Comment:		
B. FVC: VERIFICATION STATUS Source Missing		
DCC Query Comment:		

Figure 15

- Circled, in *Figure 16*, are the same four queries, as seen unmarked in *Figure 15*.
 - A. Date – questions the value of the date for line A with a CRF_QUERY. Unlike line B, the FEV1 and FVC values on line A are not in question.
 - B. Date – Notes that there is no source documentation (ie. Source Missing) for line B. The comment also notes this in the DCC Query Comment box which was entered by the technical coordinator.
 - B. FEV1, is in question because it also requires the source document to be loaded.
 - B. FVC, is in question because it also requires the source document to be loaded.

- The DCC Query Comment is always found below the Verification Status and is always the last section of the verification query for any given data field. Both technical coordinators at the DCC who do verification and coordinators at sites may make comments. Place your name and date following your comment to help keep the comments straight.

3. PULMONARY EVALUATIONS - Up to 15 pulmonary evaluations were entered to determine study arm eligibility:

A. Date 03/26/2015 FEV1 2.0 liters FVC 3.0 liters
A. Date: VERIFICATION STATUS CRF Query
DCC Query Comment: Source doc date reads 3/25/15

B. Date 04/02/2015 FEV1 2.0 liters FVC 3.0 liters
B. Date: VERIFICATION STATUS Source Missing
DCC Query Comment: Source doc not uploaded

B. FEV1: VERIFICATION STATUS Source Missing
DCC Query Comment:

B. FVC: VERIFICATION STATUS Source Missing
DCC Query Comment:

Figure 16

- Click the drop down box at each data field as it is corrected and select **Unverified**, *Figure 17*.
- Make no changes to any data field that is not marked as requiring correction.
- When all changes or additions have been made click **Submit**. This will change the CRF status to **Submitted**.

YES NO Lung transplant recipient

Lung Transplant: VERIFICATION STATUS Unverified
DCC Query Comment: No operative report uploaded

YES NO Progressive BOS defined as ongoing decline in
Source Missing

Figure 17

- Technical coordinators at the DCC will then re-verify the CRF. If all data fields are correct and complete, the CRF status will be changed to DCC Verified, and no further action is required by the site for this CRF. If there remain data fields that are still incorrect or incomplete, DCC will mark them as CRF Query or Source Missing. The status of the CRF will remain CRF Query. If a site believes it has corrected a CRF, and the status returns to CRF Query, that means the DCC still has seen problems with the accuracy or completeness of the CRF. Correct them and submit again until the status changes to DCC Verified.

10.0 Uploading Scanned Source Document PDF Files

10.1 The following CRFs require a site to upload documents to confirm data entered on a CRF:

- Confirmation of Eligibility
- Demographics / Medical History
- Baseline Therapy
- ECP Treatment
- Pulmonary Function Test
- Serious Adverse Event
- End of Study
- Crossover Safety Check

10.2 The required source documents are listed at the top of each CRF. The required de-identified source documents should be scanned and uploaded into the database in PDF format. Once a source document is de-identified please use the source document labels to add participant ID and associated visit.

10.3 If a source document has more than one page, only upload the page(s) that contain the data relevant to the CRF.

10.4 To scan source documents into PDF format

- Fill out the information on the labels: Center and Participant ID number, Associated visit, site personnel initials, and date
- Apply a source document label to every page of the source. Source document labels are located under Investigator Resources in the site login area. Use Avery 5161
- De-identify the document. **Please review the entirety of the documents (not just the header) to be sure that no PHI identifiers are submitted.**
- Scan the de-identified source document.
- Save the document as a **PDF** to a storage device such as a thumb drive or computer file, and name the document using the naming conventions in the chart below as a guide, Table 1. **NOTE:** If a site prefers, they can scan all source documents together for one event such as baseline, Confirmation of Eligibility into a single PDF.

Source Document Types	PDF file name
Signed Confirmation of Eligibility Form	COE_xxxxxx_mmddyyyy.pdf
History and Physical or Consultation Note	HX_xxxxxx_mmddyyyy.pdf
Operative Report of Transplant Procedure	OPRTP_xxxxxx_mmddyyyy.pdf
Pulmonary Function Test Reports	PFT_xxxxxx_mmddyyyy.pdf
Clinical Note or Medication Record Form	MEDS_xxxxxx_mmddyyyy.pdf
Photopheresis Procedure Note/Report	PHOTO_xxxxxx_mmddyyyy.pdf
CBC - Lab Report	CBC_xxxxxx_mmddyyyy.pdf
Progress Note or Clinical Note describing complication	PROGRESS_xxxxxx_mmddyyyy.pdf
Autopsy Report	AUTRPT_xxxxxx_mmddyyyy.pdf
Crossover Safety Check Form	CSC_xxxxxx_mmddyyyy.pdf
The COE and CSC forms should use the date the form was signed.	xxxxxx = Participant ID mm = 2-digit month

All other forms should use the date on the uploaded document.

dd = 2-digit day
yyyy = 4-digit year

Table 1

- 10.5** The following example describes the procedure to upload a signed Confirmation of Eligibility (COE) CRF. All other CRFs use the same methods to upload a source document. A list of required source documents to upload is provided on each CRF. These documents are also listed in the drop down menu, *Figure 18*.

The screenshot shows the ECP Registry website. The top navigation bar includes links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. The main content area is titled 'Site Summary > Participant Summary > Event Summary > Confirmation of Eligibility Form'. A 'Form Summary' table provides details: Site Name - ID: WashU - 101, Participant ID: 101001, Study Arm: ECP Treatment Arm, Participant Status: ENROLLED, Enrolled Date: 01-07-2015. To the right, the 'Event Type' is Confirmation of Eligibility, 'Event Title' is Confirmation of Eligibility, 'Event Label' is Confirmation of Eligibility, 'Event Status' is NEW, 'Event Date' is 01-07-2015, 'Form Type' is Confirmation of Eligibility, 'Form Title' is Confirmation of Eligibility Form, 'Form Status' is NEW, and 'Form Date' is 01-07-2015. A box highlights the 'CONFIRMATION OF ELIGIBILITY - Case Report Form (CRF)'. Below this, a red box contains the text: 'Important and Time-Sensitive: Please PRINT this subject's Confirmation of Eligibility (COE) Form, have an authorized physician investigator sign and date the COE form, and scan and upload the signed COE form along with the other Source Documents listed at the top of the COE Form. Per Protocol Section 3.7, submission of this signed COE Form is required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed.' A red arrow points to the text 'Please include the following types of source documents:'. Another red arrow points to the 'Select Source Document Type' dropdown menu, which is set to 'A Signed Confirmation of Eligibility Form must be uploaded'. A third red arrow points to the 'Browse...' button in the 'Attach Source Document' section.

Figure 18

- 10.6** Select the **Source Document Type** from the drop down menu for the PDF, *Figure 19*.

- 10.7** Click the **Browse** button, *Figure 20*.

- 10.8** Find the PDF source document you want to upload and double click it.

10.9 You will be directed back to the **CRF** page.

10.10 The path followed to the PDF file displays next to the **Browse** button (see figure 21).

10.11 Click the **Upload** button.

Please include the following types of source documents:

1. A Signed Confirmation of Eligibility Form must be uploaded
2. History and Physical Or Consultation Note
3. Operative Report of Transplant Procedure
4. Pulmonary Function Test Reports (for each FEV-1 submitted)

Source Document Type	Document Name	Submission Date
Select Source Document Type	A Signed Confirmation of Eligibility Form must be uploaded	
Attach Source Document:	<input type="button" value="Browse..."/> <input type="button" value="Upload"/>	
	History and Physical or Consultation Note	
	Operative Report of Transplant Procedure	
	Pulmonary Function Test Reports (for each FEV-1 submitted)	

Save **Submit**

Figure 19-Confirmation of Eligibility CRF

Please include the following types of source documents:

1. A Signed Confirmation of Eligibility Form must be uploaded
2. History and Physical Or Consultation Note
3. Operative Report of Transplant Procedure
4. Pulmonary Function Test Reports (for each FEV-1 submitted)

Source Document Type	Document Name	Submission Date
Select Source Document Type	A Signed Confirmation of Eligibility Form must be uploaded	
Attach Source Document:	<input type="button" value="Browse..."/> <input type="button" value="Upload"/>	
Save	Submit	

Figure 20-Confirmation of Eligibility CRF

10.12 When uploaded, a highlighted entry displays for the source document. The name of the PDF, not the path name is highlighted yellow. See *Figure 21*.

Please include the following types of source documents:

1. A Signed Confirmation of Eligibility Form must be uploaded
2. History and Physical Or Consultation Note
3. Operative Report of Transplant Procedure
4. Pulmonary Function Test Reports (for each FEV-1 submitted)

Source Document Type	Document Name	Submission Date	
A Signed Confirmation of Eligibility Form must be uploaded	COE_101001_01072015.pdf	2015-01-07	View Delete
Select Source Document Type <input type="button" value="A Signed Confirmation of Eligibility Form must be uploaded"/>			
Attach Source Document: <input type="button" value="Browse..."/> <input type="button" value="Upload"/>			
<input type="button" value="Save"/> <input type="button" value="Submit"/>			

Figure 21-Confirmation of Eligibility CRF Need updated CRF

10.13 To confirm that the correct PDF has been uploaded, click the **View** button next to the highlighted entry.

10.14 If there is an error with the upload, click the **Delete** button next to the highlighted document listing. Reload the document correctly.

10.15 Continue until all source document PDF files have been uploaded for the CRF. Select the correct Source Document Type for each document uploaded.

10.16 CLICK SAVE

10.17 CLICK SUBMIT

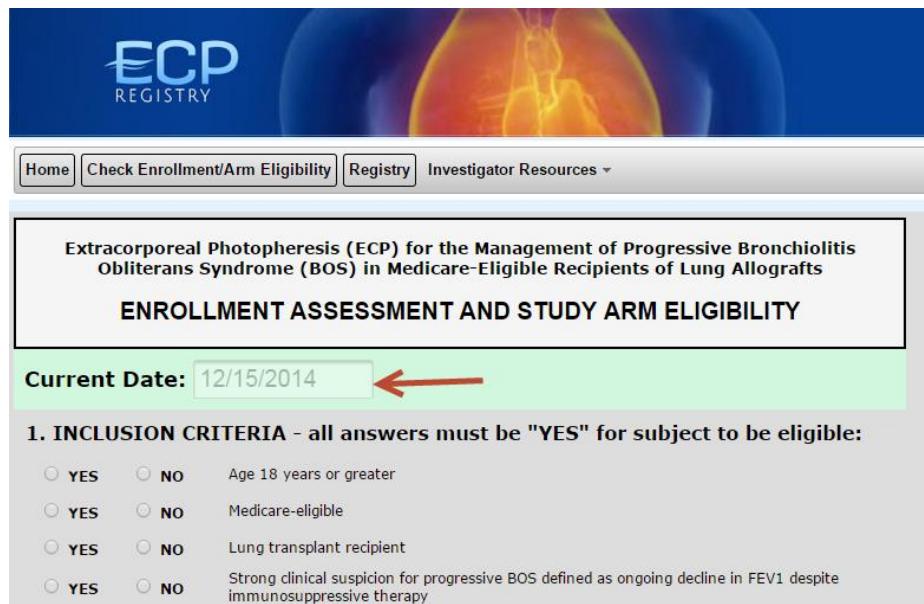
11.0 Enrollment Eligibility and Study Arm Determination

11.1 To begin to determine if an individual can be enrolled into the ECP Registry study, and to which study arm he/she will be assigned, click the **Check Enrollment/Arm Eligibility** button, *Figure 22* on the Site Resources page.



Figure 22

11.2 The **Enrollment Assessment and Study Arm Eligibility** worksheet displays. The current date is automatically populated, as shown in *Figure 23*. Use the tab key or mouse to navigate to answer all questions.



Home Check Enrollment/Arm Eligibility Registry Investigator Resources ▾

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

ENROLLMENT ASSESSMENT AND STUDY ARM ELIGIBILITY

Current Date: 12/15/2014

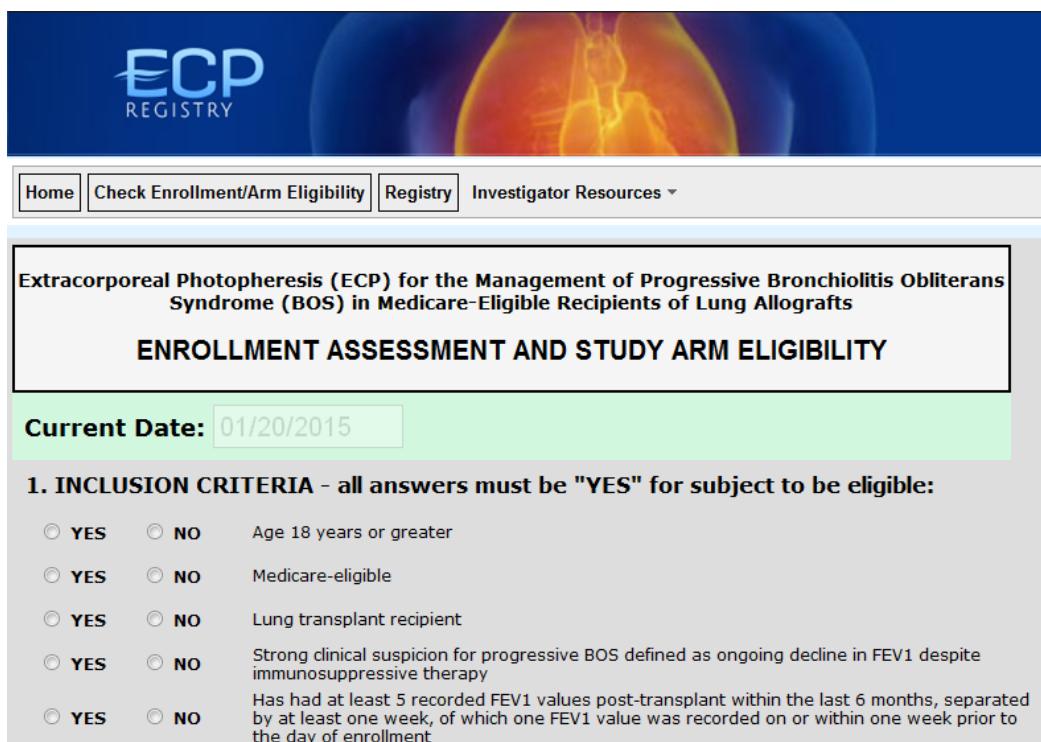
1. INCLUSION CRITERIA - all answers must be "YES" for subject to be eligible:

YES NO Age 18 years or greater
 YES NO Medicare-eligible
 YES NO Lung transplant recipient
 YES NO Strong clinical suspicion for progressive BOS defined as ongoing decline in FEV1 despite immunosuppressive therapy

Figure 23

11.3 The Enrollment Assessment and Study Arm Eligibility worksheet is divided into four sections.

- The **Inclusion Criteria** section is shown in *Figure 24*. Answer all inclusion questions by clicking the appropriate radio button. All answers must be “YES” to be eligible for the ECP registry.



Home Check Enrollment/Arm Eligibility Registry Investigator Resources ▾

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

ENROLLMENT ASSESSMENT AND STUDY ARM ELIGIBILITY

Current Date: 01/20/2015

1. INCLUSION CRITERIA - all answers must be "YES" for subject to be eligible:

YES NO Age 18 years or greater
 YES NO Medicare-eligible
 YES NO Lung transplant recipient
 YES NO Strong clinical suspicion for progressive BOS defined as ongoing decline in FEV1 despite immunosuppressive therapy
 YES NO Has had at least 5 recorded FEV1 values post-transplant within the last 6 months, separated by at least one week, of which one FEV1 value was recorded on or within one week prior to the day of enrollment

Figure 24

- The **Exclusion Criteria** section is shown in *Figure 25*. Answer all Exclusion questions by clicking the appropriate radio button. All answers must be “NO” for the participant to be eligible.

2. EXCLUSION CRITERIA - all answers must be "NO" for subject to be eligible for study inclusion:

- | | | |
|---------------------------|--------------------------|---|
| <input type="radio"/> YES | <input type="radio"/> NO | Currently participating in another clinical treatment trial with an investigational agent |
| <input type="radio"/> YES | <input type="radio"/> NO | Has condition that may interfere with subject's ability to perform pulmonary function testing |
| <input type="radio"/> YES | <input type="radio"/> NO | Known allergy or hypersensitivity to pharmacologic agents used during ECP |
| <input type="radio"/> YES | <input type="radio"/> NO | Has acute condition that contraindicates ECP, including but not limited to new or evolving myocardial infarction or central nervous system disorder, hemodynamic instability or hypovolemia, acute bleeding, or respiratory distress; or lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, albinism, or other dermatologic or ocular condition that contraindicates the use of methoxsalen or markedly enhances photosensitivity; or other condition that poses unacceptable risk for study-related complications as judged by the referring clinician |
| <input type="radio"/> YES | <input type="radio"/> NO | Has other condition that would significantly interfere with ability to adhere to the protocol or affect interpretability of the study results |
| <input type="radio"/> YES | <input type="radio"/> NO | Aphakia or absence of ocular lenses |
| <input type="radio"/> YES | <input type="radio"/> NO | Pregnancy (confirmed by a positive pregnancy test) |
| <input type="radio"/> YES | <input type="radio"/> NO | Inability to provide informed consent or to comply with study treatments or assessments (e.g. due to cognitive impairment or geographic distance) |

Figure 25-Confirmation of Eligibility

- The **Pulmonary Evaluations** section is shown in *Figure 26*.
 - Enter the date of each recorded FEV1 and FVC using MM/DD/YYYY format, or click on the  calendar icon and select the date from the pop up calendar.
 - Enter the values of each recorded FEV1 and FVC (up to 15) obtained within the last 6 months. If more than 15 FEV1s are available in the last 6 months, record only the most recent 15 FEV1s. Record the FEV1 values from the oldest date to the most recent.
 - A minimum of 5 recorded FEV1 and FVC values post-transplant must be entered, all within the last 6 months.
 - The recorded FEV1 and FVC values must be at least one week apart.
 - The most recent FEV1 value must be from within the last week.
 - Enter FEV1 and FVC values in chronological order beginning with the oldest date first, in data row A.

3. PULMONARY EVALUATIONS - Please enter all pre-bronchodilator FEV1s and FVCs obtained within the last 6 months:

- A minimum of 5 recorded FEV1 values post-transplant, recorded in the last 6 months, separated from each other by at least one week, must be entered.
- One FEV1 value recorded within the last week must be entered.
- Please input the FEV1 values from the oldest date at the top (ie. A. Date) to the newest date at the bottom.

A. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
B. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
C. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
D. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
E. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
If additional FEV1 values have been obtained during the last 6 months, please provide:						
F. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
G. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
H. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
I. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
J. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
K. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
L. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
M. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
N. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters
O. Date	<input type="text"/>		FEV1	<input type="text"/> liters	FVC	<input type="text"/> liters

Figure 26-Confirmation of Eligibility

- **Confirmation of Enrollment**, item # 4, is shown in *Figure 27*. Enter the date the participant signed the IRB-approved Informed Consent Form and the version date of the Informed Consent Form.

4. CONFIRMATION OF ENROLLMENT

A. Date the approved Informed Consent Form was signed by the subject


B. Informed Consent Form Version Date


Figure 27-Confirmation of Enrollment

- 11.4** Confirm that all information entered is correct, and click the **Determine Enrollment and Study Arm Eligibility** button at the bottom of the page, *Figure 27*.

Critical Note: Eligibility and study arm determination are based upon the data on this form. Do not click the **Determine Enrollment and Study Arm Eligibility** button until you are sure all data are correct.

- 11.5** Clicking the **Determine Enrollment and Study Arm Eligibility** button directs you to the **Enrollment Determination Results** page for the ECP Treatment Arm, *Figure 28*. *Figure 29 - Shows the Enrollment Determination Results page for the Observation Arm and Figure 30 - Shows the Enrollment Determination Results for a participant excluded from enrollment*.

NOTE: *Figure 31* states the following: 'The participant is assigned to the "Observational Arm".' The forms will use the word 'Observational', but this MOP will use the word 'Observation' to agree with the protocol until the software can be changed to replace the word 'Observational' in the forms.

- 11.6** These are the three possible results:

- If the data entered for the participant meet all of the inclusion/exclusion criteria, and if the rate of lung function decline is sufficient and statistically significant per the parameters outlined in the study protocol, the individual will be enrolled and placed into the ECP Treatment Arm of the study, *Figure 28*.
- If the inclusion/exclusion criteria are met, but the magnitude of decline in slope is not sufficient, or if sufficient, is not statistically significant (i.e., $p < 0.05$), per study protocol, then the individual will be enrolled and placed into the Observation Arm of the study, *Figure 29*.
- If the inclusion/exclusion criteria are not met, then the individual is not eligible to participate in the study, *Figure 30*.

The screenshot shows the ECP Registry website with a blue header and a background image of a human heart. The header includes the ECP Registry logo and navigation links: Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources.

Enrollment Determination Results

This patient is now ENROLLED into the Study. (An arrow points to this text.)

Study Arm Eligibility Results

This patient is assigned to the "ECP Treatment Arm". Please follow the Protocol's treatment and evaluation procedures for ECP Treatment Arm participants.

Rate of lung function decline (Slope) = -113.10286 ml / month
Statistically significant rate of decline (P-Value less than 0.05) = 3.14425E-5
Last FEV1 value = 2200.0 ml

This patient's participant identification number is 101010.

Please make a NOTE of your patient's participant identification number: 101010, because all interaction with the Washington University Academic Research Organization (ARO) concerning this participant will use this identifier.

Important and Time-Sensitive: Please PRINT this subject's Confirmation of Eligibility (COE) Form, have an authorized physician investigator sign and date the COE form, and scan and upload the signed COE form along with the other Source Documents listed at the top of the COE Form. Per Protocol Section 3.7, submission of this signed COE Form with DCC Verification is required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed.

[Go to the COE Form to Print](#)

Figure 28 - Shows the Enrollment Determination Results page for the ECP Treatment Arm

ECP REGISTRY

Enrollment Determination Results

This patient is now ENROLLED into the Study. (An arrow points to this text.)

Study Arm Assignment Results

This patient is assigned to the "Observational Arm". This patient is not currently eligible to receive ECP because the rate (slope) of FEV1 decline does not meet the study Protocol's threshold to qualify to receive ECP (see Protocol Section 3.6).

Eligibility failed on the following criterion:

because the slope ≥ -30 when the minimum FEV1 ≥ 1200 ml

Rate of lung function decline (Slope) = -2.1838036 ml / month
Statistically significant rate of decline (P-Value less than 0.05) = 0.46217558
Last FEV1 value = 2600.0 ml

This patient's participant identification number is 101009.

Please make a NOTE of your patient's participant identification number: 101009, because all interaction with the Washington University Academic Research Organization (ARO) concerning this participant will use this identifier.

Please follow the Protocol's treatment and evaluation procedures for Observation Arm patients, and enter all subsequent clinically obtained FEV-1 values into the Observation Pulmonary Evaluations Log. If your patient exhibits further decline and you wish him/her to receive ECP, you may enter up to 4 additional FEV-1 values (spaced at least one week apart) into the Observation Pulmonary Evaluations Log and request a re-assessment of whether he/she has become eligible for the ECP Treatment Arm, per Protocol Section 3.6. Please contact your CCC nurse coordinator if you have questions.

Important and Time-Sensitive: Please PRINT this subject's Confirmation of Eligibility (COE) Form, have an authorized physician investigator sign and date the COE form, and scan and upload the signed COE form along with the other Source Documents listed at the top of the COE Form. Per Protocol Section 3.7, submission of this signed COE Form is required.

[Go to the COE Form to Print](#)

Figure 29 - Shows the Enrollment Determination Results page for the Observation Arm

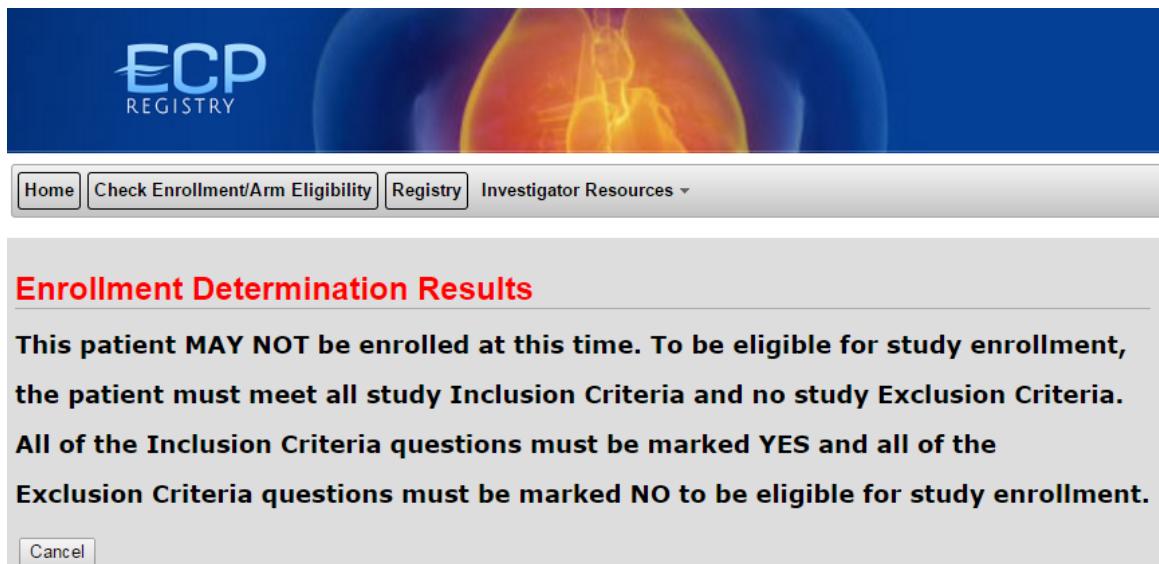


Figure 30 - Shows the Enrollment Determination Results for a participant excluded from enrollment

- 11.7** If eligible for enrollment into the ECP Registry, the participant will either be placed into the “ECP Treatment Arm”, or the “Observation Arm”. All participants enrolled will be assigned a Participant ID noted on the Enrollment Determination Results page. Keep a record of the assigned Participant’s ID. All interactions with Washington University Academic Research Organization (ARO) concerning this participant will use this identifier.
- 11.8** Click the **Go to the COE form to Print** button at the bottom of the **Enrollment Determination Results** page. This will direct you to the **Site Summary** page.
- 11.9** On the **Site Summary** page locate the correct patient by assigned **Participant ID** and click **View** on that line.
- 11.10** The **Participant Summary** page is now displayed and lists one event, the **Confirmation of Eligibility (COE)**. Click **View**, which directs you to the **Event Summary** page.
- 11.11** The **Confirmation of Eligibility** event is listed here, and the **Status** column reads **New**. Click **View**. **The Confirmation of Eligibility form is populated with data entered in the Enrollment Assessment and Study Arm Eligibility form.**
- 11.12** Print the **COE** CRF by right clicking on the mouse. A pop up box will display. Click **PRINT**
- 11.13** Have the site PI or Co-Investigator sign the **Confirmation of Eligibility CRF**. See *Figure 31* - The bottom of Confirmation of Eligibility CRF form where PI or Co-I will sign and date.
- 11.14** Instructions to complete the Confirmation of Eligibility CRF are provided in section 12.1.

5. INVESTIGATOR ATTESTATION

I have reviewed and confirmed that the information recorded on these CRF Pages is accurate. I attest that this patient meets all study eligibility criteria and is appropriate to enroll in the ECP Registry

Comments:

Investigator Name (please print) _____

Investigator Signature _____ Date: _____

Figure 31 - The bottom of Confirmation of Eligibility CRF form where PI or Co-I will sign and date

12.0 ECP Treatment Arm - Case Report Forms

12.1 Confirmation of Eligibility CRF

- Complete the Confirmation of Eligibility CRF for both ECP Treatment and/or Observation Arm participants by adding the appropriate source documents including the signed and dated printed Confirmation of Eligibility CRF.

- The following source documents are required to complete the online Confirmation of Eligibility CRF process:
 - A signed Confirmation of Eligibility CRF
 - A History and Physical or Consultation Notes
 - An Operative Report of Transplant Procedure
 - Pulmonary Function Test Report for each PFT submitted

- Usage: This CRF collects these source documents to verify data on the Confirmation of Eligibility CRF
 - Signed Confirmation of Eligibility CRF
 - Medical history
 - Transplant operative procedure report
 - Pulmonary function tests

- To complete the **Confirmation of Eligibility** CRF:
 - Click the **Registry** button to be directed to the **Site Summary** page, *Figure 32*.



Figure 32 Outdated Now have a Help button

- On the **Site Summary** page find the assigned **Participant ID** and click **View**. *Figure 33*.



Figure 33

- The **Participant Summary** page is now displayed, *Figure 34*.
- Locate the **Event Type** “**Confirmation of Eligibility**” and click **View**. Note that the **Status** is **NEW**.

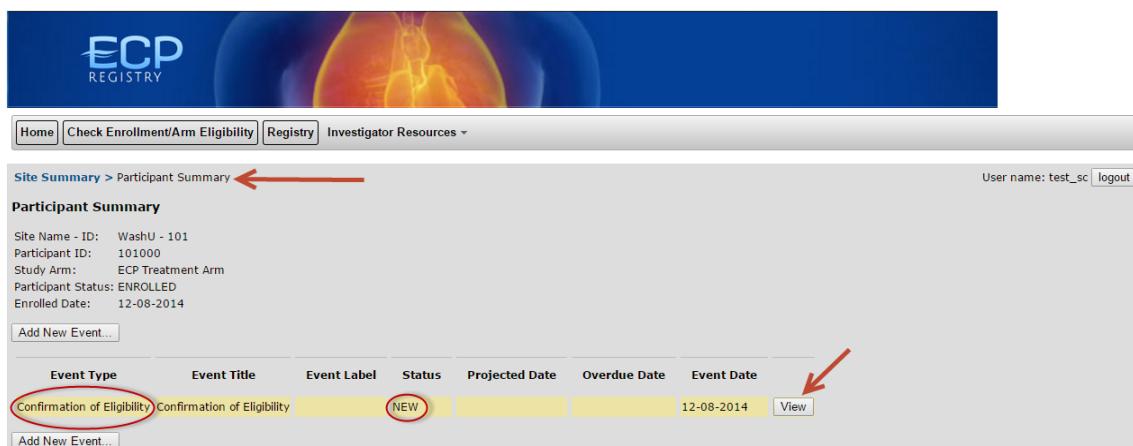


Figure 34

- On the **Event Summary** page, click **View**, *Figure 35*.



ECP REGISTRY

Home Check Enrollment/Arm Eligibility Registry Investigator Resources

Site Summary > Participant Summary > Event Summary

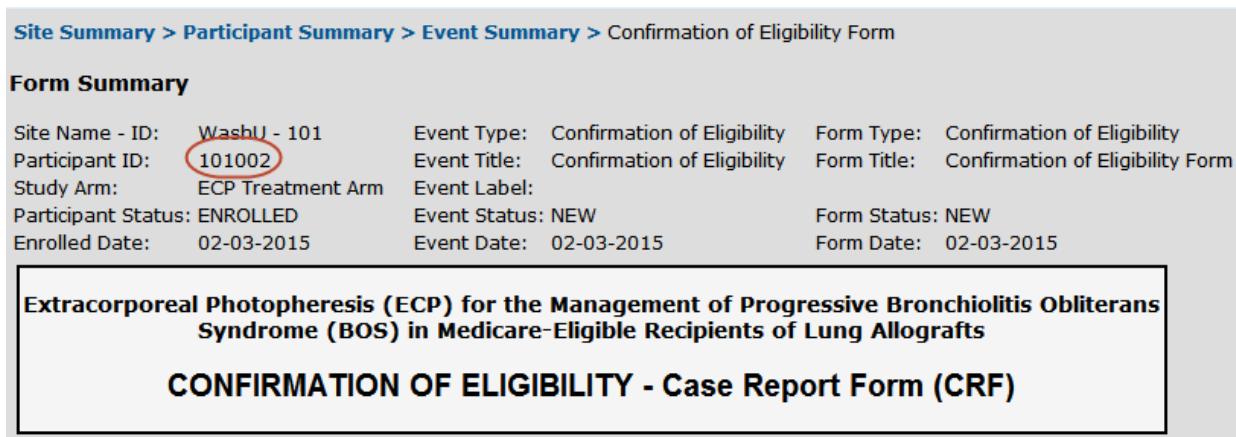
Event Summary

Site Name - ID: WashU - 101	Event Type: Confirmation of Eligibility
Participant ID: 101000	Event Title: Confirmation of Eligibility
Study Arm: ECP Treatment Arm	Event Label:
Participant Status: ENROLLED	Event Status: NEW
Enrolled Date: 12-08-2014	Event Date: 12-08-2014

Form Type	Form Title	Status	Date
Confirmation of Eligibility	Confirmation of Eligibility Form	NEW	12-08-2014

Figure 35

- The **Confirmation of Eligibility** CRF is now displayed.
- Confirm the correct **Participant ID**, *Figure 36*.



Site Summary > Participant Summary > Event Summary > Confirmation of Eligibility Form

Form Summary

Site Name - ID: WashU - 101	Event Type: Confirmation of Eligibility	Form Type: Confirmation of Eligibility
Participant ID: 101002	Event Title: Confirmation of Eligibility	Form Title: Confirmation of Eligibility Form
Study Arm: ECP Treatment Arm	Event Label:	Form Status: NEW
Participant Status: ENROLLED	Event Status: NEW	Form Date: 02-03-2015
Enrolled Date: 02-03-2015	Event Date: 02-03-2015	

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

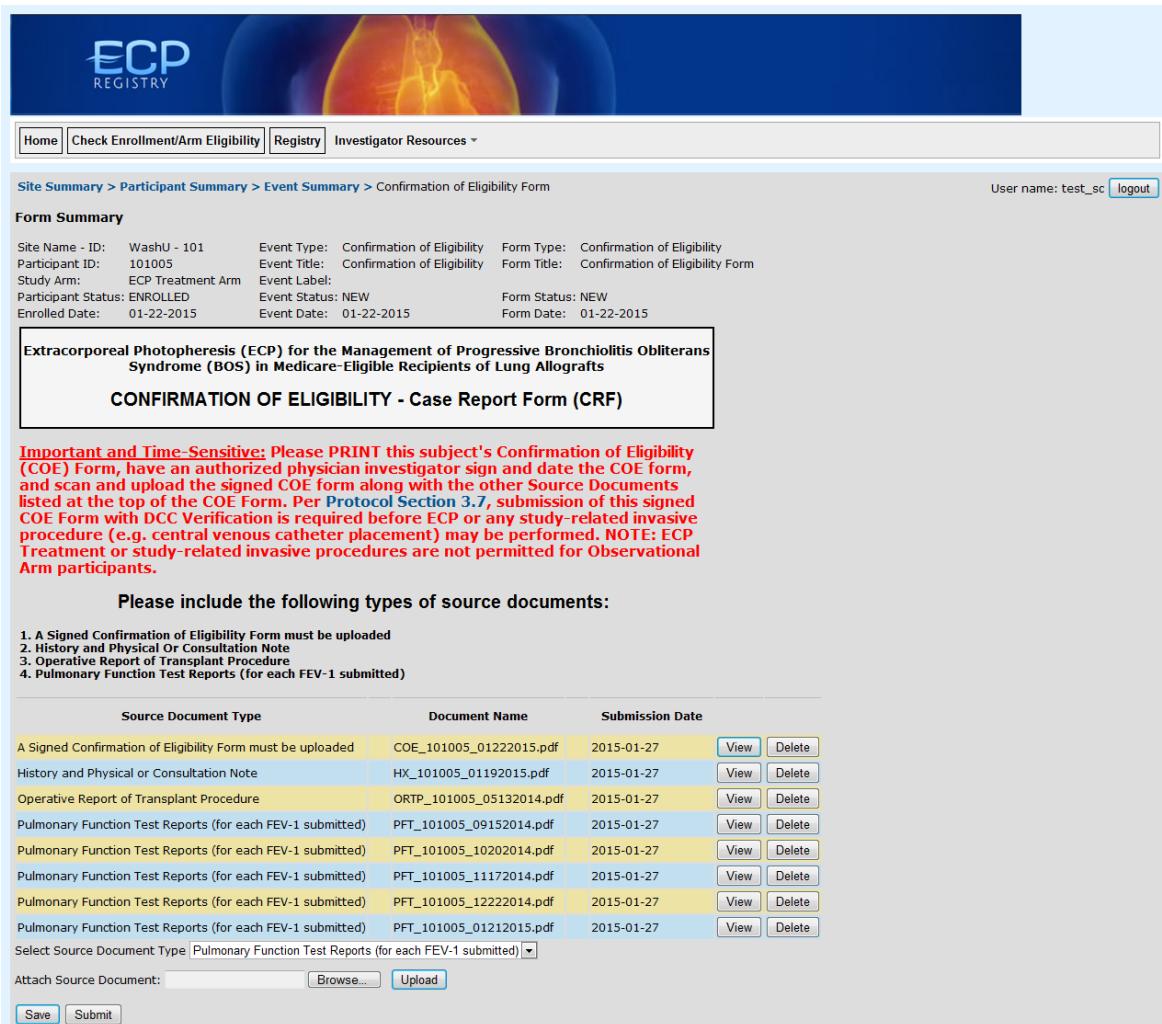
CONFIRMATION OF ELIGIBILITY - Case Report Form (CRF)

Figure 36

- Scan and upload all required source documents. For help uploading the required source documents as PDFs, see **Section 10.0 Uploading Scanned Source Document PDF files**.

Manual of Procedures

- *Figure 37* shows an example of the top portion of a Confirmation of Eligibility CRF with all required documents uploaded. The number of uploaded PFTs on a given Confirmation of Eligibility CRF will vary, as will the names given to the PDF documents.



The screenshot shows the ECP Registry website. The top navigation bar includes links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. The user is logged in as 'test_sc'. The main page displays a 'Form Summary' for a participant in the 'ECP Treatment Arm'. The summary includes fields for Site Name, Participant ID, Study Arm, Participant Status, and Enrolled Date. Below the summary is a box containing the 'CONFIRMATION OF ELIGIBILITY - Case Report Form (CRF)'. A red warning message in this box states: 'Important and Time-Sensitive: Please PRINT this subject's Confirmation of Eligibility (COE) Form, have an authorized physician investigator sign and date the COE form, and scan and upload the signed COE form along with the other Source Documents listed at the top of the COE Form. Per Protocol Section 3.7, submission of this signed COE Form with DCC Verification is required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed. NOTE: ECP Treatment or study-related invasive procedures are not permitted for Observational Arm participants.' Below the CRF box, there is a table of uploaded source documents, each with a 'View' and 'Delete' button. The table includes columns for Source Document Type, Document Name, and Submission Date. At the bottom of the page are buttons for 'Save', 'Upload', and 'Submit'.

Figure 37

- Answer question 4D, "Has the signed Confirmation of Eligibility CRF been uploaded?" *Figure 38*.

4. CONFIRMATION OF ELIGIBILITY

- A. Date eligibility status confirmed**
- B. Date the approved Informed Consent Form was signed by the subject**
- C. Informed Consent Form Version Date**
- D. Has the signed Confirmation of Eligibility CRF been uploaded?**

04/14/2015
04/13/2015
04/01/2015

YES NO

Figure 38

- Confirm that all data are accurate and that the required source documents have been uploaded before submitting the Confirmation of Eligibility CRF.
After submitting the Confirmation of Eligibility CRF, you may not make changes to the Confirmation of Eligibility CRF questions, but pdf documents can be uploaded, and the option to delete source documents is no longer available.
- Select **Submit** button at the bottom of the **Confirmation of Eligibility CRF** when the data are correct and complete, *Figure 39*.

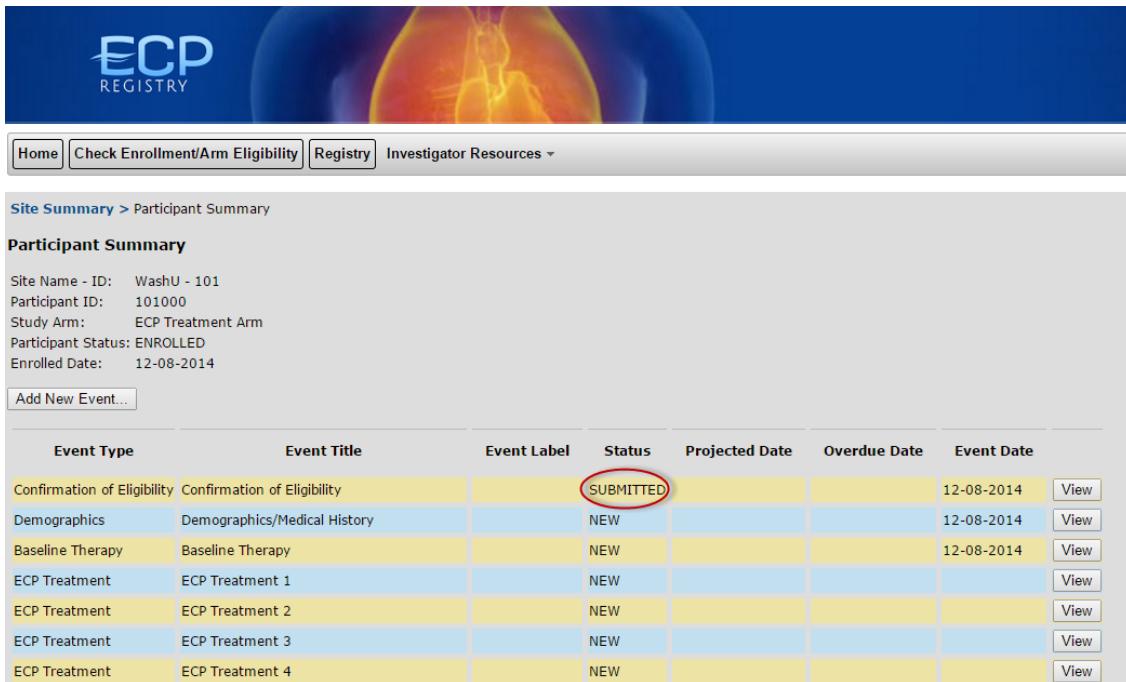
5. INVESTIGATOR ATTESTATION

I have reviewed and confirmed that the information recorded on these CRF Pages is accurate. I attest that this patient meets all study eligibility criteria and is appropriate to enroll in the ECP Registry

Investigator Name (please print) _____
Investigator Signature _____ Date: _____
Save **Submit** 

Figure 39

- After submitting the **Confirmation of Eligibility CRF** the **Participant Summary** page displays.
- The **Status** of the **Confirmation of Eligibility** event in the **Participant Summary** page has changed to **SUBMITTED**, *Figure 40*.



Site Summary > Participant Summary

Participant Summary

Site Name - ID: WashU - 101
Participant ID: 101000
Study Arm: ECP Treatment Arm
Participant Status: ENROLLED
Enrolled Date: 12-08-2014

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Confirmation of Eligibility	Confirmation of Eligibility		SUBMITTED			12-08-2014	View
Demographics	Demographics/Medical History		NEW			12-08-2014	View
Baseline Therapy	Baseline Therapy		NEW			12-08-2014	View
ECP Treatment	ECP Treatment 1		NEW				View
ECP Treatment	ECP Treatment 2		NEW				View
ECP Treatment	ECP Treatment 3		NEW				View
ECP Treatment	ECP Treatment 4		NEW				View

Figure 40

NOTE: Per Protocol Section 3.7, submission of this signed Confirmation of Eligibility CRF and DCC Verification of the form are required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed.

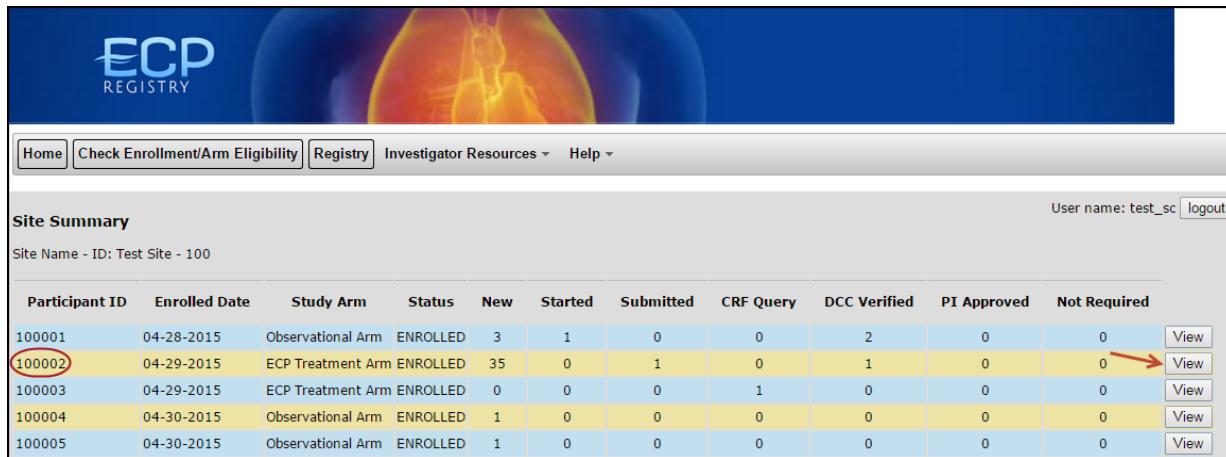
NOTE: After submission of the Confirmation of Eligibility CRF, if, during the DCC verification process, an error is noted and the site is queried and changes are made by a site to a Confirmation of Eligibility CRF, the DCC will report in writing by email to the site and to the Clinical Coordinating Center the results of these changes, after personally contacting the CCC of the event. For example, any change to PFT values, including the date or FEV-1 values, may result in a change in the value of slope of the decline in lung function and its significance. It may also result in a change in the study arm assignment. If there must be a change to the inclusion and/or inclusion criteria, this will result in the participant being not eligible to participate in the ECP Registry.

- The **Status** of the **Confirmation of Eligibility** event in the **Participant Summary** page changes to **DCC VERIFIED** when all data fields on the **Confirmation of Eligibility CRF** have been verified by the DCC. For an explanation of the DCC verification process, see [Section 9.0 CRF Data Verification](#).
- When the status of the **Confirmation of Eligibility CRF** becomes DCC Verified, the **Participant Summary** page will be populated with additional CRFs. Instructions for completing these CRFs are provided in the following CRF Sections.

12.2 Demographics/Medical History Case Report Form

- This CRF is completed for both ECP Treatment and Observation Arm participants. The source documents required are listed at the top of the CRF.
- To complete the CRF:
 - Click the **Registry** button, which will direct you to the **Site Summary** page, *Figure 41*.
 - On the **Site Summary** page locate the correct participant using the assigned **Participant ID** and click **View**. *Figure 41*.

Manual of Procedures



Participant ID	Enrolled Date	Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	
100001	04-28-2015	Observational Arm	ENROLLED	3	1	0	0	2	0	0	View
100002	04-29-2015	ECP Treatment Arm	ENROLLED	35	0	1	0	1	0	0	View
100003	04-29-2015	ECP Treatment Arm	ENROLLED	0	0	0	1	0	0	0	View
100004	04-30-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View
100005	04-30-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View

Figure 41

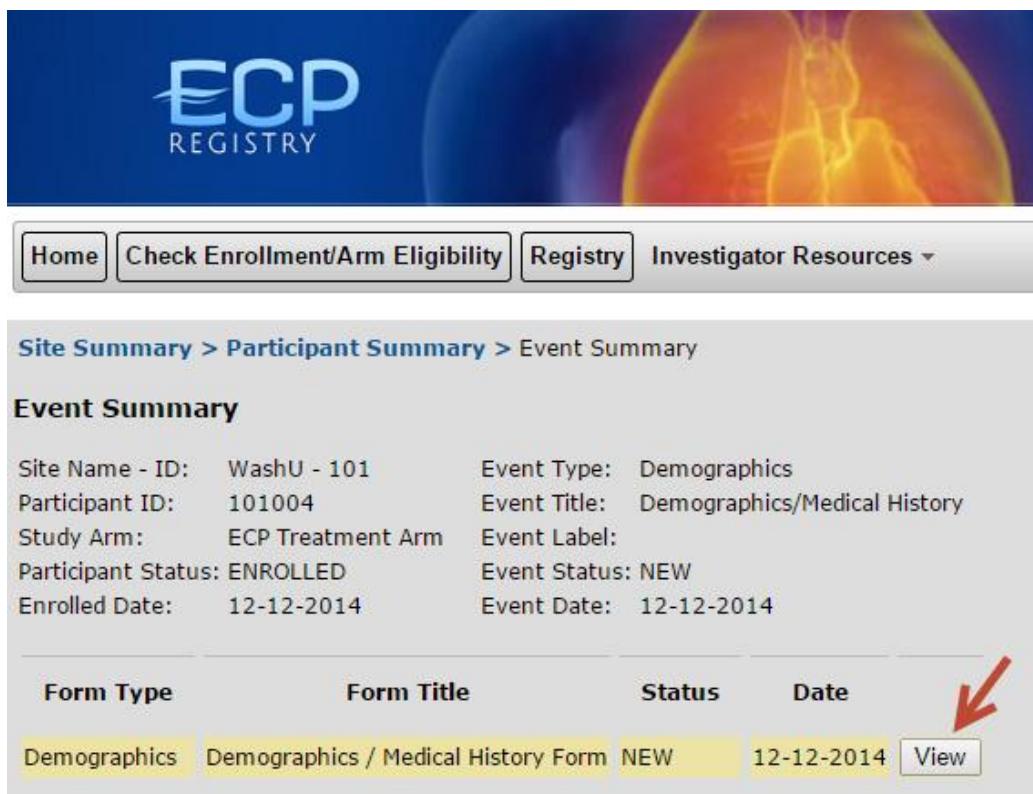
- The **Participant Summary** page is displayed, *Figure 42*.
- If the **Demographics/Medical History** event **Status** column reads **NEW**, that CRF has not been started or submitted, click **View**, *Figure 42*.
- The columns for the **Projected Date** and the **Overdue Date** are populated after the first ECP treatment CRF is submitted.



Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Pulmonary Evaluation	Pulmonary Evaluation: 30 day assessment		SUBMITTED			04-27-2015	View
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			04-29-2015	View
Demographics	Demographics/Medical History		NEW			04-29-2015	View
Baseline Therapy	Baseline Therapy		NEW			04-29-2015	View
ECP Treatment	ECP Treatment 1		NEW				View
ECP Treatment	ECP Treatment 2		NEW				View
ECP Treatment	ECP Treatment 3		NEW				View
ECP Treatment	ECP Treatment 4		NEW				View

Figure 42

- Clicking **View** directs you to the **Event Summary** page. The **Demographics/Medical History** event is listed here, click **View**, *Figure 43*.

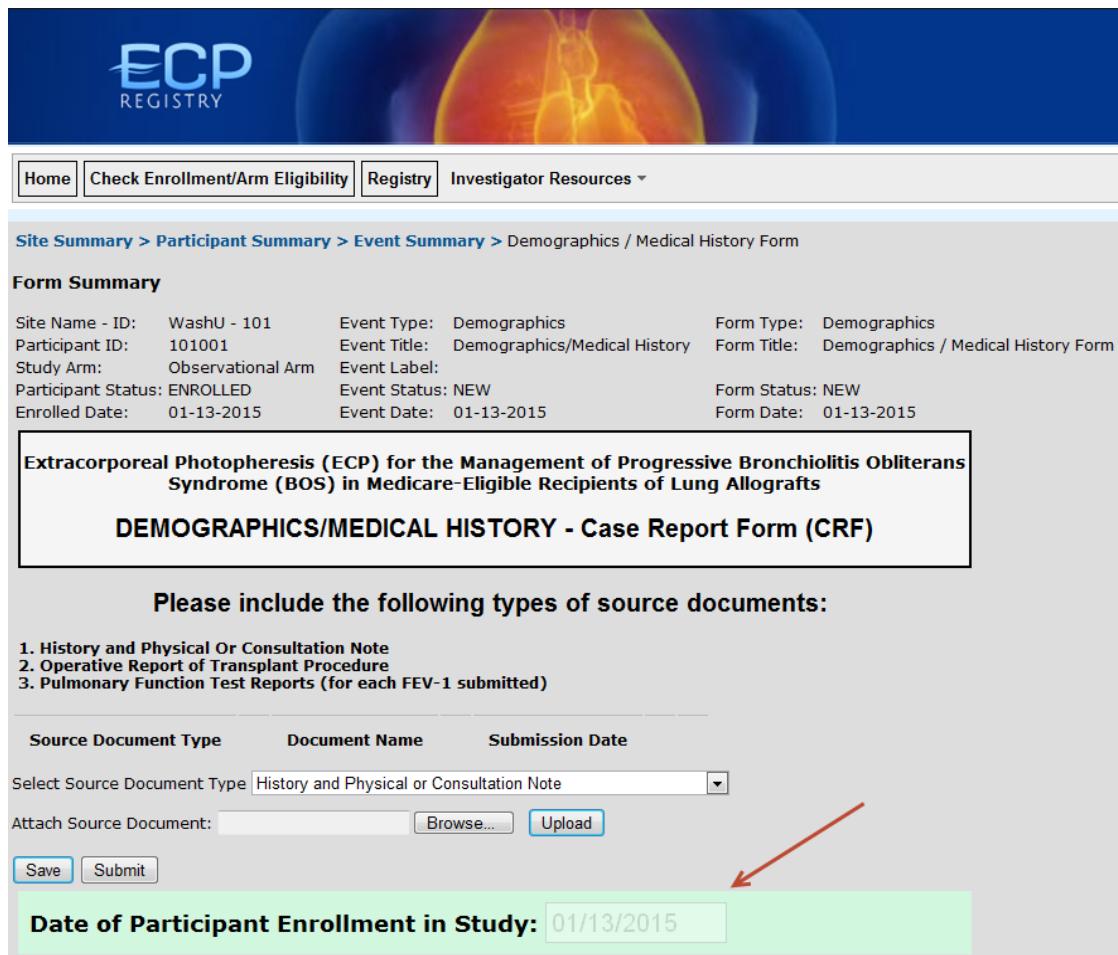


The screenshot shows the ECP Registry website interface. At the top, there is a navigation bar with links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. Below the navigation bar, the page title is "Site Summary > Participant Summary > Event Summary". The main content area is titled "Event Summary". It displays participant details: Site Name - ID: WashU - 101, Participant ID: 101004, Study Arm: ECP Treatment Arm, Participant Status: ENROLLED, Enrolled Date: 12-12-2014. To the right of these details, it shows Event Type: Demographics, Event Title: Demographics/Medical History, Event Label: (empty), Event Status: NEW, and Event Date: 12-12-2014. Below this information is a table with columns: Form Type, Form Title, Status, and Date. The table contains one row: Demographics / Demographics / Medical History Form, NEW, 12-12-2014, and a "View" button. A red arrow points to the "View" button.

Form Type	Form Title	Status	Date
Demographics	Demographics / Medical History Form	NEW	12-12-2014

Figure 43

- Clicking **View** directs you to the **Demographics/Medical History** CRF page.
- The **Date of Participant Enrollment in Study** is automatically populated by the system for this CRF, *Figure 44*.



ECP REGISTRY

Home | Check Enrollment/Arm Eligibility | Registry | Investigator Resources ▾

Site Summary > Participant Summary > Event Summary > Demographics / Medical History Form

Form Summary

Site Name - ID:	WashU - 101	Event Type:	Demographics	Form Type:	Demographics
Participant ID:	101001	Event Title:	Demographics/Medical History	Form Title:	Demographics / Medical History Form
Study Arm:	Observational Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	01-13-2015	Event Date:	01-13-2015	Form Date:	01-13-2015

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

DEMOGRAPHICS/MEDICAL HISTORY - Case Report Form (CRF)

Please include the following types of source documents:

1. History and Physical Or Consultation Note
2. Operative Report of Transplant Procedure
3. Pulmonary Function Test Reports (for each FEV-1 submitted)

Source Document Type	Document Name	Submission Date
Select Source Document Type	History and Physical or Consultation Note	
Attach Source Document:	<input type="button" value="Browse..."/>	<input type="button" value="Upload"/>
<input type="button" value="Save"/>	<input type="button" value="Submit"/>	

Date of Participant Enrollment in Study: 01/13/2015

Figure 44

- The entire Demographics/Medical History CRF is shown in *Figure 45-Demographics/Medical History*, *Figure 46-Demographics/Medical History* and *Figure 47-Demographics/Medical History*.

Manual of Procedures

Site Summary > Participant Summary > Event Summary > Demographics / Medical History Form

Form Summary

Site Name - ID:	Test Site - 100	Event Type:	Demographics	Form Type:	Demographics
Participant ID:	100002	Event Title:	Demographics/Medical History	Form Title:	Demographics / Medical History Form
Study Arm:	Observational Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	04-20-2015	Event Date:	04-20-2015	Form Date:	04-20-2015

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

DEMOGRAPHICS/MEDICAL HISTORY - Case Report Form (CRF)

Please include the following types of source documents:

1. History and Physical Or Consultation Note
2. Operative Report of Transplant Procedure
3. Pulmonary Function Test Reports (for each FEV-1 submitted)

Source Document Type	Document Name	Submission Date
Select Source Document Type	History and Physical or Consultation Note	
Attach Source Document:	<input type="button" value="Browse..."/>	No file selected.
		<input type="button" value="Upload"/>
<input type="button" value="Save"/>	<input type="button" value="Submit"/>	

Date of Participant Enrollment in Study: 04/20/2015

SECTION A. Demographic Information

1. Age:

2. Gender: Male Female

3. Race:
 White
 Black or African-American
 Asian
 American Indian
 Alaska Native
 Native Hawaiian or Other Pacific Islander
 Other
 No Response

4. Are you of Hispanic or Latino origin: YES NO

SECTION B. Previous Medical History and Pulmonary Function Testing Results

5. Please provide a description of the underlying disease necessitating lung transplantation:
 Chronic Obstructive Pulmonary Disease (COPD) including Emphysema
 Interstitial Lung Disease
 Cystic Fibrosis
 Pulmonary Hypertension
 Alpha 1-Antitrypsin Deficiency Emphysema
 Replacing previously transplanted lung that failed
 Other

If other, please describe:

6. Date of lung transplantation:

7. Operation performed:
 Single
 Bilateral
 Heart-lung
 Other

If other, please describe:

Figure 45-Demographics/Medical History

8. Weight at time of transplant: kilograms

9. Height: Centimeters

10. Medical History - Co-Morbid Conditions at any time prior to enrollment:

- YES NO Hypertension
 YES NO Diabetes
 YES NO GERD - if yes, treatment: medical therapy fundoplication
 YES NO High Cholesterol
 YES NO Current Smoker
 YES NO Previous Smoker
 YES NO Coronary Artery Disease - if yes: angina myocardial infarction
 YES NO Congestive Heart Failure
 YES NO Chronic Kidney Disease
 YES NO Stroke
 YES NO Neurologic Disorder
 YES NO Other Active Conditions

If other active conditions, please describe:

11. Has the patient received any anti-platelet drug(s) within the last six months:

- YES NO Anti-Thrombotic
 YES NO Anti-Platelet Agent

12. Check all drugs that were previously used as maintenance immunosuppression and/or BOS prevention in this participant:

- YES NO Tacrolimus
 YES NO Prednisone
 YES NO Alemtuzumab
 YES NO Sirolimus (Rapamycin)
 YES NO Everolimus
 YES NO Cyclosporine A
 YES NO Methotrexate
 YES NO Macrolide Antibiotic, Azithromycin
 YES NO Mycophenolate Mofetil (Cellcept or Myfortic)
 YES NO Anti-Thermyocyte Globulin - ATG (Thymoglobulin or Atgam)

13. Check all drugs that were previously used as active treatment of BOS in this participant:

- YES NO Tacrolimus
 YES NO Prednisone
 YES NO Alemtuzumab
 YES NO Sirolimus (Rapamycin)
 YES NO Everolimus
 YES NO Cyclosporine A
 YES NO Methotrexate
 YES NO Macrolide Antibiotic, Azithromycin
 YES NO Mycophenolate Mofetil (Cellcept or Myfortic)
 YES NO Anti-Thermyocyte Globulin - ATG (Thymoglobulin or Atgam)
 YES NO Total Lymphoid Irradiation

Figure 46-Demographics/Medical History

Manual of Procedures

14. Has the participant received prednisone therapy within the last 6 months? YES NO
If yes, daily starting dose: mg

15. During the last 6 months, has the patient required a prednisone dose escalation for any period of greater than 5 days? YES NO
If yes, to what daily dose: mg
Estimate average daily dose over 6 months: mg

16. Date of diagnosis of post-transplantation BOS: 

17. Post-transplant BOS stage at diagnosis: 0 0-p 1 2 3

Stage	Definition
BOS Stage 0	FEV1 > 90% and FEF 25%-75% > 75% of baseline
BOS Stage 0-p	FEV1 = 81% to 90% of baseline and or FEF 25%-75% 75% of baseline
BOS Stage 1	FEV1 = 66% to 80% of baseline
BOS Stage 2	FEV1 = 51% to 65% of baseline
BOS Stage 3	FEV1 less than or equal to 50% of baseline

18. Please provide the baseline pulmonary function testing results using the ISHLT definition = the average of the two highest FEV1 measurements obtained 3 weeks apart after transplantation. Also please provide the results of the two component PFT assessments used for this calculation:

a. Baseline FEV1 (pre-bronchodilator)(mean FEV1 values below): liters

b. First component assessment:

i. Date: 

ii. FEV1 (pre-bronchodilator): liters

iii. FVC (pre-bronchodilator): liters

c. Second component assessment:

i. Date: 

ii. FEV1 (pre-bronchodilator): liters

iii. FVC (pre-bronchodilator): liters

SECTION C. Clinical Status at or Within One Week of Enrollment

19. Donor specific antibody at time of study enrollment? YES NO

20. Is the participant on any anticoagulant or anti-platelet drugs? YES NO
If yes, list drugs:
Name drug 1:
Name drug 2:
Name drug 3:

21. Date when the following baseline vital signs were obtained (values should be obtained within one week prior to enrollment): 

22. Weight: kilograms

23. Blood pressure: systolic mmHg diastolic mmHg

24. Heart rate: beats per minute

25. Respiratory rate: breaths per minute

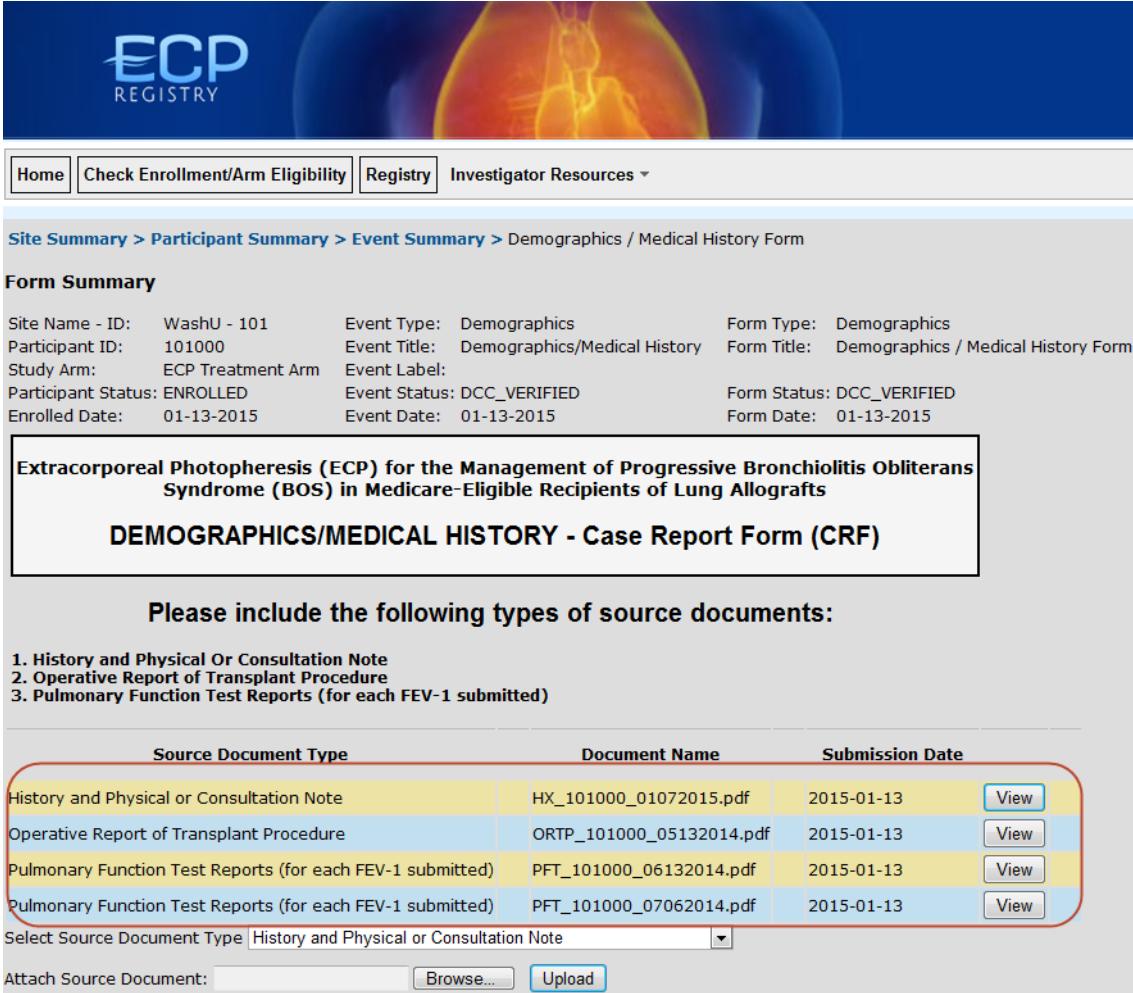
26. Resting oxygen saturation: %

27. Is the participant receiving supplemental oxygen? YES NO
If yes, how much? liters/minute

28. Comments:

Figure 47-Demographics/Medical History

- Complete sections A, B, and C of the CRF, *Figure 45-Demographics/Medical History*, *Figure 46-Demographics/Medical History*, and *Figure 47-Demographics/Medical History*. Use the tab key or mouse to navigate to all questions. Click Save every 5 to 10 minutes to save data so that your entries are not accidentally lost.
- Scan and upload all required source documents, *Figure 48*. For help uploading the required source documents as PDFs, see **Section 10.0 Uploading Scanned Source Document PDF files**.



The screenshot shows the ECP Registry website interface. At the top, there is a navigation bar with links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. Below the navigation bar, the URL indicates the user is in the Site Summary > Participant Summary > Event Summary > Demographics / Medical History Form section. The main content area is titled 'Form Summary' and displays various form details. Below this, a section titled 'Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts' is shown. A large box contains the title 'DEMOGRAPHICS/MEDICAL HISTORY - Case Report Form (CRF)'. Below this box, a section titled 'Please include the following types of source documents:' lists three items: 1. History and Physical Or Consultation Note, 2. Operative Report of Transplant Procedure, and 3. Pulmonary Function Test Reports (for each FEV-1 submitted). A table then lists the source documents submitted, showing columns for Source Document Type, Document Name, and Submission Date. The table includes four rows: History and Physical or Consultation Note (hx_101000_01072015.pdf, 2015-01-13, View), Operative Report of Transplant Procedure (ORTP_101000_05132014.pdf, 2015-01-13, View), Pulmonary Function Test Reports (for each FEV-1 submitted) (PFT_101000_06132014.pdf, 2015-01-13, View), and another Pulmonary Function Test Reports (for each FEV-1 submitted) (PFT_101000_07062014.pdf, 2015-01-13, View). A dropdown menu for 'Select Source Document Type' is set to 'History and Physical or Consultation Note'. Below the table, there is a section for attaching source documents with 'Attach Source Document:' and 'Upload' buttons.

Figure 48

- To return to this document to complete it later, click **Save**. The status of the CRF will be changed to **Started**.
- Confirm that all data entered are accurate and that the required source document PDFs have been uploaded.

- After submitting the CRF, you may not make changes, and the option to delete PDFs is no longer available.
- Select **Submit** at the bottom of the CRF when the data are correct and complete. *Figure 49.*

27. Is the participant receiving supplemental oxygen? YES NO

If yes, how much? liters/minute

28. Comments:

Save ←

Figure 49

- If the CRF is incomplete or contains values out of range, the submission will not be accepted. The document will display error messages in red to prompt you to correct or enter the values, *Figure 50.*

Home Check Enrollment/Arm Eligibility Registry Investigator Resources ▾

Site Summary > Participant Summary > Event Summary > Demographics / Medical History Form

Form Summary

Site Name - ID: WashU - 101	Event Type: Demographics	Form Type: Demographics
Participant ID: 101007	Event Title: Demographics/Medical History	Form Title: Demographics / Medical History Form
Study Arm: ECP Treatment Arm	Event Label:	
Participant Status: ENROLLED	Event Status: NEW	Form Status: NEW
Enrolled Date: 12-16-2014	Event Date: 12-16-2014	Form Date: 12-16-2014

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

DEMOGRAPHICS/MEDICAL HISTORY - Case Report Form (CRF)

Please include the following types of source documents:

1. History and Physical Or Consultation Note
2. Operative Report of Transplant Procedure
3. Pulmonary Function Test Reports (for each FEV-1 submitted)

Source Document Type	Document Name	Submission Date
Select Source Document Type	History and Physical or Consultation Note	

Attach Source Document: No file selected.

Date of Participant Enrollment in Study:

SECTION A. Demographic Information

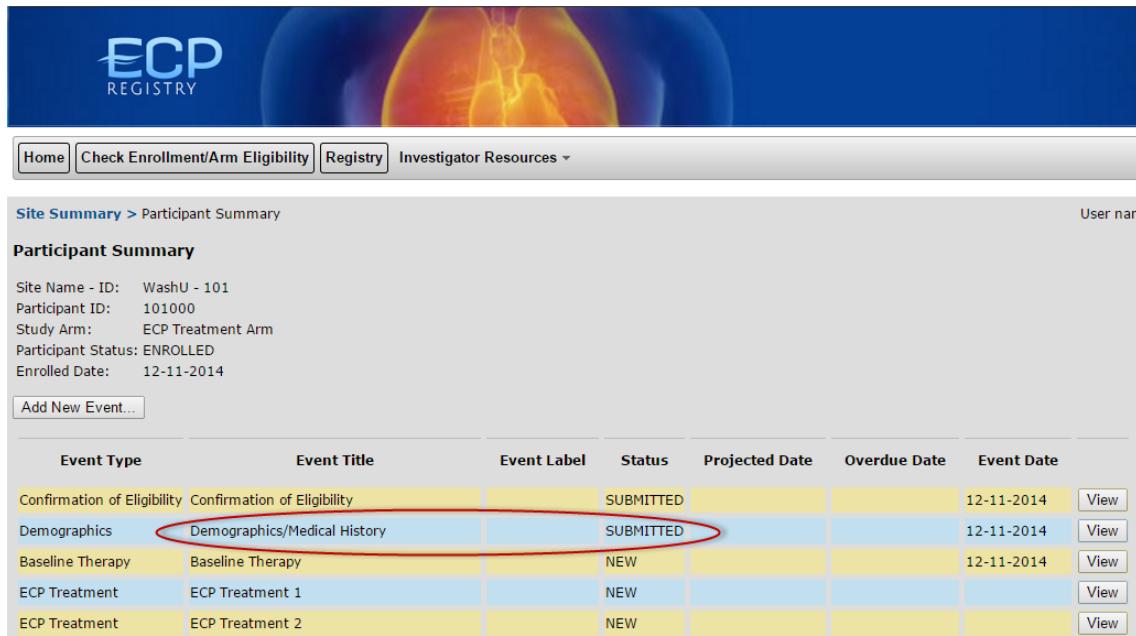
1. Age: 

Validation Error: Age ranges between 18 and 99 years

2. Gender: Male Female

Figure 50

- After submitting the **Demographics/Medical History** CRF you will be directed back to the **Participant Summary** page.
- The **Status** of the event in the **Participant Summary** page will be changed to **SUBMITTED**, *Figure 51*.



Site Summary > Participant Summary

Participant Summary

Site Name - ID: WashU - 101
 Participant ID: 101000
 Study Arm: ECP Treatment Arm
 Participant Status: ENROLLED
 Enrolled Date: 12-11-2014

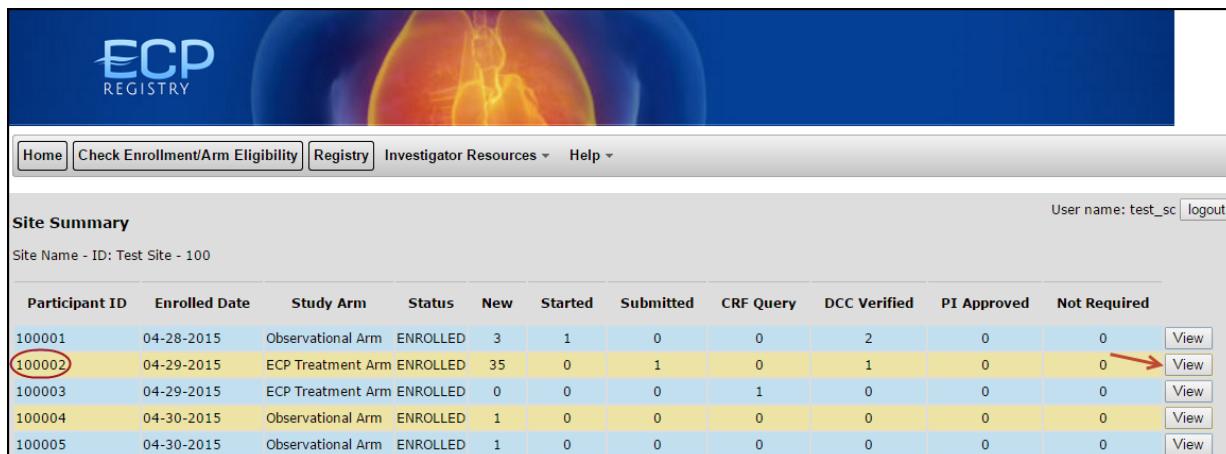
Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility	SUBMITTED			12-11-2014	View
Demographics	Demographics/Medical History	SUBMITTED			12-11-2014	View
Baseline Therapy	Baseline Therapy	NEW			12-11-2014	View
ECP Treatment	ECP Treatment 1	NEW				View
ECP Treatment	ECP Treatment 2	NEW				View

Figure 51

12.3 Baseline Therapy Case Report Form

- This CRF is completed for both ECP Treatment and Observation Arm participants.
- To Complete the CRF:
 - Click the **Registry** button, which will direct you to the **Site Summary** page.
 - On the **Site Summary** page locate the correct patient by assigned **Participant ID** and click **View**. *Figure 52*.



Site Summary

User name: test_sc [logout](#)

Site Name - ID: Test Site - 100

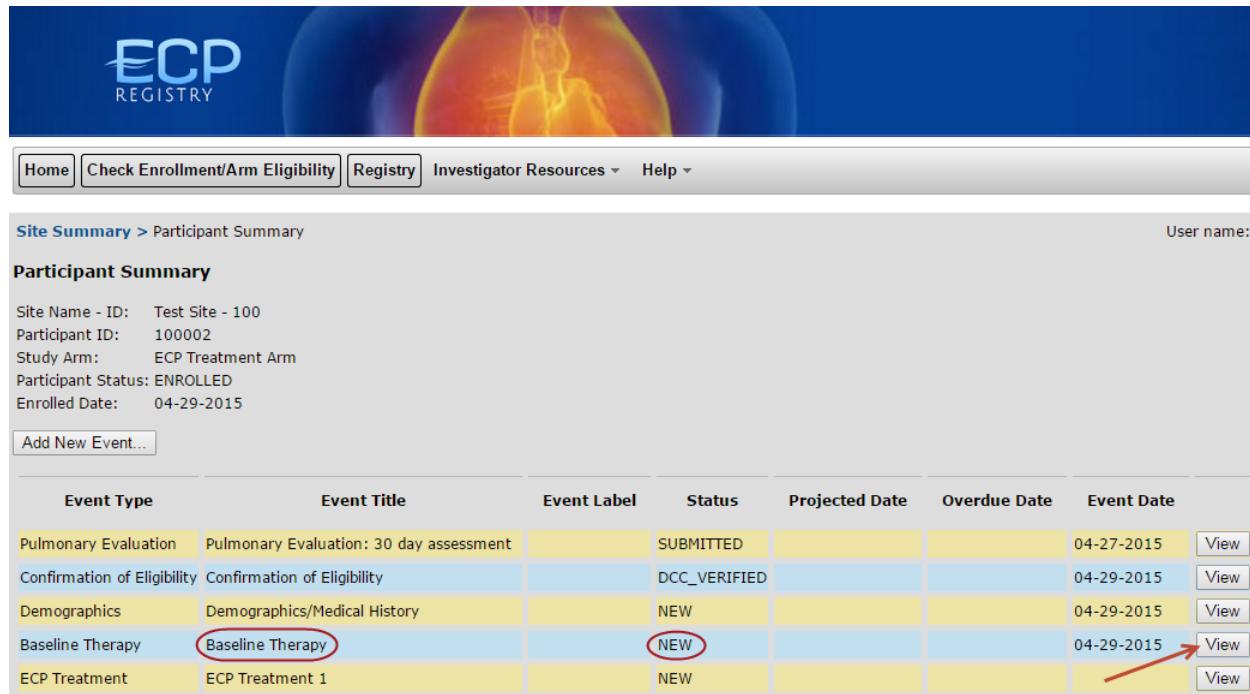
Participant ID	Enrolled Date	Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	
100001	04-28-2015	Observational Arm	ENROLLED	3	1	0	0	2	0	0	View
100002	04-29-2015	ECP Treatment Arm	ENROLLED	35	0	1	0	1	0	0	View
100003	04-29-2015	ECP Treatment Arm	ENROLLED	0	0	0	1	0	0	0	View
100004	04-30-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View
100005	04-30-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View

Figure 52

- The **Participant Summary** page is now displayed, *Figure 53*.

Manual of Procedures

- The **Baseline Therapy** event **Status** column reads **NEW**, because the CRF has not been started or submitted, click **View**, *Figure 53*.
- The columns for the **Projected Date** and the **Overdue Date** are not populated until the first ECP Treatment CRF is completed. Those columns will only display dates for the ECP Treatment arm participant.



Site Summary > Participant Summary User name:

Participant Summary

Site Name - ID: Test Site - 100
Participant ID: 100002
Study Arm: ECP Treatment Arm
Participant Status: ENROLLED
Enrolled Date: 04-29-2015

[Add New Event...](#)

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Pulmonary Evaluation	Pulmonary Evaluation: 30 day assessment		SUBMITTED			04-27-2015	View
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			04-29-2015	View
Demographics	Demographics/Medical History		NEW			04-29-2015	View
Baseline Therapy	Baseline Therapy		NEW			04-29-2015	View
ECP Treatment	ECP Treatment 1		NEW				View

Figure 53

- Clicking **View** directs you to the **Event Summary** page, *Figure 54*, where the **Baseline Therapy** event is listed. Click **View**.



The screenshot shows the ECP Registry website. At the top, there is a navigation bar with four buttons: Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. Below the navigation bar, the page title is "Site Summary > Participant Summary > Event Summary". The main content is titled "Event Summary" and contains the following participant details:

Site Name - ID:	Test Site - 100	Event Type:	Baseline Therapy
Participant ID:	100002	Event Title:	Baseline Therapy
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	04-29-2015	Event Date:	04-29-2015

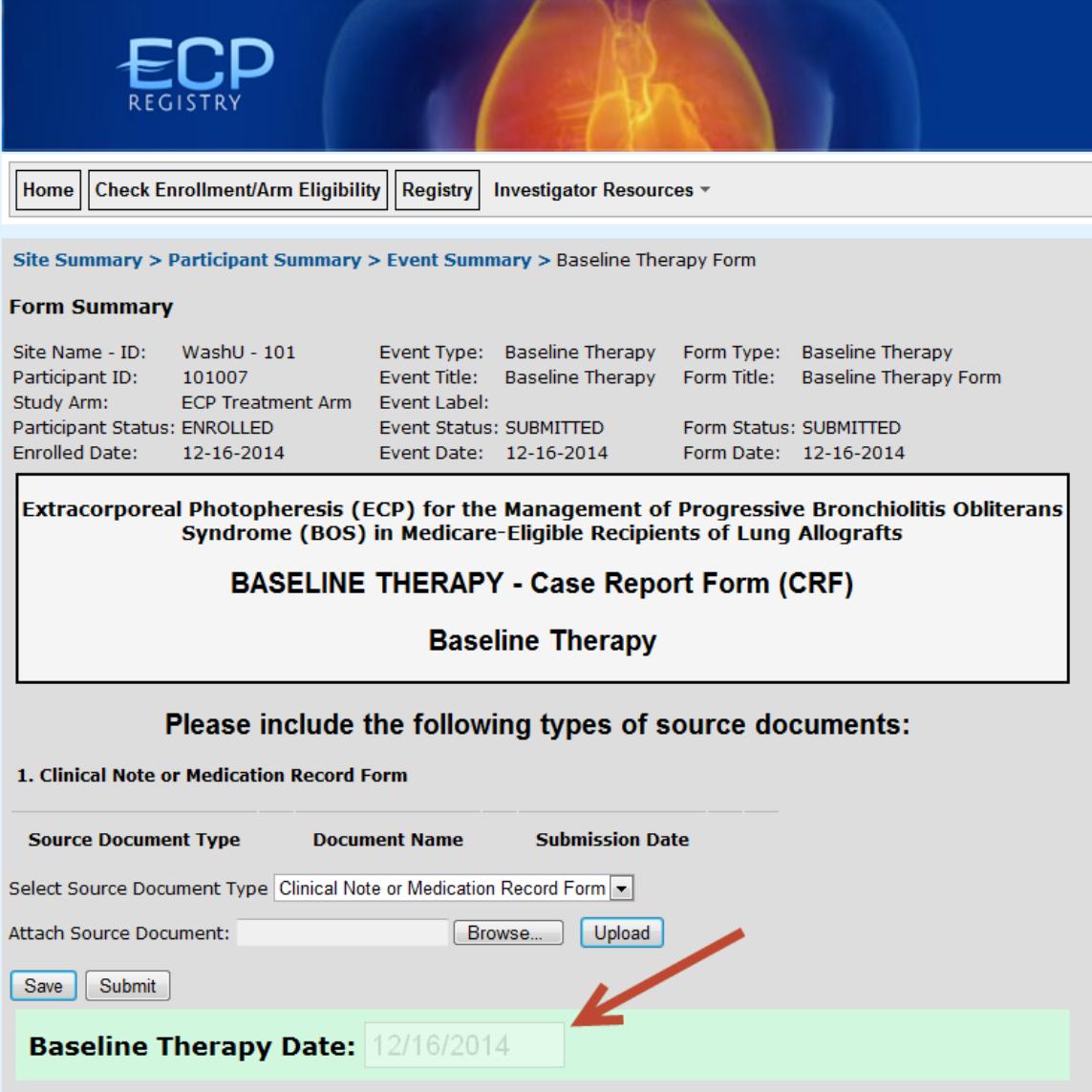
Below this, there is a table with four columns: Form Type, Form Title, Status, and Date. The data is as follows:

Form Type	Form Title	Status	Date
Baseline Therapy	Baseline Therapy Form	NEW	04-29-2015

A red arrow points to the "View" button in the Date column.

Figure 54

- Clicking **View** directs you to the **Baseline Therapy** CRF page.
- The **Baseline Therapy Date** is automatically populated by the system on this CRF. It is always the same date as the COE CRF and Enrolled Date, *Figure 55*.



ECP REGISTRY

Site Summary > Participant Summary > Event Summary > Baseline Therapy Form

Form Summary

Site Name - ID:	WashU - 101	Event Type:	Baseline Therapy	Form Type:	Baseline Therapy
Participant ID:	101007	Event Title:	Baseline Therapy	Form Title:	Baseline Therapy Form
Study Arm:	ECP Treatment Arm	Event Label:		Form Status:	SUBMITTED
Participant Status:	ENROLLED	Event Status:	SUBMITTED	Form Date:	12-16-2014
Enrolled Date:	12-16-2014	Event Date:	12-16-2014	Form Date:	12-16-2014

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

BASELINE THERAPY - Case Report Form (CRF)

Baseline Therapy

Please include the following types of source documents:

1. Clinical Note or Medication Record Form

Source Document Type	Document Name	Submission Date
Select Source Document Type	Clinical Note or Medication Record Form	
Attach Source Document:	<input type="button" value="Browse..."/>	<input type="button" value="Upload"/>
<input type="button" value="Save"/>	<input type="button" value="Submit"/>	
Baseline Therapy Date: <input type="text" value="12/16/2014"/>		

Figure 55

- Complete the CRF. Use the tab key or mouse to navigate to all questions. Click **Save** every 5 to 10 minutes to save data.
- Scan and upload all required source documents. For help uploading the required source documents as PDFs, see **section 10.0 Uploading Scanned Source Document PDF files**.
- If you wish to return to this document to complete it later, click **Save**. The **Status** of the CRF will be changed to **Started**. You may then return to the document later and complete it or make changes. **Figure 56**.



The screenshot shows the ECP Registry website. At the top, there is a logo for 'ECP REGISTRY' with a background image of a heart. Below the logo is a navigation bar with four buttons: 'Home', 'Check Enrollment/Arm Eligibility', 'Registry', and 'Investigator Resources'. The main content area is titled 'Site Summary > Participant Summary > Event Summary'. Below this, a section titled 'Event Summary' contains the following details:

Site Name - ID:	WashU - 101	Event Type:	Baseline Therapy
Participant ID:	101007	Event Title:	Baseline Therapy
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	STARTED
Enrolled Date:	12-16-2014	Event Date:	12-16-2014

Below this is a table with four columns: 'Form Type', 'Form Title', 'Status', and 'Date'. The first row is highlighted in yellow. The 'Status' column for this row is circled in red. The table data is as follows:

Form Type	Form Title	Status	Date
Baseline Therapy	Baseline Therapy Form	STARTED	12-16-2014

[View](#)

Figure 56

- Confirm that all data entered are accurate and that the required source document PDFs have been uploaded. **After submitting the CRF, you may not make changes and the option to delete PDFs is no longer available.**
- Select **Submit** at the bottom of the CRF when the data are correct and complete. *Figure 57.*

Baseline Therapy Date:

1. Check all immunosuppressive drugs that are currently being used by the participant:

YES NO Tacrolimus

YES NO Prednisone If yes, enter daily dose: mg (input range: 0-150)

YES NO Sirolimus (Rapamycin)

YES NO Everolimus

YES NO Azathioprine

YES NO Cyclosporine A

YES NO Methotrexate

YES NO Macrolide Antibiotic, Azithromycin

YES NO Mycophenolate Mofetil (Cellcept or Myfortic)

YES NO Total Lymphoid Irradiation

2. Is the participant taking an anticoagulant drug? YES NO

If yes, list drugs:

Name anticoagulant 1:

Name anticoagulant 2:

Name anticoagulant 3:

3. Is the participant taking an anti-platelet drug? YES NO

If yes, list drugs:

Name anti-platelet 1:

Name anti-platelet 2:

Name anti-platelet 3:

Save **Submit** 

Figure 57

- If the CRF is incomplete or contains values out of range, the submission will not be accepted. Instead, the document will display error messages in red, prompting the user to correct or enter the values, *Figure 58*. Note in the example that there is no response to item #3. Click Yes or No and submit the CRF again.

3. Is the participant taking an anti-platelet drug? YES NO

If yes, list drugs:

Name anti-platelet 1:

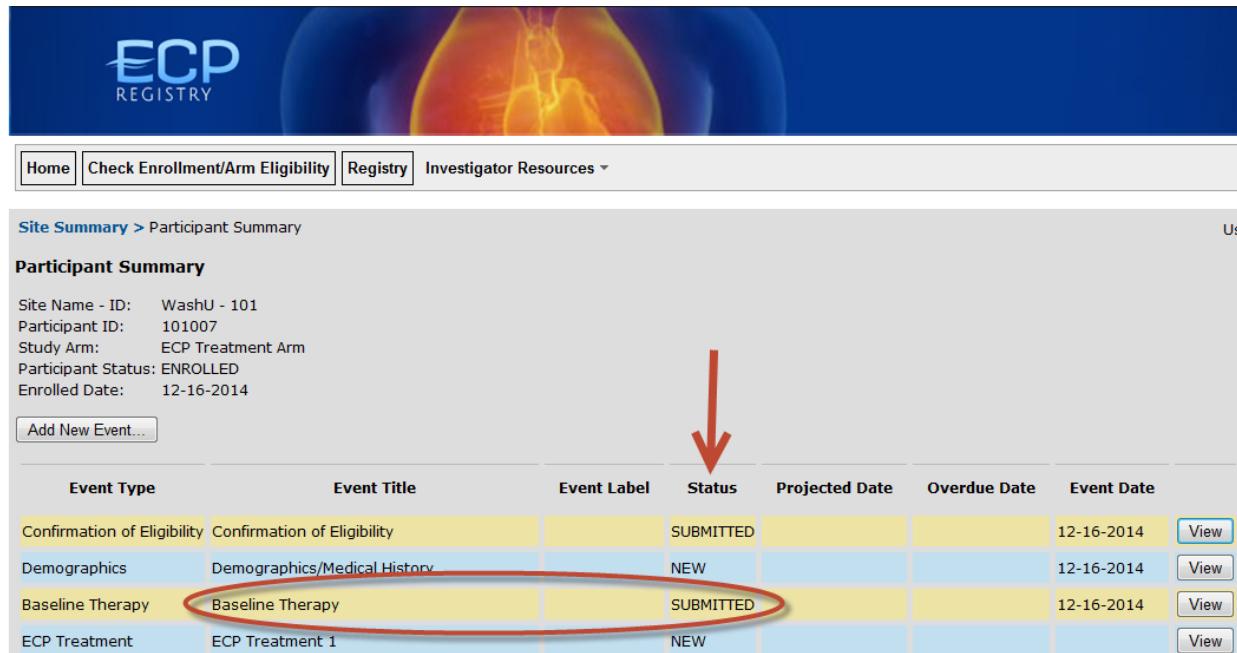
Name anti-platelet 2:

Name anti-platelet 3:

Please enter anti-platelet.

Figure 58

- After submitting the **Baseline Therapy** CRF, you will be directed back to the **Participant Summary** page.
- The **Status** of the event in the **Participant Summary** page changed to **SUBMITTED**, *Figure 59*.



Participant Summary

Site Name - ID: WashU - 101
 Participant ID: 101007
 Study Arm: ECP Treatment Arm
 Participant Status: ENROLLED
 Enrolled Date: 12-16-2014

[Add New Event...](#)

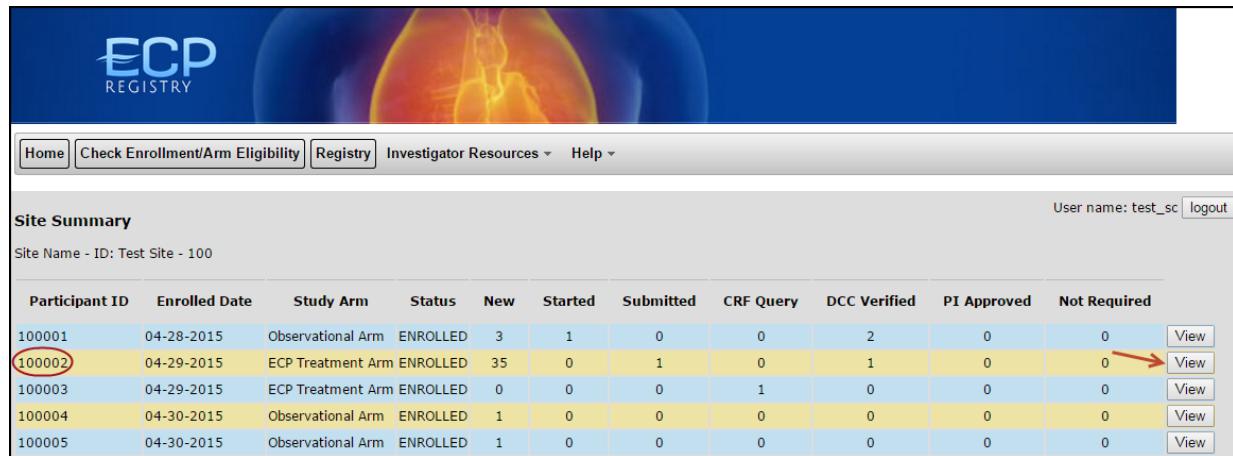
Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		SUBMITTED		12-16-2014	View
Demographics	Demographics/Medical History		NEW		12-16-2014	View
Baseline Therapy	Baseline Therapy		SUBMITTED		12-16-2014	View
ECP Treatment	ECP Treatment 1		NEW			View

Figure 59

12.4 ECP Treatment Visit Case Report Form

- The following source documents are required to complete this online CRF:
 - Photopheresis Procedure Note/Report
 - CBC - Lab Report
 - Progress Note or Clinical Note describing complications, if any

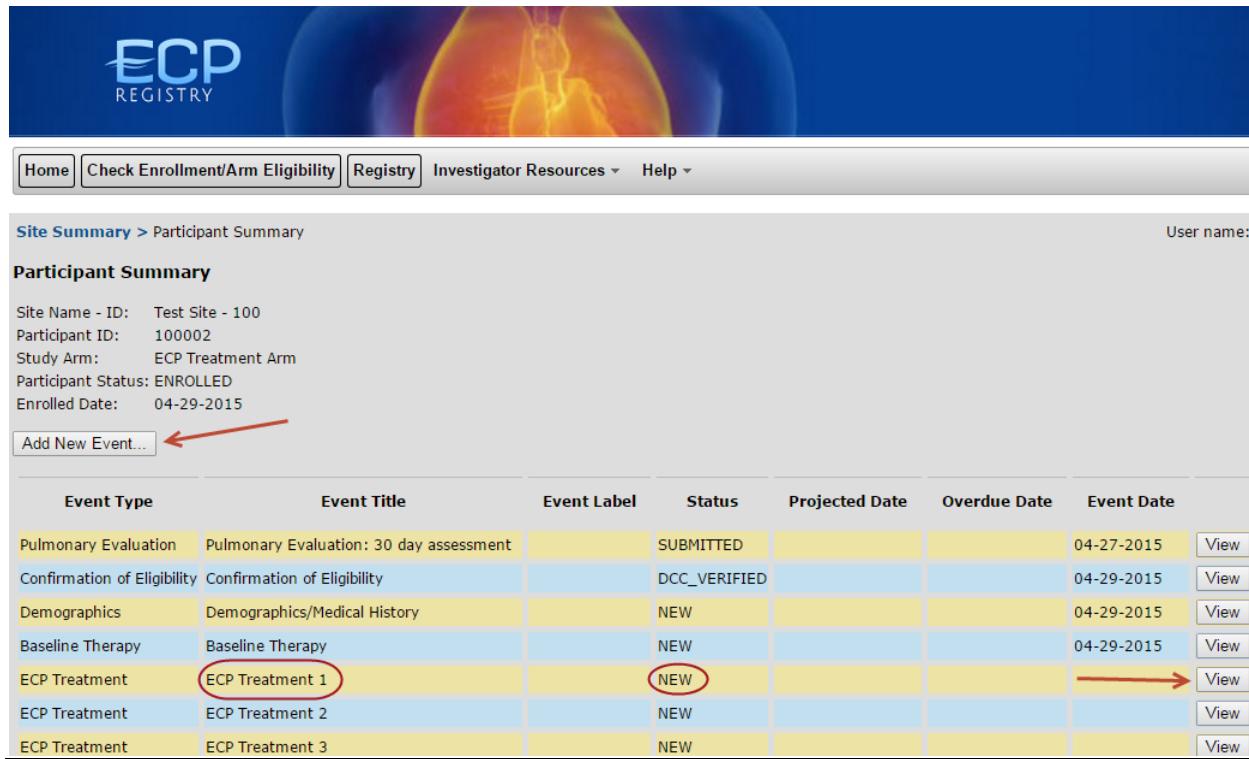
- One form must be completed per ECP treatment.
- To Complete the CRF:
 - Click the **Registry** button, which will direct you to the **Site Summary** page.
 - On the **Site Summary** page locate the correct patient by the assigned **Participant ID** and click **View**, *Figure 60*.



Participant ID	Enrolled Date	Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	
100001	04-28-2015	Observational Arm	ENROLLED	3	1	0	0	2	0	0	View
100002	04-29-2015	ECP Treatment Arm	ENROLLED	35	0	1	0	1	0	0	View
100003	04-29-2015	ECP Treatment Arm	ENROLLED	0	0	0	1	0	0	0	View
100004	04-30-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View
100005	04-30-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View

Figure 60

- The **Participant Summary** page is now displayed, *Figure 61*.
- If the **ECP Treatment Visit** event **Status** column reads **New**, the CRF has not been started or submitted, click **View**, *Figure 61*.
- The columns for the **Projected Date** are not populated until the first ECP Treatment CRF is submitted.
- If the ECP Treatment is not one of the regularly scheduled treatments, create a new ECP Treatment CRF by clicking the **Add New Event** button on the Participant Summary page.



Site Summary > Participant Summary

User name:

Participant Summary

Site Name - ID: Test Site - 100
Participant ID: 100002
Study Arm: ECP Treatment Arm
Participant Status: ENROLLED
Enrolled Date: 04-29-2015

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Pulmonary Evaluation	Pulmonary Evaluation: 30 day assessment		SUBMITTED		04-27-2015	View
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED		04-29-2015	View
Demographics	Demographics/Medical History		NEW		04-29-2015	View
Baseline Therapy	Baseline Therapy		NEW		04-29-2015	View
ECP Treatment	ECP Treatment 1		NEW			View
ECP Treatment	ECP Treatment 2		NEW			View
ECP Treatment	ECP Treatment 3		NEW			View

Figure 61

- Clicking **View** directs you to the **Event Summary** page.
- The **ECP Treatment Visit** event is listed here, click **View**, *Figure 62*.



The screenshot shows the ECP Registry website. At the top, there is a logo for 'ECP REGISTRY' with a background image of a human heart. Below the logo is a navigation bar with four buttons: 'Home', 'Check Enrollment/Arm Eligibility', 'Registry', and 'Investigator Resources'. The main content area has a breadcrumb navigation: 'Site Summary > Participant Summary > Event Summary'. The 'Event Summary' section displays the following data:

Site Name - ID:	WashU - 101	Event Type:	ECP Treatment
Participant ID:	101001	Event Title:	ECP Treatment 1
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	12-12-2014	Event Date:	

Below this, there is a table with four columns: 'Form Type', 'Form Title', 'Status', and 'Date'. The data in the table is:

Form Type	Form Title	Status	Date
ECP Treatment	ECP Treatment Visit 1 Form	NEW	12-19-2014

A red arrow points to the 'View' button in the 'Date' column.

Figure 62

- Clicking **View** directs you to the **ECP Treatment Visit** CRF page, *Figure 63*.
- Enter the **ECP Treatment Visit** date or use the calendar icon to select the date.

ECP REGISTRY

Home Check Enrollment/Arm Eligibility Registry Investigator Resources

Site Summary > Participant Summary > Event Summary > ECP Treatment Visit Form

Form Summary

Site Name - ID:	WashU - 101	Event Type:	ECP Treatment	Form Type:	ECP Treatment
Participant ID:	101001	Event Title:	ECP Treatment 1	Form Title:	ECP Treatment Visit Form
Study Arm:	ECP Treatment Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	12-12-2014	Event Date:		Form Date:	12-19-2014

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

ECP TREATMENT VISIT - Case Report Form (CRF)

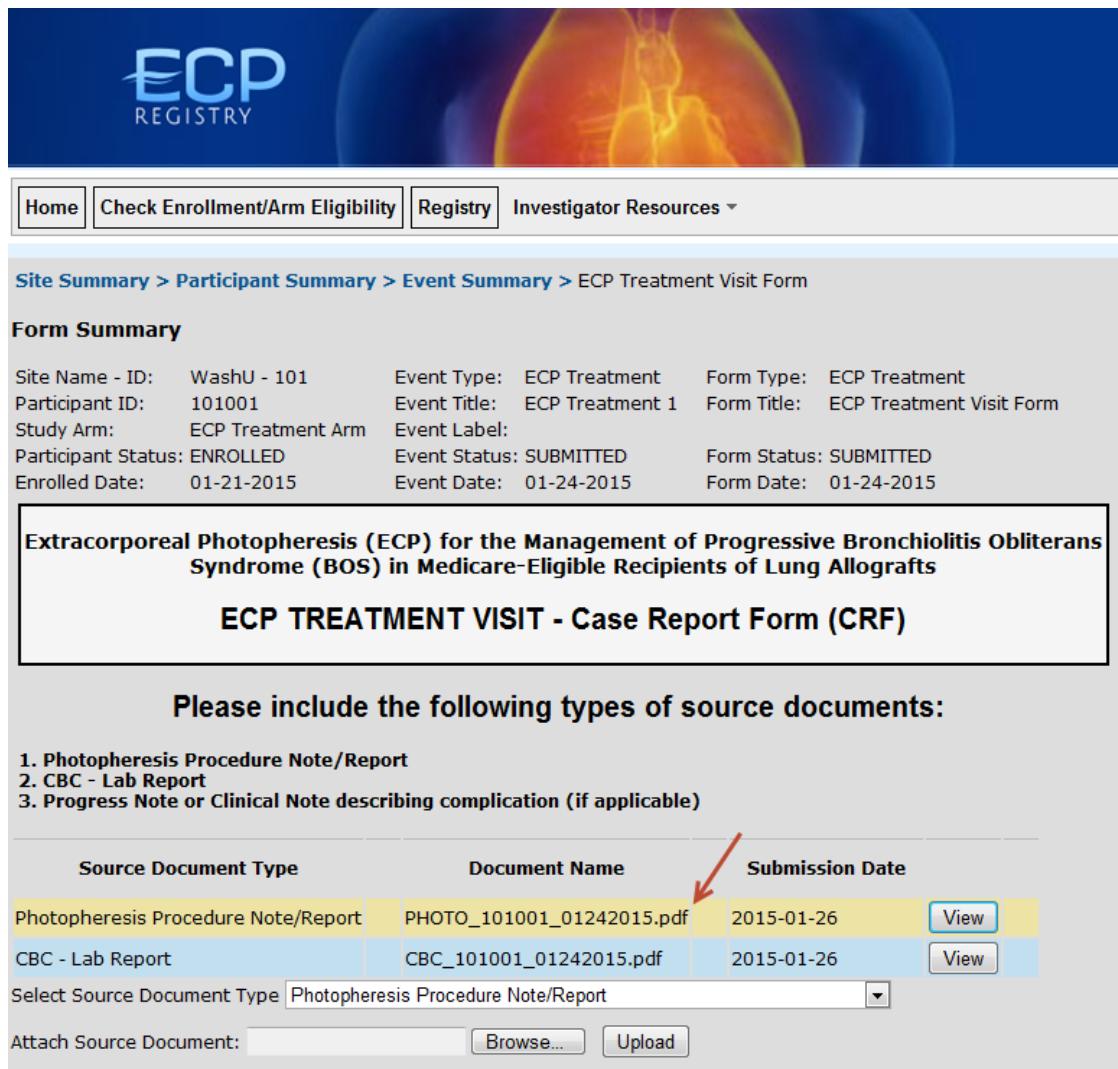
Please include the following types of source documents:

1. Photopheresis Procedure Note/Report
2. CBC - Lab Report
3. Progress Note or Clinical Note describing complication (if applicable)

Source Document Type	Document Name	Submission Date
Select Source Document Type	Photopheresis Procedure Note/Report	
Attach Source Document:	<input type="button" value="Browse..."/>	<input type="button" value="Upload"/>
<input type="button" value="Save"/>	<input type="button" value="Submit"/>	
ECP Treatment Visit Date: <input type="text"/> <input type="button" value=""/>		

Figure 63

- Complete the CRF. Use the tab key or mouse to navigate to all questions. Click **Save** every 5 to 10 minutes to save data.
- Scan and upload all required source documents, listed on the ECP Treatment CRF, *Figure 64*. For help uploading the required source documents as PDFs, see **10.0 Uploading Scanned Source Document PDF files**.



Site Summary > Participant Summary > Event Summary > ECP Treatment Visit Form

Form Summary

Site Name - ID:	WashU - 101	Event Type:	ECP Treatment	Form Type:	ECP Treatment
Participant ID:	101001	Event Title:	ECP Treatment 1	Form Title:	ECP Treatment Visit Form
Study Arm:	ECP Treatment Arm	Event Label:		Form Status:	SUBMITTED
Participant Status:	ENROLLED	Event Status:	SUBMITTED	Form Date:	01-24-2015
Enrolled Date:	01-21-2015	Event Date:	01-24-2015	Form Date:	01-24-2015

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

ECP TREATMENT VISIT - Case Report Form (CRF)

Please include the following types of source documents:

1. Photopheresis Procedure Note/Report
2. CBC - Lab Report
3. Progress Note or Clinical Note describing complication (if applicable)

Source Document Type	Document Name	Submission Date
Photopheresis Procedure Note/Report	PHOTO_101001_01242015.pdf	2015-01-26
CBC - Lab Report	CBC_101001_01242015.pdf	2015-01-26

Select Source Document Type: Photopheresis Procedure Note/Report

Attach Source Document:

Figure 64

- Note data item #6 on *Figure 65*. If two ECP Treatment are scheduled on consecutive days and a CBC was not obtained on the second day, check “**Not Applicable**” on the ECP Treatment CRF that is completed for the second day’s treatment. Otherwise, enter the date of the CBC and the required values.
- Note that different units are requested for different CBC values. As an example, circled in *Figure 65*, the platelets entry requires K/Cumm and lymphocytes requires %.
- Note Section A #7 please contact your hospital Lab department to determine the type of hemocytometer.
- To return to this document later to complete it, click **Save**. The Status of the CRF will be changed to Started and entries will be saved.

- Confirm that all data entered are accurate and that the required source documents have been uploaded.
- After submitting the CRF, you may not make changes, and the option to delete PDFs is no longer available.
- Select Submit when the data are correct and complete.

Save | Submit

ECP Treatment Visit Date:

SECTION A. Pre-Treatment Assessment

1. Weight: kilograms

2. Blood pressure: systolic mmHg diastolic mmHg

3. Heart rate: beats per minute

4. Respiratory rate: breaths per minute

5. Oxygen saturation: %

6. Complete blood count (CBC) with differential on the day of ECP: Not Applicable

Date of CBC:

WBCs: (K/cumm)

RBCs: (K/cumm)

Hemoglobin: (g/dl)

Hematocrit: (%)

Platelets: (K/cumm)

Neutrophils: (%)

Lymphocytes: (%)

Monocytes: (%)

Eosinophils: (%)

Basophils: (%)

7. Type of hemocytometer used to measure the CBC:

8. Is the patient currently receiving prednisone: YES NO

Current daily dose mg

SECTION B. Treatment Parameters

9. ECP type of machine used: UVAR CELLEX (Check only one that applies)

10. Enter the type of anticoagulant used for the procedure: Citrate Heparin Other

11. If the UVAR machine was used, have five cycles been processed? YES NO Not Applicable

If not, specify the number of cycles:

12. If the CELLEX machine was used, have 1500ml plasma been processed? YES NO Not Applicable

If not, specify the volume processed:

13. If the answer to Question 11 or 12 is NO, please describe the reason why:

14. Type of venous access: Central Venous Catheter Peripheral IV IVAD (Port)

15. Was the ECP treatment completed as planned? YES NO

If not, please indicate the reason why:

16. Were there any complications? YES NO

If yes, please describe and complete Adverse Event CRF if applicable:

17. Comments:

Save | Submit

Figure 65

- If the CRF is incomplete or contains values out of range, the submission will not be accepted. Instead, the document will display error messages in red to prompt you to correct or enter the values, *Figure 66*.

ECP Treatment Visit Date: 01/26/2015

SECTION A. Pre-Treatment Assessment

1. Weight: 77.0 kilograms

2. Blood pressure: systolic 120 mmHg diastolic 8 mmHg

Validation Error: Diastolic ranges between 30 and 150 mmHg.

3. Heart rate: 76 beats per minute

4. Respiratory rate: 25 breaths per minute

5. Oxygen saturation: %

Validation Error: Oxygen saturation ranges between 80 and 100%.

6. Complete blood count (CBC) with differential on the day of ECP: 01/26/2015

WBCs: 10.0 (K/cumm)

RBCs: 2.0 (K/cumm)

Hemoglobin: 12.0 (g/dl)

Hematocrit: 26.0 (%)

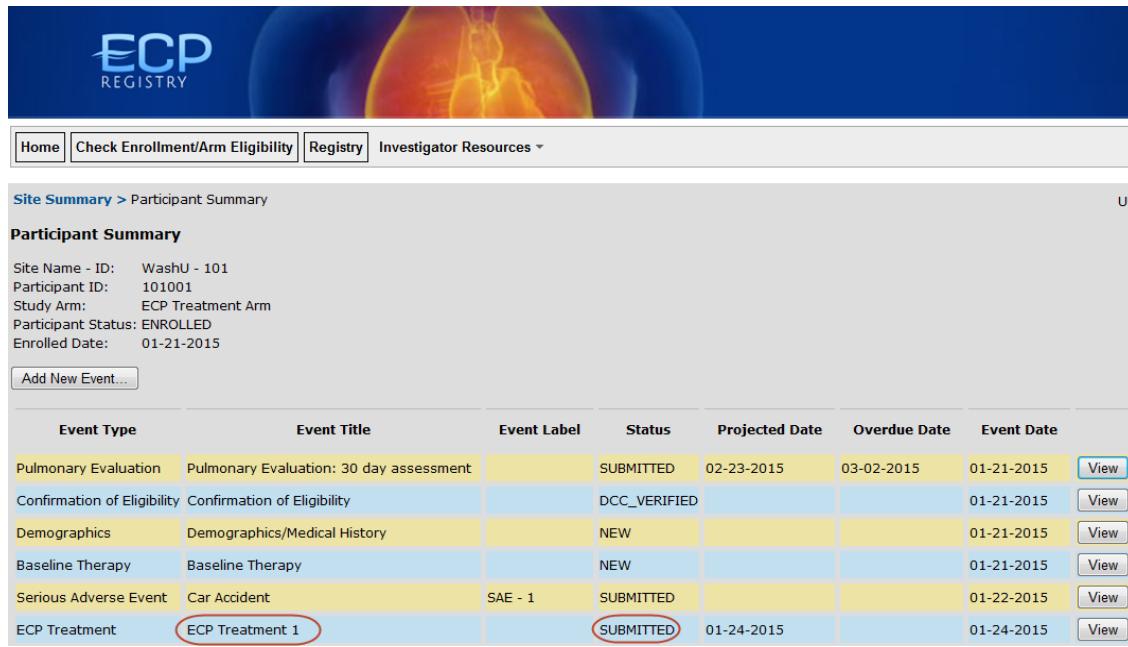
Platelets: 1 (K/cumm)

Validation Error: Platelets range between 25 and 1,000.

Red arrows point to the following fields: the diastolic blood pressure value (8), the oxygen saturation percentage (%), and the platelets value (1). The text "Data out of range" is written in orange next to the arrows.

Figure 66

- After submitting the **ECP Treatment Visit** CRF, you will be directed back to the **Participant Summary** page.
- The **Status** of the event in the **Participant Summary** page has changed to **SUBMITTED**, *Figure 67*.
- DCC staff will now validate the data on the ECP Treatment CRF.
- Monitor the Site Summary page regularly for participants with CRFs marked with a status of CRF Query. Fix any queries and re-submit those CRFs.



Site Summary > Participant Summary

Participant Summary

Site Name - ID: WashU - 101
Participant ID: 101001
Study Arm: ECP Treatment Arm
Participant Status: ENROLLED
Enrolled Date: 01-21-2015

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Pulmonary Evaluation	Pulmonary Evaluation: 30 day assessment		SUBMITTED	02-23-2015	03-02-2015	01-21-2015	View
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			01-21-2015	View
Demographics	Demographics/Medical History		NEW			01-21-2015	View
Baseline Therapy	Baseline Therapy		NEW			01-21-2015	View
Serious Adverse Event	Car Accident	SAE - 1	SUBMITTED			01-22-2015	View
ECP Treatment	ECP Treatment 1		SUBMITTED	01-24-2015		01-24-2015	View

Figure 67

12.5 Pulmonary Evaluation CRF

- To Complete a Pulmonary Evaluation CRF:
 - Click the **Registry** button, which will direct you to the **Site Summary** page.
 - On the **Site Summary** page locate the correct patient by the assigned Participant ID and click **View**.
 - The **Participant Summary** page is now displayed *Figure 68*.
 - The data in the columns for the **Projected Date** and the **Overdue Date** of the Pulmonary Evaluation CRFs are not populated until the first ECP Treatment CRF is submitted.
 - If the **Pulmonary Evaluation** event Status column reads **NEW**, no data have been entered on the CRF. Clicking **View** on the Pulmonary Evaluation CRF line directs the user to the **Event Summary** page. *Figure 69*.
 - If a Pulmonary Evaluation is not one of the regularly scheduled events shown on the Participant Summary listing, create a new Pulmonary Evaluation CRF by clicking the **Add New Event** button on the Participant Summary page, *Figure 68*.

Manual of Procedures

Site Summary > Participant Summary

User name: [redacted]

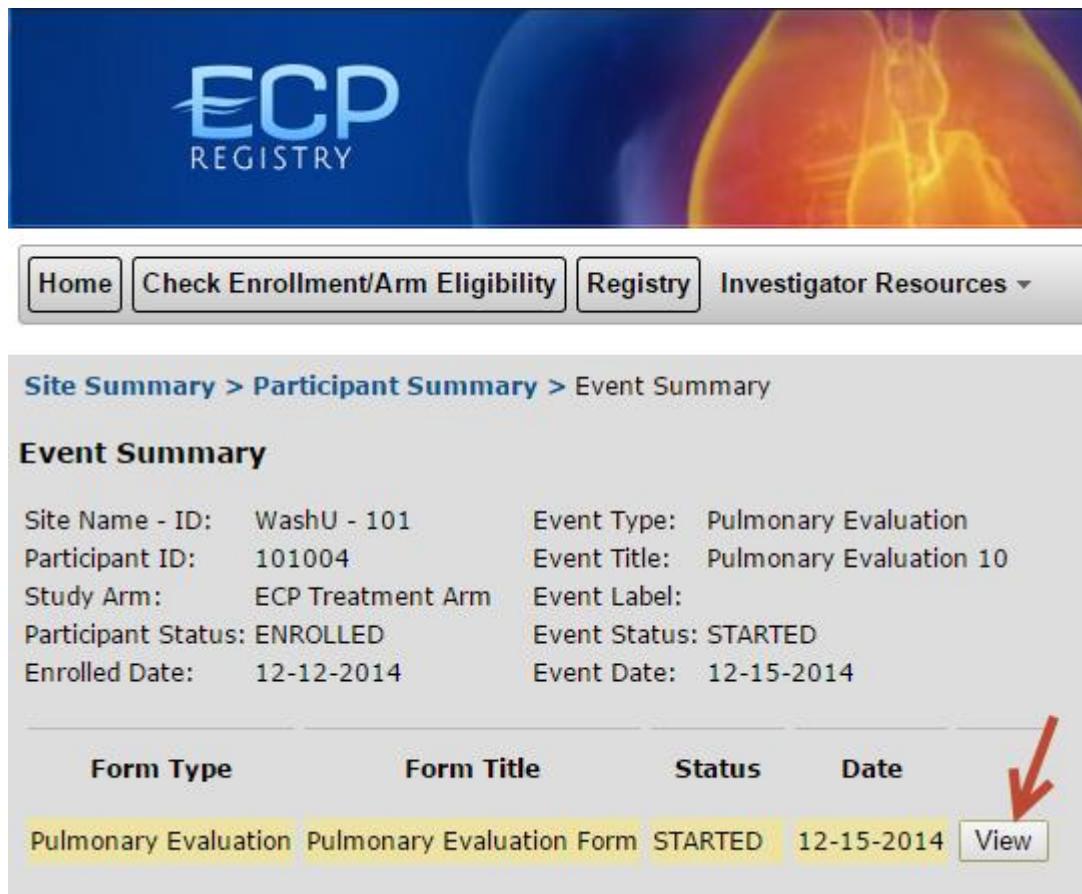
Participant Summary

Site Name - ID: Test Site - 100
Participant ID: 100003
Study Arm: ECP Treatment Arm
Participant Status: ENROLLED
Enrolled Date: 04-29-2015

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
ECP Treatment	ECP Treatment 1		DCC_VERIFIED	04-29-2015		04-29-2015
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			04-29-2015
Demographics	Demographics/Medical History		SUBMITTED			04-29-2015
Baseline Therapy	Baseline Therapy		SUBMITTED			04-29-2015
ECP Treatment	ECP Treatment 2		DCC_VERIFIED	05-02-2015		05-02-2015
ECP Treatment	ECP Treatment 3		DCC_VERIFIED	05-06-2015		05-06-2015
ECP Treatment	ECP Treatment 4		DCC_VERIFIED	05-09-2015		05-09-2015
ECP Treatment	ECP Treatment 5		SUBMITTED	05-13-2015		05-13-2015
ECP Treatment	ECP Treatment 6		SUBMITTED	05-16-2015		05-16-2015
ECP Treatment	ECP Treatment 7		SUBMITTED	05-20-2015		05-20-2015
ECP Treatment	ECP Treatment 8		SUBMITTED	05-23-2015		05-23-2015
ECP Treatment	ECP Treatment 9		SUBMITTED	05-26-2015		05-26-2015
ECP Treatment	ECP Treatment 10		NEW	05-29-2015		
Pulmonary Evaluation	Pulmonary Evaluation: 30 day assessment		NEW	05-29-2015	06-05-2015	
ECP Treatment	ECP Treatment 11		NEW	06-10-2015		

Figure 68



ECP REGISTRY

[Home](#) [Check Enrollment/Arm Eligibility](#) [Registry](#) [Investigator Resources](#) ▾

Site Summary > Participant Summary > Event Summary

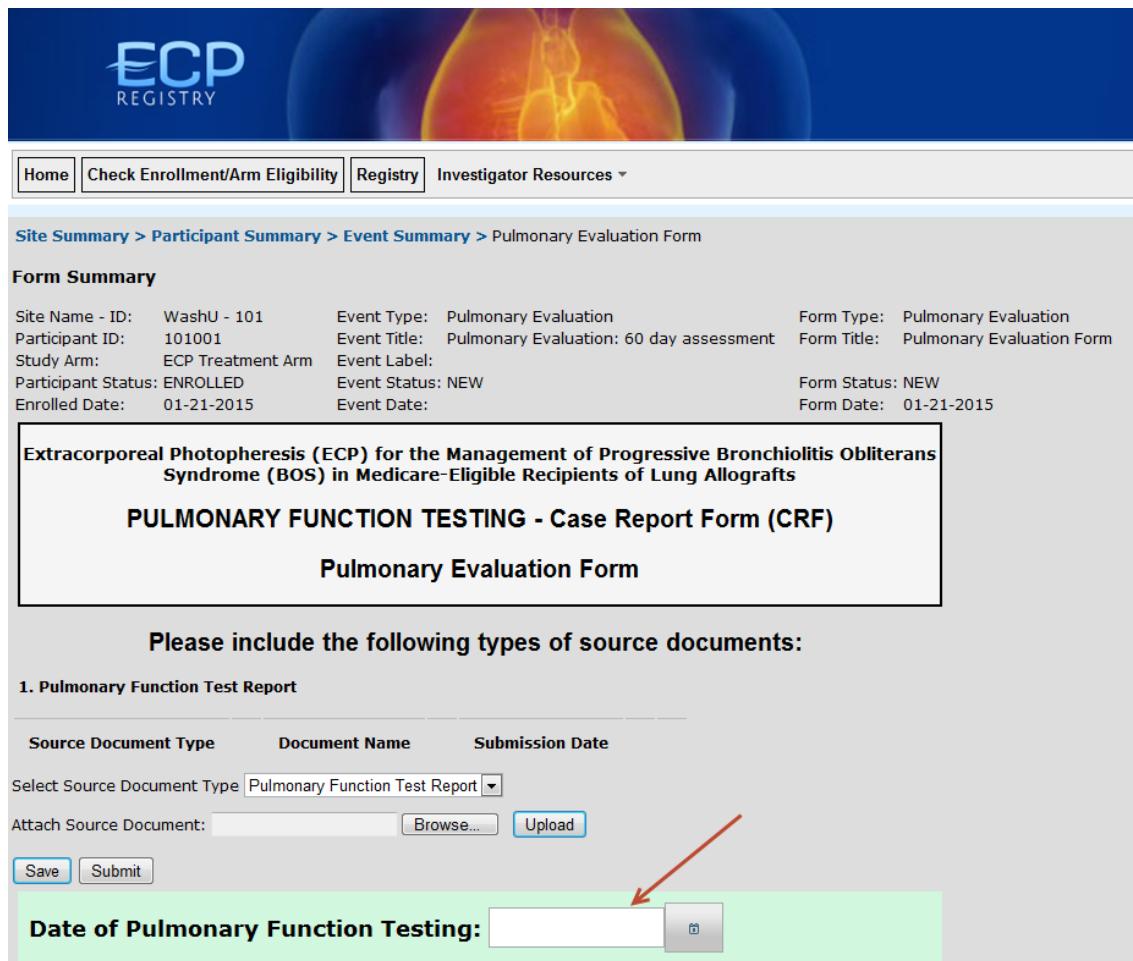
Event Summary

Site Name - ID:	WashU - 101	Event Type:	Pulmonary Evaluation
Participant ID:	101004	Event Title:	Pulmonary Evaluation 10
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	STARTED
Enrolled Date:	12-12-2014	Event Date:	12-15-2014

Form Type	Form Title	Status	Date	
Pulmonary Evaluation	Pulmonary Evaluation Form	STARTED	12-15-2014	View

Figure 69

- Clicking View directs you to the **Pulmonary Evaluation** CRF page.
- Enter the Pulmonary Evaluation date or use the calendar icon and select the date. *Figure 70.*



Site Summary > Participant Summary > Event Summary > Pulmonary Evaluation Form

Form Summary

Site Name - ID: WashU - 101	Event Type: Pulmonary Evaluation	Form Type: Pulmonary Evaluation
Participant ID: 101001	Event Title: Pulmonary Evaluation: 60 day assessment	Form Title: Pulmonary Evaluation Form
Study Arm: ECP Treatment Arm	Event Label:	
Participant Status: ENROLLED	Event Status: NEW	Form Status: NEW
Enrolled Date: 01-21-2015	Event Date:	Form Date: 01-21-2015

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

PULMONARY FUNCTION TESTING - Case Report Form (CRF)

Pulmonary Evaluation Form

Please include the following types of source documents:

1. Pulmonary Function Test Report

Source Document Type	Document Name	Submission Date
Select Source Document Type: Pulmonary Function Test Report		
Attach Source Document:	<input type="button" value="Browse..."/>	<input type="button" value="Upload"/>
<input type="button" value="Save"/>	<input type="button" value="Submit"/>	

Date of Pulmonary Function Testing:

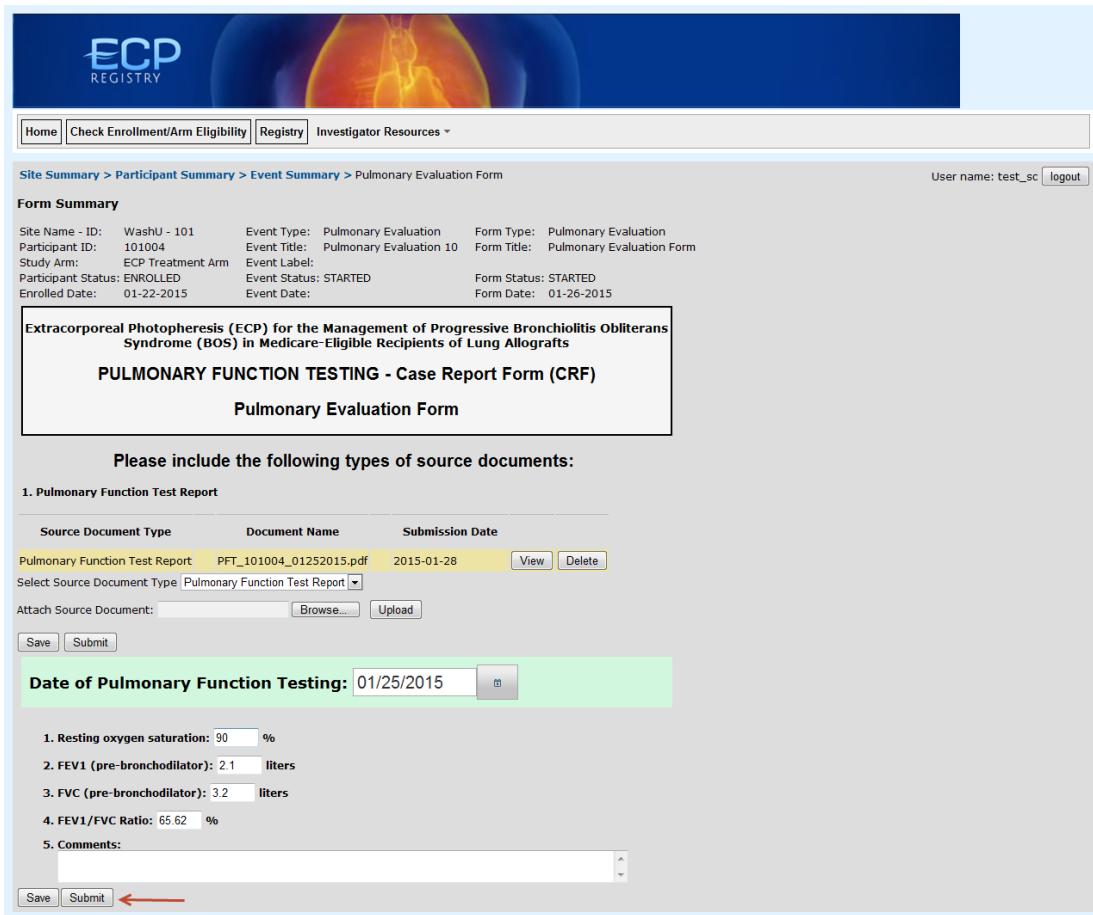
Figure 70

- Complete the CRF, *Figure 71*. Use the tab key or mouse to navigate to all questions. Click Save every 5 to 10 minutes to save data.
- Scan and upload the required source document. For help uploading the required source document as PDFs, see **section 10.0 Uploading Scanned Source Document PDF files**.
- If you wish to return to this document to complete it later, click **Save**. The **Status** of the CRF will be changed to **Started**.
- Note all FEV1 and FVC collected are the pre-bronchodilator values

Confirm that all data entered are accurate and that the required source document PDF has been uploaded. **After submitting the CRF, you may not make changes and the option to delete PDFs is no longer available.**

- Select **Submit** at the bottom of the CRF when the data are correct and complete. *Figure 71*.

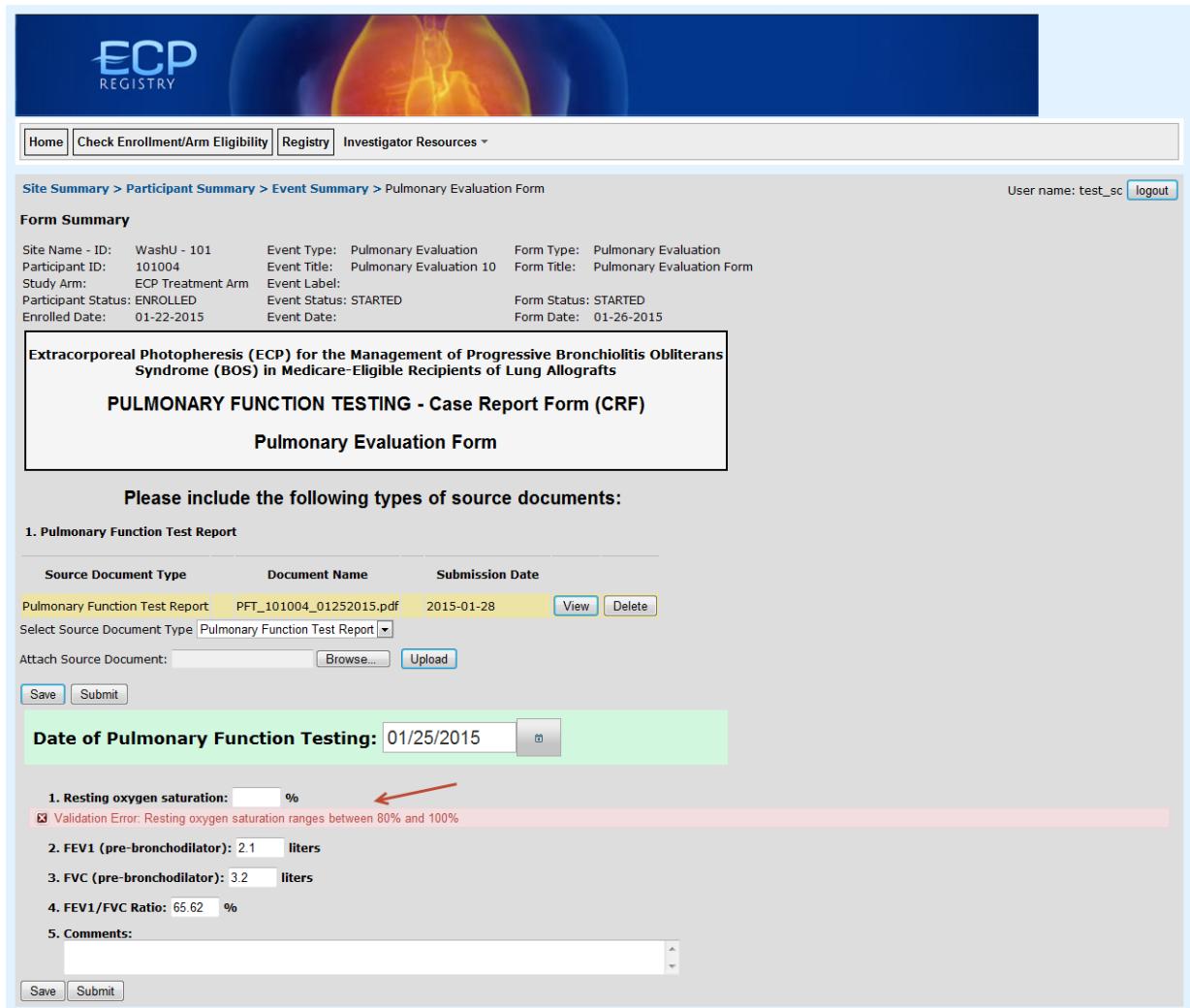
Manual of Procedures



The screenshot shows the ECP Registry software interface. At the top, there is a navigation bar with links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. Below the navigation bar, the URL is Site Summary > Participant Summary > Event Summary > Pulmonary Evaluation Form. The user name is test_sc and there is a logout link. The main content area is titled "Form Summary" and displays participant details: Site Name - ID: WashU - 101, Participant ID: 101004, Study Arm: ECP Treatment Arm, Participant Status: ENROLLED, Enrolled Date: 01-22-2015, Event Type: Pulmonary Evaluation, Event Title: Pulmonary Evaluation 10, Event Label: ECP Treatment Arm, Event Status: STARTED, Event Date: 01-26-2015, Form Type: Pulmonary Evaluation, Form Title: Pulmonary Evaluation Form, Form Status: STARTED, and Form Date: 01-26-2015. Below this, a box contains the title "Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts" and the section "PULMONARY FUNCTION TESTING - Case Report Form (CRF)". A sub-section titled "Pulmonary Evaluation Form" is shown. A note says "Please include the following types of source documents:" followed by a list: "1. Pulmonary Function Test Report". A table lists a single document: Source Document Type (Pulmonary Function Test Report), Document Name (PFT_101004_01252015.pdf), and Submission Date (2015-01-28). Buttons for View and Delete are present. Below this, a "Select Source Document Type" dropdown is set to "Pulmonary Function Test Report". A "Browse..." and "Upload" button are available for attaching a source document. "Save" and "Submit" buttons are at the bottom. A "Date of Pulmonary Function Testing" field is set to 01/25/2015. A list of pulmonary function test results is shown: 1. Resting oxygen saturation: 90 %, 2. FEV1 (pre-bronchodilator): 2.1 liters, 3. FVC (pre-bronchodilator): 3.2 liters, 4. FEV1/FVC Ratio: 65.62 %. A "Comments" text area is present. "Save" and "Submit" buttons are at the bottom, with a red arrow pointing to the "Submit" button.

Figure 71

- If the CRF is incomplete or contains values out of range, the submission will not be accepted. Instead, the document will display error messages in red to prompt you to correct or enter the values. *Figure 72*.



The screenshot shows the ECP Registry software interface. At the top, there is a banner with the ECP Registry logo and a stylized image of a human torso with internal organs. Below the banner, a navigation bar includes links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. The main content area shows a breadcrumb navigation path: Site Summary > Participant Summary > Event Summary > Pulmonary Evaluation Form. On the right, a user is logged in as 'test_sc' with a 'logout' link. The 'Form Summary' section displays participant details: Site Name - ID: WashU - 101, Participant ID: 101004, Study Arm: ECP Treatment Arm, Participant Status: ENROLLED, Enrolled Date: 01-22-2015. Event details include Event Type: Pulmonary Evaluation, Event Title: Pulmonary Evaluation 10, Event Label: Pulmonary Evaluation, Event Status: STARTED, Form Status: STARTED, and Form Date: 01-26-2015. A title box for the 'PULMONARY FUNCTION TESTING - Case Report Form (CRF)' is present, along with a sub-section for the 'Pulmonary Evaluation Form'. A note at the top of the form area says: 'Please include the following types of source documents:'. Below this, a table lists a 'Pulmonary Function Test Report' with document name 'PFT_101004_01252015.pdf' and submission date '2015-01-28'. Buttons for 'View' and 'Delete' are shown. A 'Select Source Document Type' dropdown is set to 'Pulmonary Function Test Report'. An 'Attach Source Document' section with 'Browse...' and 'Upload' buttons is shown. At the bottom of the form area, there are 'Save' and 'Submit' buttons. A green box highlights the 'Date of Pulmonary Function Testing: 01/25/2015' field. Below the date, a validation error message is displayed: 'Validation Error: Resting oxygen saturation ranges between 80% and 100%' with a red arrow pointing to the error message. The form also includes fields for FEV1, FVC, and FEV1/FVC Ratio, as well as a 'Comments' text area and a 'Comments' dropdown. The bottom of the form area has 'Save' and 'Submit' buttons.

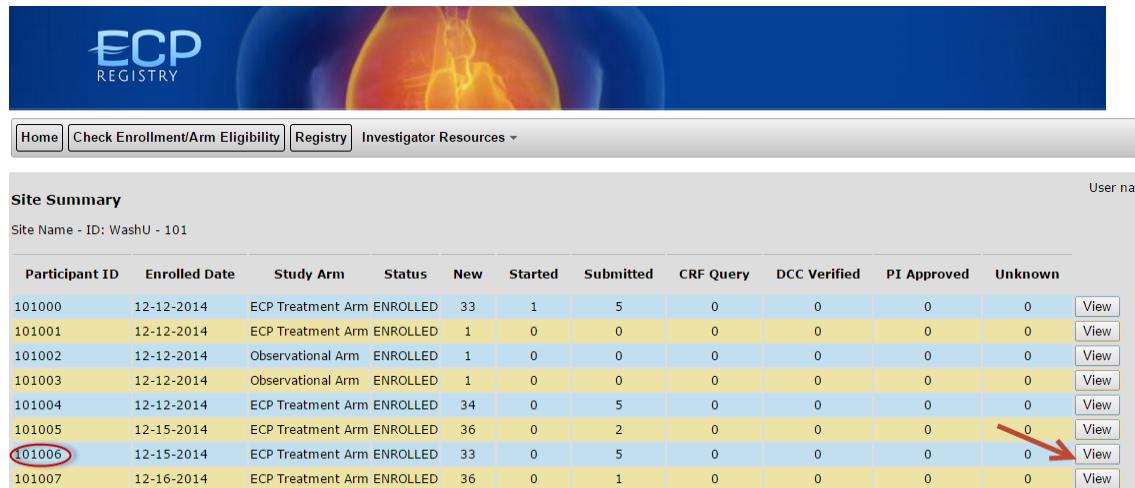
Figure 72

- After submitting the **Pulmonary Evaluation** CRF, you will be directed back to the **Participant Summary** page.
- The **Status** of the event in the **Participant Summary** page changed to **SUBMITTED**.
- DCC staff will validate the data on the Pulmonary Evaluation CRF.
- Monitor the Site Summary page regularly for participants with CRFs marked with a status of CRF Query. Fix any queries and re-submit those CRFs.

12.6 Change in Therapy Case Report Form

- Usage: Complete the Change in Therapy CRF when a participant has a change in therapy in either the treatment arm or the observation arm.

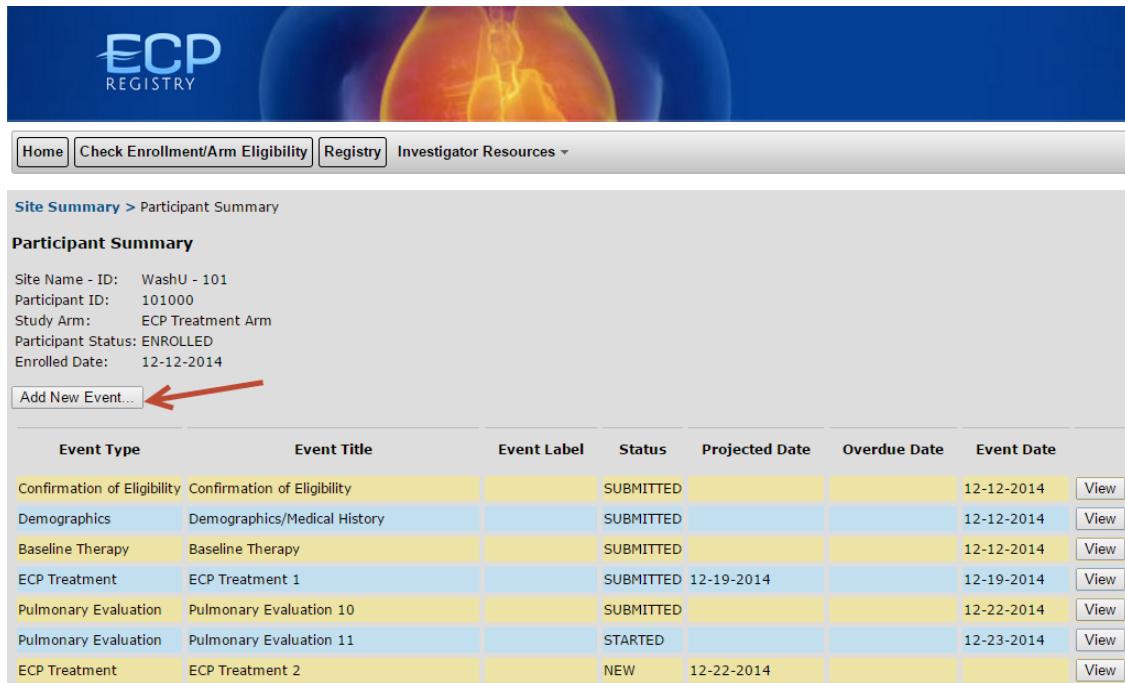
- No source documents are loaded for the Change in Therapy CRF.
- To Complete the CRF:
 - Click the **Registry** button, which will direct you to the **Site Summary** page.
 - On the **Site Summary** page locate the correct patient by the assigned **Participant ID** and click **View**. *Figure 73.*



Participant ID	Enrolled Date	Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Unknown	
101000	12-12-2014	ECP Treatment Arm	ENROLLED	33	1	5	0	0	0	0	View
101001	12-12-2014	ECP Treatment Arm	ENROLLED	1	0	0	0	0	0	0	View
101002	12-12-2014	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View
101003	12-12-2014	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View
101004	12-12-2014	ECP Treatment Arm	ENROLLED	34	0	5	0	0	0	0	View
101005	12-15-2014	ECP Treatment Arm	ENROLLED	36	0	2	0	0	0	0	View
101006	12-15-2014	ECP Treatment Arm	ENROLLED	33	0	5	0	0	0	0	View
101007	12-16-2014	ECP Treatment Arm	ENROLLED	36	0	1	0	0	0	0	View

Figure 73

- The **Participant Summary** page is now displayed, *Figure 74*.
- The **Change in Therapy** event is not automatically populated within the **Participant Summary** page because this type of event cannot be predicted.
- To create a **Change in Therapy** CRF event, click the **Add New Event** button on the **Participant Summary** page. *Figure 74.*



Site Summary > Participant Summary

Participant Summary

Site Name - ID: WashU - 101
Participant ID: 101000
Study Arm: ECP Treatment Arm
Participant Status: ENROLLED
Enrolled Date: 12-12-2014

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		SUBMITTED		12-12-2014	View
Demographics	Demographics/Medical History		SUBMITTED		12-12-2014	View
Baseline Therapy	Baseline Therapy		SUBMITTED		12-12-2014	View
ECP Treatment	ECP Treatment 1		SUBMITTED	12-19-2014	12-19-2014	View
Pulmonary Evaluation	Pulmonary Evaluation 10		SUBMITTED		12-22-2014	View
Pulmonary Evaluation	Pulmonary Evaluation 11		STARTED		12-23-2014	View
ECP Treatment	ECP Treatment 2		NEW	12-22-2014		View

Figure 74

- An **Add New Event** selection box appears which lists **Change in Therapy** among the selections, *Figure 75*.
- Click **Change in Therapy** and click **Submit**. *Figure 75*.

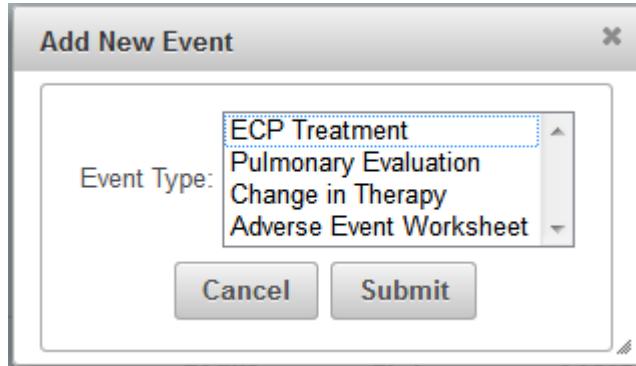


Figure 75

- An Event Summary page for the new Change in Therapy CRF is now displayed.
- Note that the event title, in this case, is **Change in Therapy 1**. The number after a Change in Therapy CRF indicates the ordinal value of this CRF, it being the first Change in Therapy CRF created.
- Select **View**, *Figure 76*, to display the CRF, *Figure 77*.



The screenshot shows the ECP Registry website. At the top, there is a logo for 'ECP REGISTRY' with a background image of a heart. Below the logo is a navigation bar with links for 'Home', 'Check Enrollment/Arm Eligibility', 'Registry', and 'Investigator Resources'. The main content area is titled 'Site Summary > Participant Summary > Event Summary'. Under this, there is a section for 'Event Summary' with the following details:

Site Name - ID:	WashU - 101	Event Type:	Change in Therapy
Participant ID:	101005	Event Title:	Change in Therapy 1
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	12-15-2014	Event Date:	12-16-2014

Below this is a table with columns 'Form Type', 'Form Title', 'Status', and 'Date'. The data is as follows:

Form Type	Form Title	Status	Date
Change in Therapy	Change in Therapy Form	NEW	12-17-2014

A red arrow points to the 'View' button in the 'Date' column.

Figure 76

- Data fields #1-3 are pre-populated with the most recent data from either the **Baseline Therapy** CRF or the most recent **Change in Therapy** CRF. Make any changes to data fields 1-3.
- Data field 4 must be completed at the time the form is completed. For the question, "Has ECP therapy been discontinued?" there are three possible responses, "Yes", "No" and "Not Applicable". Not applicable is always entered if the participant is in the observation arm. *Figure 77*.
- If you wish to return to this document to complete it later, click **Save**. The **Status** of the CRF will be changed to **Started**.
- When complete, check the form for accuracy and click **Submit**.
- No DCC verification is done on the Change in Therapy CRF. Keep all source in patient research binder.

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Site Summary > Participant Summary > Event Summary > Change in Therapy Form

User name: test_sc | logout

Form Summary

Site Name - ID: WashU - 101	Event Type: Change in Therapy	Form Type: Change in Therapy
Participant ID: 101004	Event Title: Change in Therapy 1	Form Title: Change in Therapy Form
Study Arm: ECP Treatment Arm	Event Label:	
Participant Status: ENROLLED	Event Status: NEW	Form Status: NEW
Enrolled Date: 01-22-2015	Event Date:	Form Date: 01-26-2015

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

CHANGE IN THERAPY DURING THE STUDY - Case Report Form (CRF)

Change in Therapy 1

The information listed in this Change in Therapy form has been pre-populated from information contained in either the Baseline Therapy form or the previous Change in Therapy form. Please review all items and update for medications that have changed. Then submit the form.

Change in Therapy Date: 01/26/2015

1. Check all immunosuppressive drugs that are currently being used by the participant:

YES NO Tacrolimus

YES NO Prednisone If yes, enter daily dose: 7 mg (input range: 0-150)

YES NO Sirolimus (Rapamycin)

YES NO Everolimus

YES NO Azathioprine

YES NO Cyclosporine A

YES NO Methotrexate

YES NO Macrolide Antibiotic, Azithromycin

YES NO Mycophenolate Mofetil (Cellcept or Myfortic)

YES NO Total Lymphoid Irradiation

2. Is the participant taking an anticoagulant drug? YES NO

If yes, list drugs:

Name anticoagulant 1: coumadin

Name anticoagulant 2:

Name anticoagulant 3:

3. Is the participant taking an anti-platelet drug? YES NO

If yes, list drugs:

Name anti-platelet 1: Aspirin

Name anti-platelet 2:

Name anti-platelet 3:

4. Has ECP therapy been discontinued? YES NO Not Applicable

a. If yes, date of discontinuation

b. If yes, reason for discontinuation:

5. Comments:



Figure 77

- After submitting the **Change in Therapy** CRF, you will be directed back to the **Participant Summary** page.
- The **Status** of the event in the **Participant Summary** page has changed to **SUBMITTED**. *Figure 78*. Because there will be no verification by the DCC, the status remains **SUBMITTED**.

The screenshot shows the ECP Registry interface. At the top, there is a navigation bar with links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. Below the navigation bar, the page title is "Site Summary > Participant Summary". On the right side, there is a "User name" field. The main content area is titled "Participant Summary" and displays participant details: Site Name - ID: WashU - 101, Participant ID: 101004, Study Arm: ECP Treatment Arm, Participant Status: ENROLLED, and Enrolled Date: 12-12-2014. Below this, there is a button labeled "Add New Event...". The main table lists study events with the following data:

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		SUBMITTED			12-12-2014
Demographics	Demographics/Medical History		NEW			12-12-2014
Baseline Therapy	Baseline Therapy		SUBMITTED			12-12-2014
Pulmonary Evaluation	Pulmonary Evaluation 10		SUBMITTED			12-15-2014
Change in Therapy	Change in Therapy 1		SUBMITTED			12-15-2014
ECP Treatment	ECP Treatment 1		NEW			

Figure 78

12.7 End of Study CRF

- To Complete the CRF:
 - Click the **Registry** button, which will direct you to the **Site Summary** page.
 - On the **Site Summary** page locate the correct patient by assigned **Participant ID** and click **View**.
 - The **Participant Summary** page is now displayed.
 - For the ECP treatment arm, locate the **End of Study** CRF, found last or near last in the listing of CRFs on the Participant Summary page, *Figure 8*. Click view to display the Event Summary page, *Figure 79*.

- For the Observation arm, the **End of Study** CRF is created by clicking the **Add New Event** button, *Figure 96*. Click End of Study in the drop down box. The Event Summary page then displays.
- On the Event Summary page, click **View**, *Figure 79*, to display the **End of Study** CRF, *Figure 80*.

The screenshot shows the ECP Registry website interface. At the top, there is a navigation bar with links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. Below the navigation bar, the page title is "Site Summary > Participant Summary > Event Summary". The main content area is titled "Event Summary" and displays the following participant information:

Site Name - ID:	WashU - 101	Event Type:	End of Study
Participant ID:	101000	Event Title:	End Of Study
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	12-12-2014	Event Date:	

Below this, there is a table with columns: Form Type, Form Title, Status, and Date. The data in the table is:

Form Type	Form Title	Status	Date
End of Study	End of Study Form	NEW	12-12-2014

A red arrow points to the "View" button in the "Status" column of the table.

Figure 79

- Complete the CRF.
- Scan and upload all required source documents. For help uploading the required source documents as PDFs, see **section 10.0 Uploading Scanned Source Document PDF files**.
- Use the tab key or mouse to navigate to all questions. Click **Save** to save data, if you do not plan on submitting immediately.
- To return to this document to complete it later, click **Save**. The **Status** of the CRF will be changed to **Started**.
- When complete, confirm that all data entered are accurate and that the required source document PDFs have been uploaded. **After submitting the CRF, you may not make changes, and the option to delete PDFs is no longer available.**

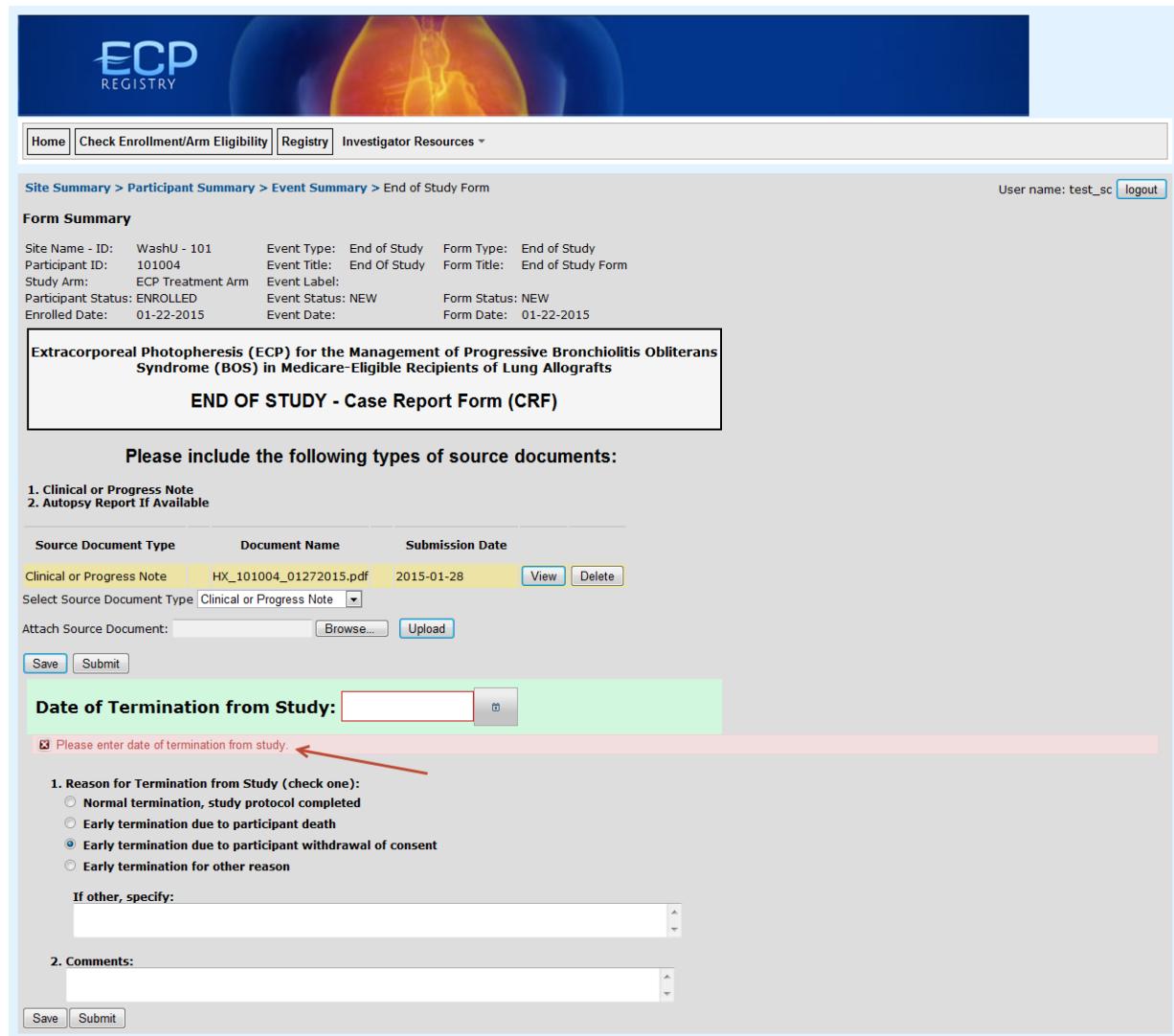
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- Select **Submit** at the bottom of the CRF when the data are correct and complete, *Figure 80*.

Figure 80

- If the CRF is incomplete or contains values out of range, the submission will not be accepted. Instead, the document will display error messages in red that prompt you to correct or enter the values, *Figure 81*.

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The screenshot shows the ECP Registry software interface. At the top, there is a logo for 'ECP REGISTRY' with a background image of a human torso. Below the logo is a navigation bar with links: 'Home', 'Check Enrollment/Arm Eligibility', 'Registry', and 'Investigator Resources'. The main content area shows a 'Form Summary' for a participant. The summary includes the following details:

Site Name - ID:	WashU - 101	Event Type:	End of Study	Form Type:	End of Study
Participant ID:	101004	Event Title:	End Of Study	Form Title:	End of Study Form
Study Arm:	ECP Treatment Arm	Event Label:		Form Status:	NEW
Participant Status:	ENROLLED	Event Status:	NEW	Form Date:	01-22-2015
Enrolled Date:	01-22-2015	Event Date:			

Below the summary, there is a section titled 'Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts' and a sub-section titled 'END OF STUDY - Case Report Form (CRF)'.

Please include the following types of source documents:

1. Clinical or Progress Note
2. Autopsy Report If Available

Source Document Type: Clinical or Progress Note, Document Name: HX_101004_01272015.pdf, Submission Date: 2015-01-28, with 'View' and 'Delete' buttons.

Select Source Document Type: Clinical or Progress Note, Attach Source Document: Browse... and Upload buttons, Save and Submit buttons.

Date of Termination from Study: [redacted] [button]

Please enter date of termination from study. [red arrow pointing to this field]

1. Reason for Termination from Study (check one):

- Normal termination, study protocol completed
- Early termination due to participant death
- Early termination due to participant withdrawal of consent
- Early termination for other reason

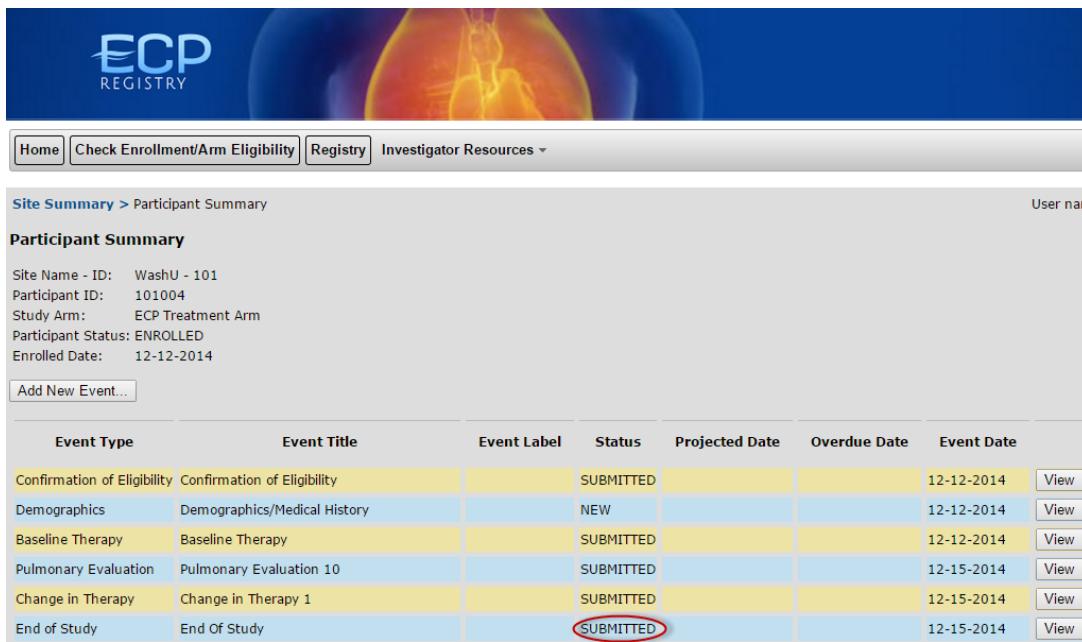
If other, specify: [text area]

2. Comments: [text area]

Save and Submit buttons.

Figure 81

- After successfully submitting the **End of Study** CRF, the **Participant Summary** page displays.
- The **Status** of the event on the **Participant Summary** page changed to **SUBMITTED**. *Figure 82.*



Site Summary > Participant Summary

User name

Participant Summary

Site Name - ID: WashU - 101
Participant ID: 101004
Study Arm: ECP Treatment Arm
Participant Status: ENROLLED
Enrolled Date: 12-12-2014

Add New Event...

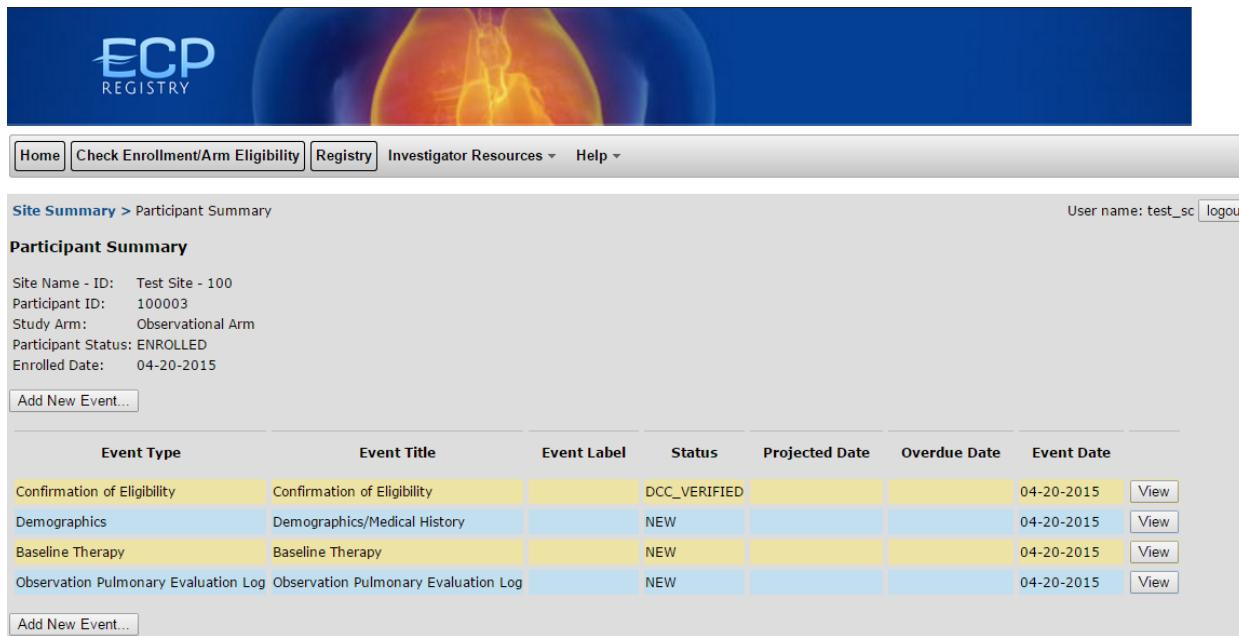
Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		SUBMITTED			12-12-2014
Demographics	Demographics/Medical History		NEW			12-12-2014
Baseline Therapy	Baseline Therapy		SUBMITTED			12-12-2014
Pulmonary Evaluation	Pulmonary Evaluation 10		SUBMITTED			12-15-2014
Change in Therapy	Change in Therapy 1		SUBMITTED			12-15-2014
End of Study	End Of Study		SUBMITTED			12-15-2014

Figure 82

13.0 Observation Arm – CRFs and Pulmonary Evaluation Log

13.1 Confirmation of Eligibility (COE) CRF

- As soon as a participant has been assigned to the **Observation Arm**, complete the **Confirmation of Eligibility CRF**. For instructions, see [section 12.1 Confirmation of Eligibility CRF](#).
- After the status of the **Confirmation of Eligibility CRF** becomes DCC Verified, the following forms are generated and added to the Participant Summary page, *Figure 83*:
 - Demographics/Medical History
 - Baseline Therapy
 - Observation Pulmonary Evaluation Log – See [section 13.4](#) for further information



The screenshot shows the ECP Registry software interface. At the top, there is a logo for 'ECP REGISTRY' and a background image of a human heart. Below the header, there is a navigation bar with links for 'Home', 'Check Enrollment/Arm Eligibility', 'Registry', 'Investigator Resources', and 'Help'. The main content area is titled 'Participant Summary' and shows participant details: Site Name - ID: Test Site - 100, Participant ID: 100003, Study Arm: Observational Arm, Participant Status: ENROLLED, and Enrolled Date: 04-20-2015. Below this, there is a button 'Add New Event...'. A table follows, listing events with columns for Event Type, Event Title, Event Label, Status, Projected Date, Overdue Date, and Event Date. The events listed are Confirmation of Eligibility, Demographics, Baseline Therapy, and Observation Pulmonary Evaluation Log. Each event has a 'View' button next to its Overdue Date. At the bottom of the table is another 'Add New Event...' button.

Figure 83

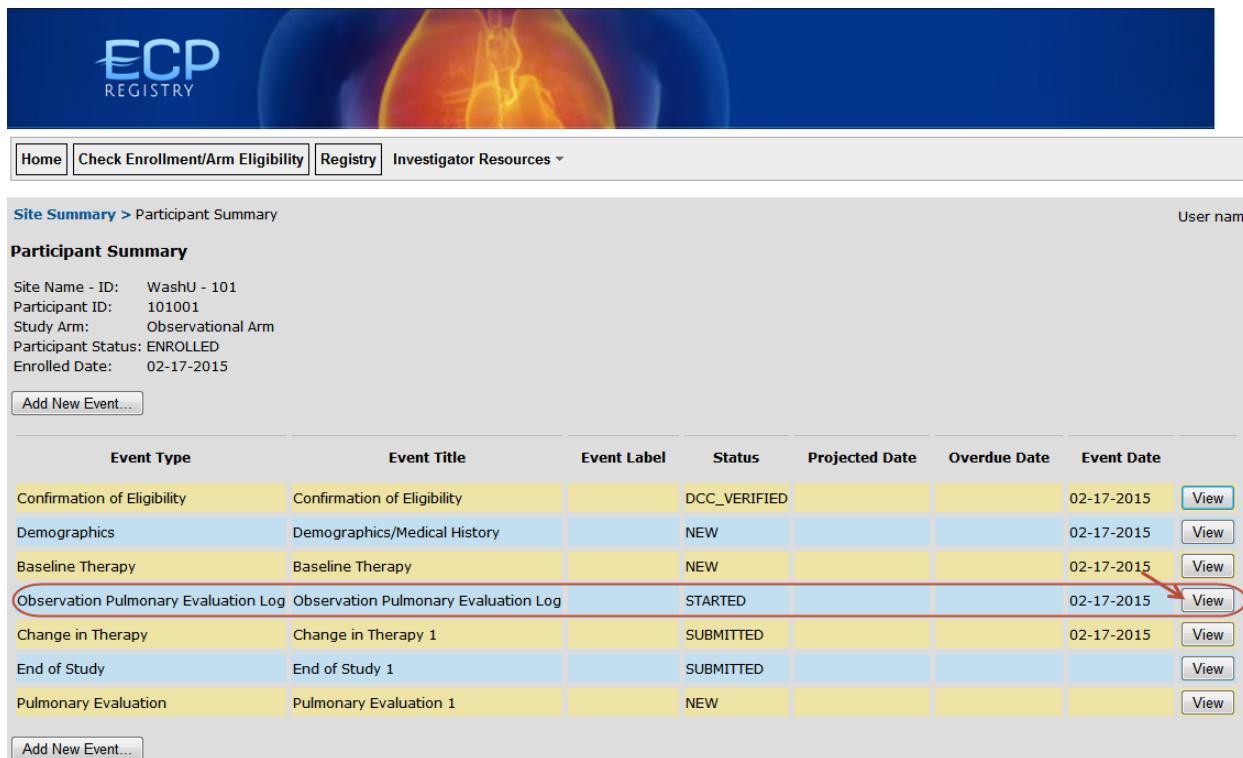
13.2 Demographics/Medical History – Complete the form. See [section 12.2](#) for further information.

13.3 Baseline Therapy – Complete the form. See [section 12.3](#) for further information.

13.4 Observation Pulmonary Evaluation Log

- The **Check ECP Treatment Eligibility** button in the Log evaluates whether the participant may cross over to the ECP Treatment Arm.
- To open the Log:
 - Click the **Registry** button, which will direct you to the **Site Summary** page.
 - On the **Site Summary** page locate the correct patient by assigned Participant ID. Click **View**.
 - The **Participant Summary** page is now displayed.
 - Locate the **Observation Pulmonary Evaluation Log** Event, *Figure 84*. Click view to display the **Event Summary** page, *Figure 85*.
 - Clicking **View** directs you to the **Observation Pulmonary Evaluation Log**, *Figure 86*.

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Site Summary > Participant Summary

Participant Summary

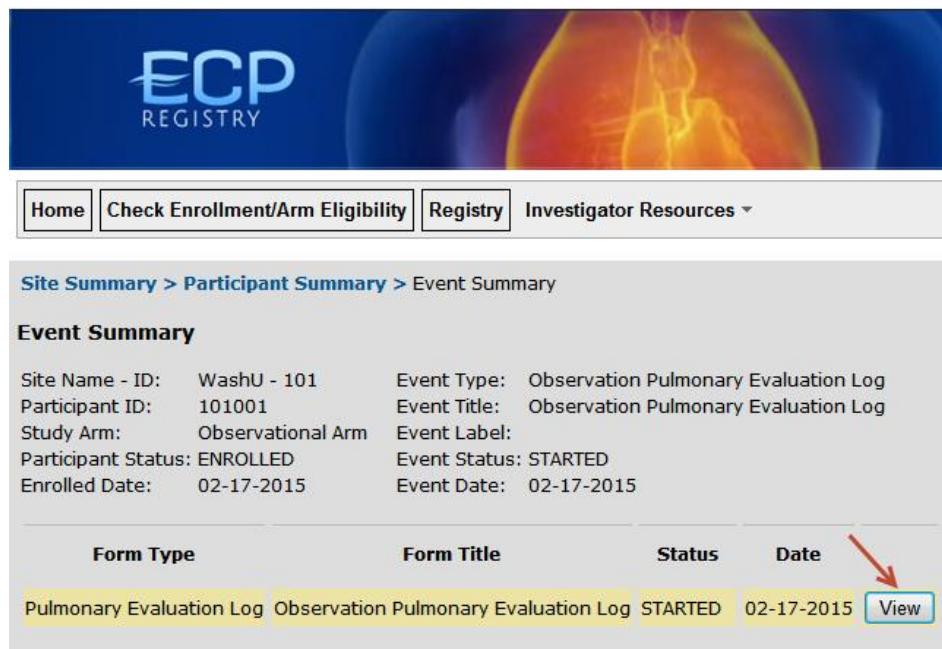
Site Name - ID: WashU - 101
Participant ID: 101001
Study Arm: Observational Arm
Participant Status: ENROLLED
Enrolled Date: 02-17-2015

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility	DCC_VERIFIED			02-17-2015	View
Demographics	Demographics/Medical History		NEW		02-17-2015	View
Baseline Therapy	Baseline Therapy		NEW		02-17-2015	View
Observation Pulmonary Evaluation Log	Observation Pulmonary Evaluation Log		STARTED		02-17-2015	View
Change in Therapy	Change in Therapy 1		SUBMITTED		02-17-2015	View
End of Study	End of Study 1		SUBMITTED			View
Pulmonary Evaluation	Pulmonary Evaluation 1		NEW			View

Add New Event...

Figure 84



Site Summary > Participant Summary > Event Summary

Event Summary

Site Name - ID: WashU - 101 Event Type: Observation Pulmonary Evaluation Log
Participant ID: 101001 Event Title: Observation Pulmonary Evaluation Log
Study Arm: Observational Arm Event Label:
Participant Status: ENROLLED Event Status: STARTED
Enrolled Date: 02-17-2015 Event Date: 02-17-2015

Form Type	Form Title	Status	Date
Pulmonary Evaluation Log	Observation Pulmonary Evaluation Log	STARTED	02-17-2015

Figure 85

Site Name - ID: WashU - 101 Event Type: Observation Pulmonary Evaluation Log Form Type: Pulmonary Evaluation Log
 Participant ID: 101001 Event Title: Observation Pulmonary Evaluation Log Form Title: Observation Pulmonary Evaluation Log
 Study Arm: Observational Arm Event Label:
 Participant Status: ENROLLED Event Status: NEW Form Status: NEW
 Enrolled Date: 01-13-2015 Event Date: 01-13-2015 Form Date: 01-13-2015

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

OBSERVATION PULMONARY EVALUATION LOG

Observation Pulmonary Evaluation Log

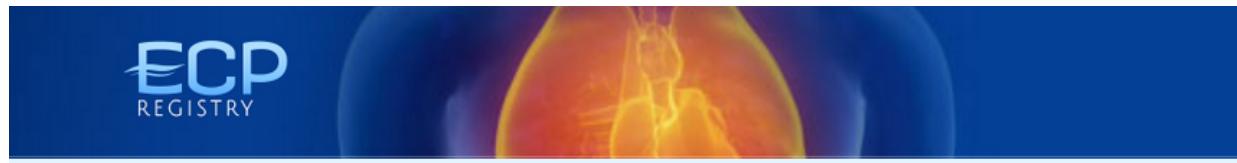
Save Check ECP Treatment Eligibility

Pulmonary Function Test Date	FEV1 liters (pre-bronchodilator)	FVC liters (pre-bronchodilator)
11/14/2014	4.0	0.0
11/22/2014	4.0	0.0
12/07/2014	4.0	0.0
12/17/2014	4.0	0.0
01/09/2015	4.0	0.0
	0.0	0.0
	0.0	0.0
	0.0	0.0
	0.0	0.0

Figure 86

- Log Description
 - The log is pre-populated with the PFTs that were used to determine participant eligibility, *Figure 86*.
 - The log will be automatically populated with PFT values whenever a Pulmonary Evaluation form status changes to **DCC Verified**.
 - Form Status - The Form Status of the Log is **NEW** before additional PFT values are added to the Observation Pulmonary Evaluation Log, *Figure 86*. When the first additional PFT values are populated in the log, the form status changes to **STARTED**. The status will remain **STARTED**, because new data may always be added to the log as long as the participant remains in the Observation arm.
 - Unlike most forms, the Log cannot be submitted. The PFT values in the Log are verified when the PFT CRF is submitted. See section 13.5.
- Check Crossover Eligibility
 - Requirements to run the check crossover eligibility test
 - May obtain up to 4 additional FEV1 measurements at intervals of no less than every 7 days. Once the Pulmonary evaluation form is verified by the DCC it will automatically populate on the Observation Pulmonary Evaluation log
 - At least 5 PFTs must have been submitted in the last six months. The crossover calculator will not use PFTs more than six months old in the calculation for crossover, even if they appear in the Log.

- One of the PFT tests must have been submitted within the previous 7 days.
- To check for eligibility to crossover to the ECP Treatment arm:
 - Click the **Check ECP Treatment Eligibility** button on the Observation Log.
 - The next screen to display shows the subset (will it only show PFT used for the calculation) of PFT evaluations from the Log, up to a maximum of 15 in the last 6 months, which will be used to determine whether the participant is eligible to crossover to the ECP Treatment arm, *Figure 87*.
 - Click the **Determine Study Arm Eligibility** button, *Figure 87*.



ECP
REGISTRY

Home Check Enrollment/Arm Eligibility Registry Investigator Resources

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

PULMONARY EVALUATIONS FOR CROSSOVER INTO THE ECP TREATMENT ARM ELIGIBILITY CALCULATOR

Participant ID: 101009

1. ELIGIBLE PULMONARY EVALUATIONS - This is the subset of evaluations from the Observation Pulmonary Evaluation Log that will be used to determine the patient's ECP Treatment Arm eligibility.

- A maximum of 15 evaluations are used.
- Evaluations must not be more than 6 months old.

Determine Study Arm Eligibility... 

A. Date 11/10/2014	FEV1 2.1	liters	FVC	liters
B. Date 12/08/2014	FEV1 2.1	liters	FVC	liters
C. Date 01/05/2015	FEV1 2.1	liters	FVC	liters
D. Date 02/02/2015	FEV1 2.1	liters	FVC	liters
E. Date 03/06/2015	FEV1 1.9	liters	FVC	liters
F. Date 03/13/2015	FEV1 1.8	liters	FVC	liters
G. Date	FEV1	liters	FVC	liters
H. Date	FEV1	liters	FVC	liters
I. Date	FEV1	liters	FVC	liters
J. Date	FEV1	liters	FVC	liters
K. Date	FEV1	liters	FVC	liters
L. Date	FEV1	liters	FVC	liters
M. Date	FEV1	liters	FVC	liters
N. Date	FEV1	liters	FVC	liters
O. Date	FEV1	liters	FVC	liters

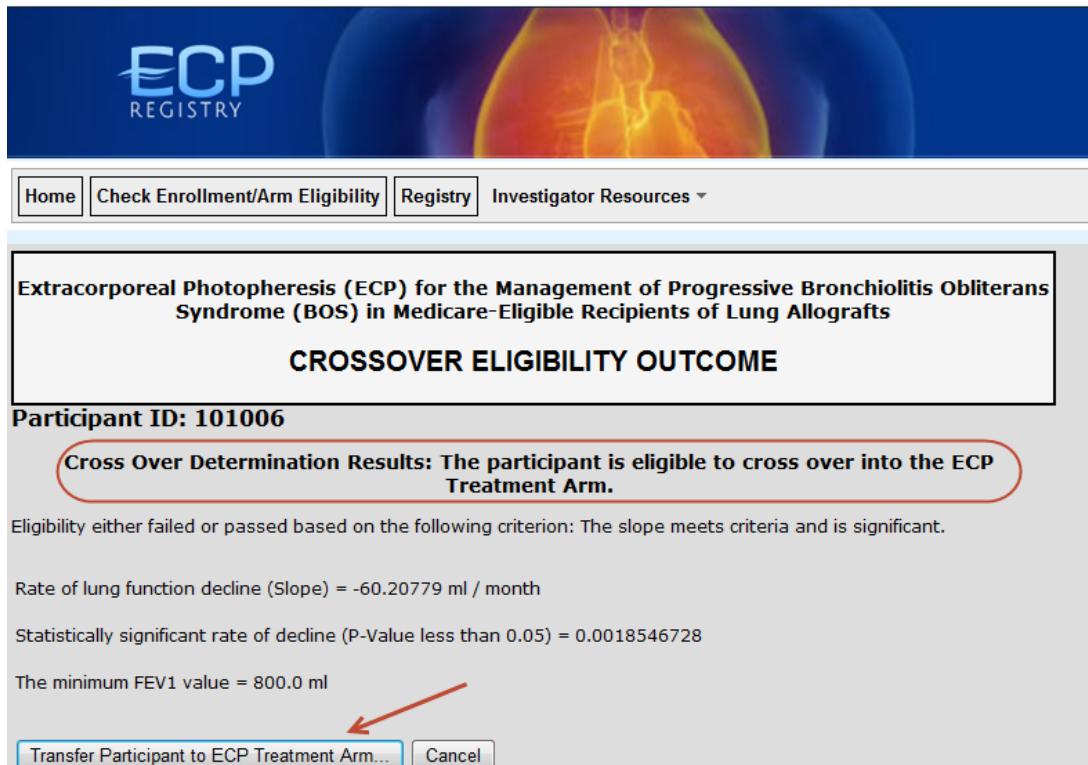
Determine Study Arm Eligibility...

Figure 87

- Possible Results of the Crossover Test Calculation
 - Ineligible for Crossover – The calculation determined that the rate of decline in lung function does not meet the criteria defined by the protocol to receive ECP treatment. A participant may have reached the crossover slope criteria, but still may not be eligible for crossover because the result is not statistically significant. *Figure 88 - Ineligible for Crossover to ECP Treatment*.
 - Eligible for Crossover - The rate of decline in lung function meets the criteria defined by the protocol to receive ECP treatment, and the rate of decline is statistically significant, *Figure 89 - Eligible for Crossover to ECP Treatment*. To begin the transfer to ECP treatment, click **Transfer Participant to ECP Treatment Arm**. To continue transfer, see pages 76-80.
 - Eligible for Crossover, But Must Acquire Clinical Override – Four additional PFT must have been acquired (at least one week apart) since enrollment or after the end of a two month holding period. The rate of decline in lung function meets the criteria defined by the protocol to receive ECP treatment, but the rate of decline is not statistically significant, *Figure 90 - Ineligible for Crossover to ECP Treatment but Eligible for Clinical Override*. In this situation, if the physician feels strongly that ECP is indicated, he/she may choose to transfer the patient into the ECP Treatment Arm via a “clinical override”. To transfer to ECP treatment, click **Transfer Participant to ECP Treatment Arm**. See pages 77-80. Otherwise, click **Keep Participant in Observation Arm**. The participant will then be put in a two month holding period. See page 82.

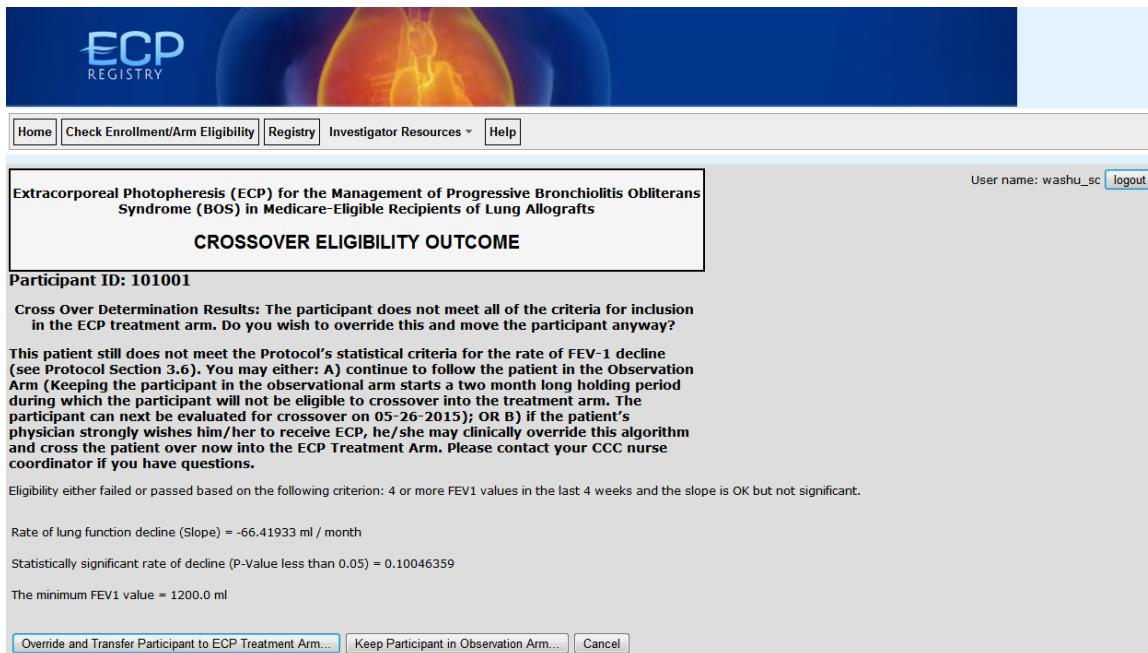
The screenshot shows the ECP Registry software interface. At the top, there is a navigation bar with links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. On the right, it shows the user name: test_tc and a logout link. The main content area has a title: "Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts" and a sub-section title: "CROSSOVER ELIGIBILITY OUTCOME". A participant ID: 101000 is displayed. A message box contains the text: "Cross Over Determination Results: This patient remains in the Observation Arm because he/she still does not meet the Protocol's criteria to receive ECP (see Protocol Section 3.6). Please continue to follow the Protocol's treatment and evaluation procedures for Observation Arm patients. Please contact your CCC nurse coordinator if you have questions." A red callout box points to this message with the text "Result of ecp treatment eligibility test". Below the message, a note states: "Eligibility either failed or passed based on the following criterion: The slope is NOT OK and/or the significance is NOT OK with fewer than 4 FEV1s collected since enrollment date or the end of the 2 month hold period." A red callout box points to this note with the text "Reason test failed ecp eligibility". At the bottom, there are links for "Rate of lung function decline (Slope) = 0.0 ml / month", "Statistically significant rate of decline (P-Value less than 0.05) = NaN", and "The minimum FEV1 value = 2000.0 ml". A "Return to Registry" button is at the bottom left.

Figure 88 - Ineligible for Crossover to ECP Treatment



The screenshot shows the ECP Registry website. The top navigation bar includes links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. The main content area displays a study titled "Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts". A section titled "CROSSOVER ELIGIBILITY OUTCOME" shows a participant with ID 101006. A red box highlights the message: "Cross Over Determination Results: The participant is eligible to cross over into the ECP Treatment Arm." Below this, text states: "Eligibility either failed or passed based on the following criterion: The slope meets criteria and is significant." It also provides statistical details: "Rate of lung function decline (Slope) = -60.20779 ml / month", "Statistically significant rate of decline (P-Value less than 0.05) = 0.0018546728", and "The minimum FEV1 value = 800.0 ml". A red arrow points to the "Transfer Participant to ECP Treatment Arm..." button. The bottom of the page includes "Cancel" and "Transfer Participant to ECP Treatment Arm..." buttons.

Figure 89 - Eligible for Crossover to ECP Treatment



The screenshot shows the ECP Registry website. The top navigation bar includes links for Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. The main content area displays a study titled "Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts". A section titled "CROSSOVER ELIGIBILITY OUTCOME" shows a participant with ID 101001. A message states: "Cross Over Determination Results: The participant does not meet all of the criteria for inclusion in the ECP treatment arm. Do you wish to override this and move the participant anyway?" Below this, text states: "This patient still does not meet the Protocol's statistical criteria for the rate of FEV-1 decline (see Protocol Section 3.6). You may either: A) continue to follow the patient in the Observation Arm (Keeping the participant in the observational arm starts a two month long holding period during which the participant will not be eligible to crossover into the treatment arm. The participant can next be evaluated for crossover on 05-26-2015); OR B) if the patient's physician strongly wishes him/her to receive ECP, he/she may clinically override this algorithm and cross the patient over now into the ECP Treatment Arm. Please contact your CCC nurse coordinator if you have questions." It also provides statistical details: "Rate of lung function decline (Slope) = -66.41933 ml / month", "Statistically significant rate of decline (P-Value less than 0.05) = 0.10046359", and "The minimum FEV1 value = 1200.0 ml". At the bottom, there are buttons for "Override and Transfer Participant to ECP Treatment Arm...", "Keep Participant in Observation Arm...", and "Cancel". The top right corner shows the user name "washu_sc" and a "logout" link.

Figure 90 - Ineligible for Crossover to ECP Treatment but Eligible for Clinical Override

- Procedure to Cross Over to ECP Treatment Arm
 - Click the Transfer Participant to ECP Treatment Arm button, *Figure 89 - Eligible for Crossover to ECP Treatment*.

- A **Crossover Safety Check Form** is then created, and an Event Summary page, *Figure 91*, displays. Click View on the Event Summary page to display the form.



The screenshot shows the ECP Registry interface. At the top, there is a logo with the letters 'ECP' and the word 'REGISTRY'. Below the logo, there is a navigation bar with four buttons: 'Home', 'Check Enrollment/Arm Eligibility', 'Registry', and 'Investigator Resources'. The main content area is titled 'Event Summary'. The 'Event Summary' section displays the following information:

Site Name - ID:	WashU - 101	Event Type:	Crossover to Treatment Arm
Participant ID:	101006	Event Title:	Crossover to Treatment Arm 1
Study Arm:	Observational Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	01-16-2015	Event Date:	01-20-2015

Below this, there is a table with four columns: 'Form Type', 'Form Title', 'Status', and 'Date'. The table contains one row with the following data:

Form Type	Form Title	Status	Date
Crossover Safety Check	Crossover Safety Check Form NEW	01-20-2015	View

Figure 91

- The Crossover Safety check Form must be completed before crossover can occur, *Figure 92*.

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Site Summary > Participant Summary > Event Summary > Crossover Safety Check Form User name

Form Summary

Site Name - ID: Test Site - 100	Event Type: Crossover Safety Check	Form Type: Crossover Safety Check
Participant ID: 100001	Event Title: Crossover Safety Check 1	Form Title: Crossover Safety Check Form
Study Arm: Observational Arm	Event Label:	
Participant Status: ENROLLED	Event Status: NEW	Form Status: NEW
Enrolled Date: 04-28-2015	Event Date: 04-28-2015	Form Date: 04-28-2015

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

CROSSOVER SAFETY CHECK - Case Report Form (CRF)

Important and Time-Sensitive: Please answer the question below and then PRINT this participant's Crossover Safety Check (CSC) Form, have an authorized physician investigator sign and date the CSC form, and scan and upload the signed CSC. Per Protocol Section 3.7, submission of this signed CSC Form is required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed.

Please include the following types of source documents:

1. A Signed Crossover Safety Check Form must be uploaded

Source Document Type	Document Name	Submission Date
Select Source Document Type	A Signed Crossover Safety Check Form must be uploaded	
Attach Source Document:	Choose File	No file chosen
		Upload
Save	Submit	

Safety Check

1. Has the patient developed a new contraindication to the use of ECP Treatment therapy? (Please review the Protocol Section 3.3 for conditions that may apply.) YES NO

2. Has the signed Crossover Safety Check CRF been uploaded? YES NO

3. The following FEV1 values were used to calculate the Crossover Confirmation of Eligibility for this participant to be transferred from the Observational Arm to the ECP Treatment Arm.

A. Date 01/02/2015	FEV1 2.0	liters	FVC 3.0	liters
B. Date 01/09/2015	FEV1 2.0	liters	FVC 3.0	liters
C. Date 01/16/2015	FEV1 2.0	liters	FVC 3.0	liters
D. Date 01/23/2015	FEV1 2.0	liters	FVC 3.0	liters
E. Date 04/21/2015	FEV1 1.93	liters	FVC 2.9	liters
F. Date 04/28/2015	FEV1 1.8	liters	FVC 2.9	liters
G. Date	FEV1	liters	FVC	liters
H. Date	FEV1	liters	FVC	liters
I. Date	FEV1	liters	FVC	liters
J. Date	FEV1	liters	FVC	liters
K. Date	FEV1	liters	FVC	liters
L. Date	FEV1	liters	FVC	liters
M. Date	FEV1	liters	FVC	liters
N. Date	FEV1	liters	FVC	liters
O. Date	FEV1	liters	FVC	liters

INVESTIGATOR ATTESTATION

I have reviewed and confirmed that the information recorded on this CRF Page is accurate. I attest that this patient meets all study eligibility criteria and is appropriate to enroll in the ECP Registry

Investigator Name (please print) _____

Investigator Signature _____ Date: _____

Save Submit

Figure 92

- On the Crossover Safety Check form, answer the Safety Check question #1, *Figure 92* and *Figure 93*.

Safety Check

1. Has the patient developed a new contraindication to the use of ECP Treatment therapy? (Please review the [Protocol Section 3.3](#) for conditions that may apply.)

YES NO

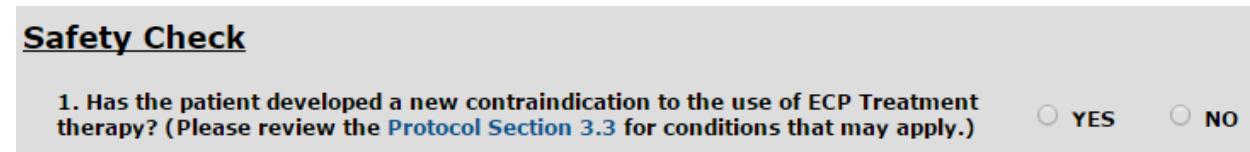
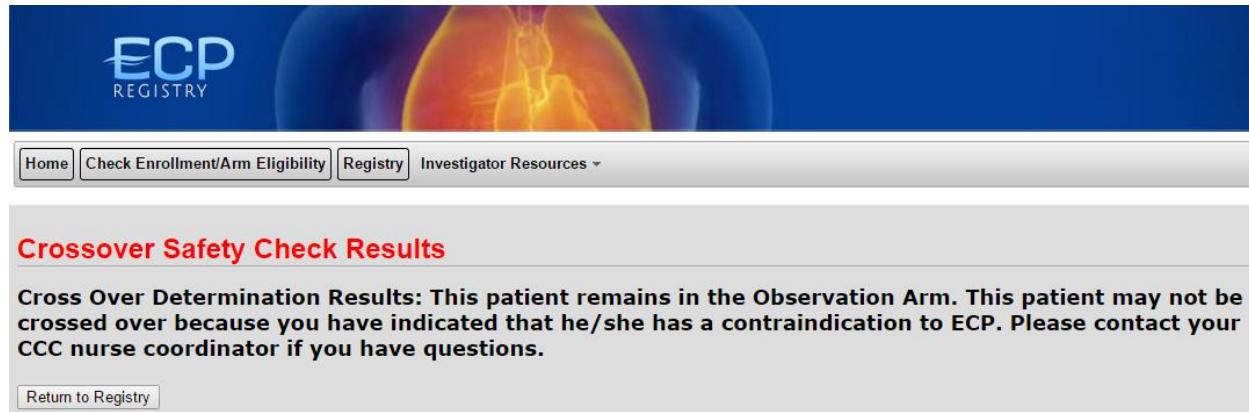


Figure 93

- Results of Response to Safety Check question #1
 - Yes – Participant is ineligible for crossover at this time because the site indicated that the participant has a contraindication to ECP treatment. He/she remains in the observation arm, *Figure 94*.



The screenshot shows the ECP Registry website. The top navigation bar includes links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. The main content area is titled "Crossover Safety Check Results" in red. A message in blue text states: "Cross Over Determination Results: This patient remains in the Observation Arm. This patient may not be crossed over because you have indicated that he/she has a contraindication to ECP. Please contact your CCC nurse coordinator if you have questions." A "Return to Registry" button is located at the bottom left of this section.

Figure 94

- No – The participant may cross over to the ECP treatment arm. Do the following:
 - ◆ Save the Crossover Safety Check form, *Figure 92*.
 - ◆ Print the Crossover Safety Check form by right clicking with the mouse on the form. A pop up box will appear click on print.
 - ◆ Obtain the signature of the PI or Co-Investigator, at the bottom of the printed form.
 - ◆ Scan the signed copy.
 - ◆ Save the signed copy in PDF format using the naming convention for the form as **CSC_xxxxxx_mmddyyyy.pdf**, *Table 1*.
 - ◆ Immediately upload the signed PDF. See [section 10.0](#) for upload instructions. When uploaded, the form name will be highlighted in yellow, *Figure 95*.
 - ◆ Answer question #2 on the Crossover Safety Check form, *Figure 95*.
 - ◆ When the form is accurate and complete, click **Submit**.
 - ◆ If the response to question #1 is "No", when the Crossover Safety Check form is submitted, the Participant Summary page will

populate with the projected dates of the ECP Treatments CRFs once the first treatment is entered ?, the Pulmonary Evaluation CRFs and the End of Study CRF.

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Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary > Participant Summary > Event Summary > Crossover Safety Check Form User name: test_sc logout

Form Summary

Site Name - ID: Test Site - 100 Event Type: Crossover Safety Check Form Type: Crossover Safety Check
Participant ID: 100001 Event Title: Crossover Safety Check 1 Form Title: Crossover Safety Check Form
Study Arm: Observational Arm Event Label:
Participant Status: ENROLLED Event Status: NEW Form Status: NEW
Enrolled Date: 04-28-2015 Event Date: 04-28-2015 Form Date: 04-28-2015

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

CROSSOVER SAFETY CHECK - Case Report Form (CRF)

Important and Time-Sensitive: Please answer the question below and then PRINT this participant's Crossover Safety Check (CSC) Form, have an authorized physician investigator sign and date the CSC form, and scan and upload the signed CSC. Per Protocol Section 3.7, submission of this signed CSC Form is required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed.

Please include the following types of source documents:

1. A Signed Crossover Safety Check Form must be uploaded

Source Document Type	Document Name	Submission Date
A Signed Crossover Safety Check Form must be uploaded	CSC_100001_04282015.pdf	04-28-2015

View Delete

Select Source Document Type | A Signed Crossover Safety Check Form must be uploaded ▾

Attach Source Document: Choose File No file chosen Upload

Save Submit

Safety Check

1. Has the patient developed a new contraindication to the use of ECP Treatment therapy? (Please review the [Protocol Section 3.3](#) for conditions that may apply.) YES NO

2. Has the signed Crossover Safety Check CRF been uploaded? YES NO

3. The following FEV1 values were used to calculate the Crossover Confirmation of Eligibility for this participant to be transferred from the Observational Arm to the ECP Treatment Arm.

A. Date 01/02/2015	FEV1 2.0	liters	FVC 3.0	liters
B. Date 01/09/2015	FEV1 2.0	liters	FVC 3.0	liters
C. Date 01/16/2015	FEV1 2.0	liters	FVC 3.0	liters
D. Date 01/23/2015	FEV1 2.0	liters	FVC 3.0	liters
E. Date 04/21/2015	FEV1 1.93	liters	FVC 2.9	liters
F. Date 04/28/2015	FEV1 1.8	liters	FVC 2.9	liters
G. Date	FEV1	liters	FVC	liters
H. Date	FEV1	liters	FVC	liters
I. Date	FEV1	liters	FVC	liters
J. Date	FEV1	liters	FVC	liters
K. Date	FEV1	liters	FVC	liters
L. Date	FEV1	liters	FVC	liters
M. Date	FEV1	liters	FVC	liters
N. Date	FEV1	liters	FVC	liters
O. Date	FEV1	liters	FVC	liters

INVESTIGATOR ATTESTATION

I have reviewed and confirmed that the information recorded on this CRF Page is accurate. I attest that this patient meets all study eligibility criteria and is appropriate to enroll in the ECP Registry

Investigator Name (please print) _____

Investigator Signature _____ Date: _____

Save Submit

Figure 95

- 2-Month Holding Period - A participant may be put in a holding period for 2 months, during which time no crossover to ECP Treatment calculation can occur.
 - Conditions leading to a 2-Month Holding period
 - Four PFTs CRFs have been submitted, post enrollment or post a two month holding period (with a total of at least five PFTs within the past six months), all at least one week apart, and one in the last 7 days, and the slope of the rate of lung function decline did not meet the requirement for the ECP Treatment arm.
 - Four PFTs have been taken, post enrollment or post a two month holding period (with a total of at least five PFTs within the past six months), all at least one week apart, and one in the last 7 days, and the slope of the rate of lung function decline does meet the requirement for the ECP Treatment arm, but the slope was not statistically significant, and the site physician did not choose to clinically override the result within 7 days of the calculation.
 - Four PFTs have been taken, post enrollment, all at least one week apart, and one in the last 7 days, and the slope of the rate of lung function decline does meet the requirement for the ECP Treatment arm, but the slope was not statistically significant. The physician actively chooses to keep the participant in the Observation Arm.
 - PFTs acquired during a 2-month holding period may be used in the calculation for crossover eligibility, but they do not count toward the required 4 PFTs needed for clinical override. Those 4 PFTs must occur after the 2-month holding period.
- Clinical Override may be required for a participant in the Observation Arm to crossover to the ECP Treatment Arm. It can occur when the decline in the slope of the rate of lung function meets the requirement for the ECP Treatment arm, but the slope is not statistically significant, and
 - At least 4 additional PFTs have been logged after the initial enrollment eligibility calculation, or
 - At least 4 additional PFTs have been logged after the end of a 2-month holding period with a total of at least five PFTs within the past six months.
- Procedure for Clinical Override
 - If the requirements for clinical override have been met, a page such as *Figure 89* displays. Click the **Override and Transfer Participant to ECP Treatment Arm** button.
 - To continue with the override and transfer to ECP treatment, see pages 77-80.

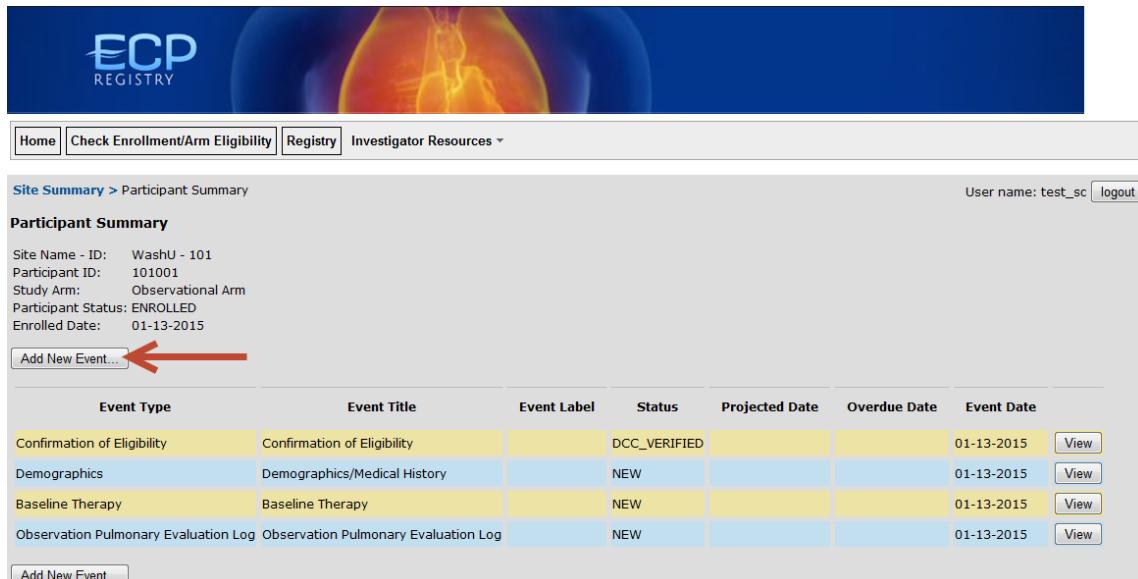
13.5 Pulmonary Evaluation CRF

- Create a **Pulmonary Evaluation CRF** for every PFT that is dated after enrollment. The PFTs should each be at least 7 days apart. The ECP Registry website will accept

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PFTs that are less than 7 days apart, but such PFTs may not be used to calculate the eligibility for crossover to ECP treatment.

- To create a **Pulmonary Evaluation CRF**, click the **Add New Event** button on the **Participant Summary** page, Figure 96.



Site Summary > Participant Summary

Participant Summary

Site Name - ID: WashU - 101
Participant ID: 101001
Study Arm: Observational Arm
Participant Status: ENROLLED
Enrolled Date: 01-13-2015

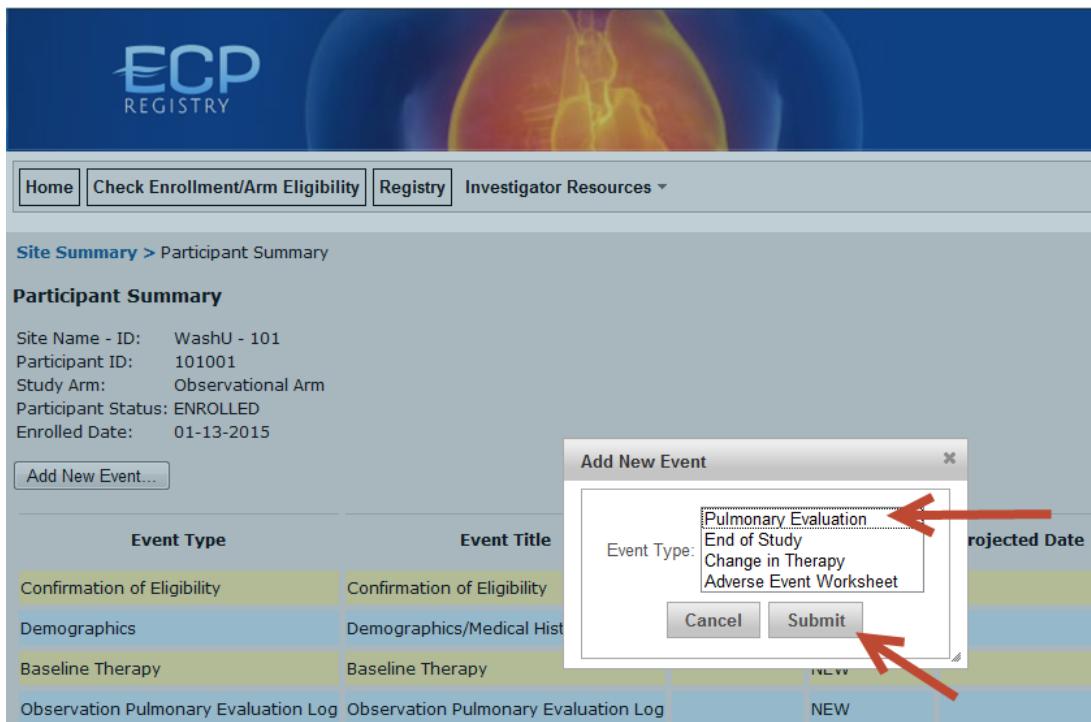
Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility	DCC_VERIFIED				01-13-2015
Demographics	Demographics/Medical History	NEW				01-13-2015
Baseline Therapy	Baseline Therapy	NEW				01-13-2015
Observation Pulmonary Evaluation Log	Observation Pulmonary Evaluation Log	NEW				01-13-2015

Add New Event...

Figure 96

- Select **Pulmonary Evaluation** in the drop down menu, Figure 97, and click **Submit**.



Site Summary > Participant Summary

Participant Summary

Site Name - ID: WashU - 101
Participant ID: 101001
Study Arm: Observational Arm
Participant Status: ENROLLED
Enrolled Date: 01-13-2015

Add New Event...

Add New Event

Event Type: Pulmonary Evaluation

Cancel Submit

Event Type	Event Title	Projected Date
Confirmation of Eligibility	Confirmation of Eligibility	
Demographics	Demographics/Medical History	
Baseline Therapy	Baseline Therapy	
Observation Pulmonary Evaluation Log	Observation Pulmonary Evaluation Log	NEW

Figure 97

- Clicking **Submit** displays the **Event Summary** page, which displays a numbered **Pulmonary Evaluation** event, *Figure 98*.

The screenshot shows the ECP Registry interface. At the top, there is a logo for 'ECP REGISTRY' with a background image of a chest X-ray. Below the logo is a navigation bar with links for 'Home', 'Check Enrollment/Arm Eligibility', 'Registry', and 'Investigator Resources'. The main content area is titled 'Event Summary' and shows the following details for a study arm:

Site Name - ID:	WashU - 101	Event Type:	Pulmonary Evaluation
Participant ID:	101002	Event Title:	Pulmonary Evaluation 1
Study Arm:	Observational Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	01-21-2015	Event Date:	

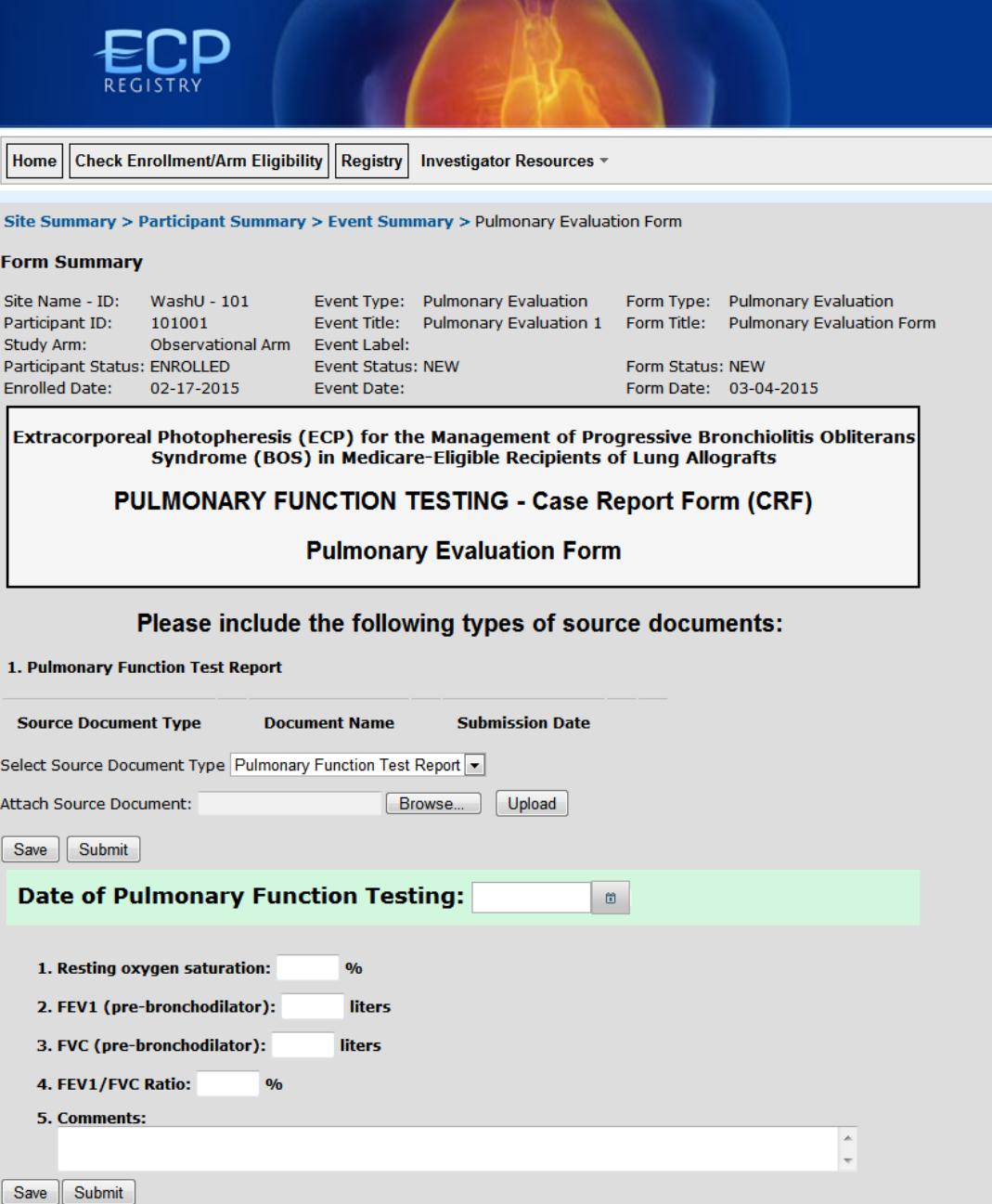
Below this, there is a table with four columns: 'Form Type', 'Form Title', 'Status', and 'Date'. The data in the table is:

Form Type	Form Title	Status	Date
Pulmonary Evaluation	Pulmonary Evaluation Form	NEW	01-28-2015

A red arrow points to the 'View' button in the 'Date' column of the table.

Figure 98

- Click **View**, *Figure 98*, to display the Pulmonary Evaluation Form, *Figure 99*.
- Complete the Pulmonary Evaluation Form and upload the required document.
- When the form is accurate and complete, submit the form.
- When the Pulmonary Evaluation CRF is marked DCC Verified, the PFT values from the form will appear in the Observation Pulmonary Evaluation Log.



The screenshot shows the ECP Registry website interface. At the top, there is a header with the ECP Registry logo and a navigation bar with links for Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. Below the header, the URL shows the participant summary page for a specific event. The main content area is titled 'Form Summary' and displays various study details. A large box contains the title 'Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts' and the sub-title 'PULMONARY FUNCTION TESTING - Case Report Form (CRF)'. Below this, a section titled 'Pulmonary Evaluation Form' is shown. A callout box asks for source documents, listing '1. Pulmonary Function Test Report' and providing fields for document type, name, and submission date. It also includes fields for attaching a source document and saving/submitting the form. A 'Date of Pulmonary Function Testing' field is shown with a date input field. Below this, a list of pulmonary function test results (Resting oxygen saturation, FEV1, FVC, FEV1/FVC Ratio) is displayed with input fields. A comments section with a text area and scroll bars is also present. At the bottom of the form are 'Save' and 'Submit' buttons.

Figure 99

13.6 Change in Therapy

To create a **Change in Therapy CRF**, click the **Add New Event** button found on the Participant Summary page, *Figure 96*. For further information, see Section 12.6 – Change in Therapy.

13.7 End of Study

To create an **End of Study CRF**, click the **Add New Event** button found on the Participant Summary page, *Figure 96*. For further information, see [Section 12.7 – End of Study](#).

14.0 Adverse Event Worksheet

Please refer to the CCC Manual of Procedures.