

**Manual of Procedures (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**

**for**

**Refractory BOS**

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 Daniel Marcus, Ph.D., Associate 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 Refractory's secure website.

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

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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:**

- Mary Clare Derfler [derflerm@wustl.edu](mailto:derflerm@wustl.edu) 314-747-2372
- Kathy Twichell [ktwichell@mir.wustl.edu](mailto:ktwichell@mir.wustl.edu) 314-747-1653

## 2.0 System Requirements

### 2.1 Acceptable Operating Systems

- Windows 10
- Windows 8
- Windows 7
- MAC

### 2.2 Acceptable Browsers

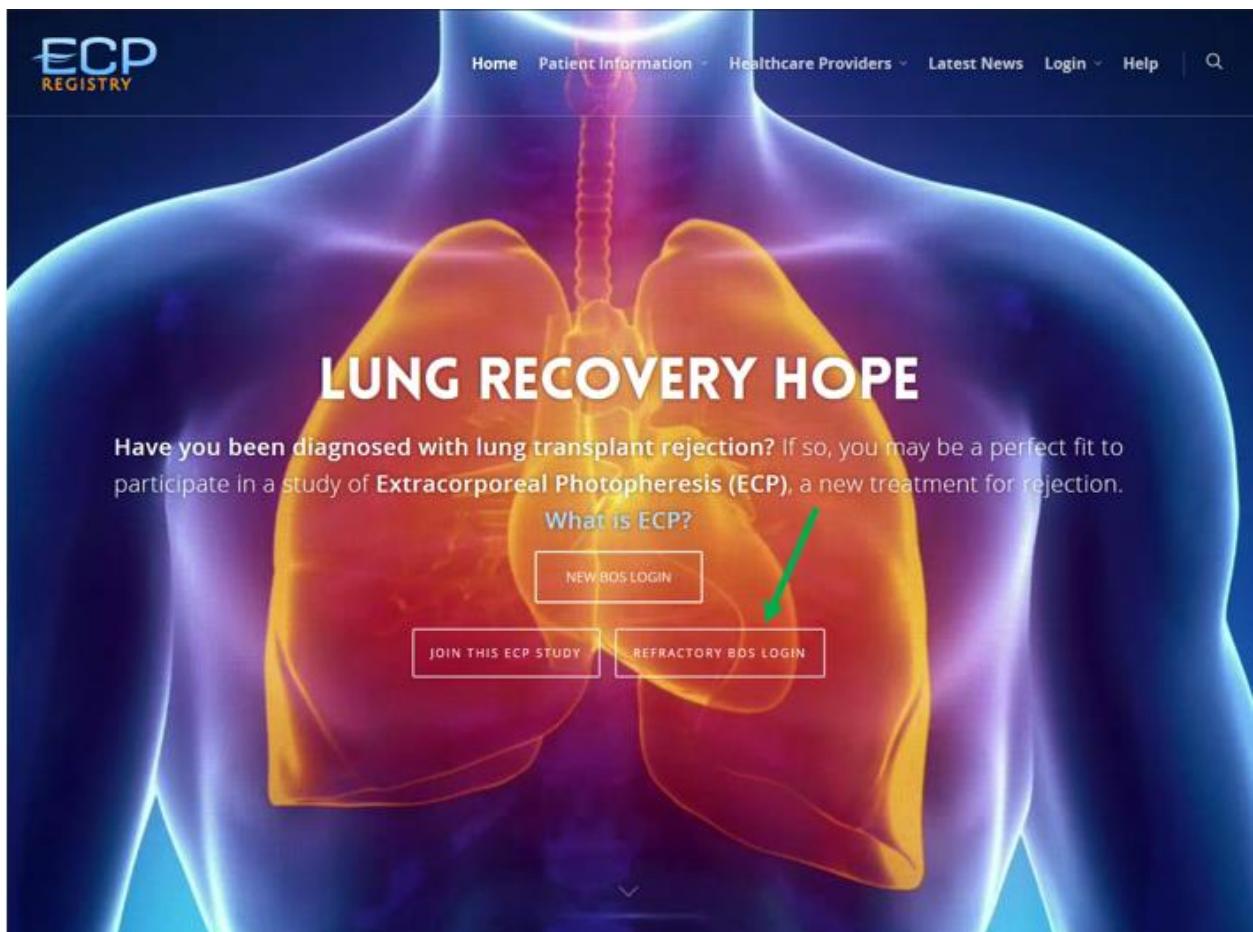
- Internet Explorer 11
- Google Chrome
- FireFox

### 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 **Refractory BOS Login** button, *Figure 1*.



*Figure 1*

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

## ECP Refractory BOS Site Resources Login

Username:

Password:

Remember Me

Figure 2

### 4.0 Site Resources Page

- 4.1 Following login, you will see in large blue letters “**ECP REFRACTORY BOS WEBSITE**” to let you know you are in the ECP Refractory BOS Website and not the ECP New BOS Website. There are three top-level menu buttons (**Home**, **Check Enrollment/Arm Eligibility**, and **Refractory BOS**) and two additional menu items (**Investigator Resources** and **Help**), *Figure 3*.

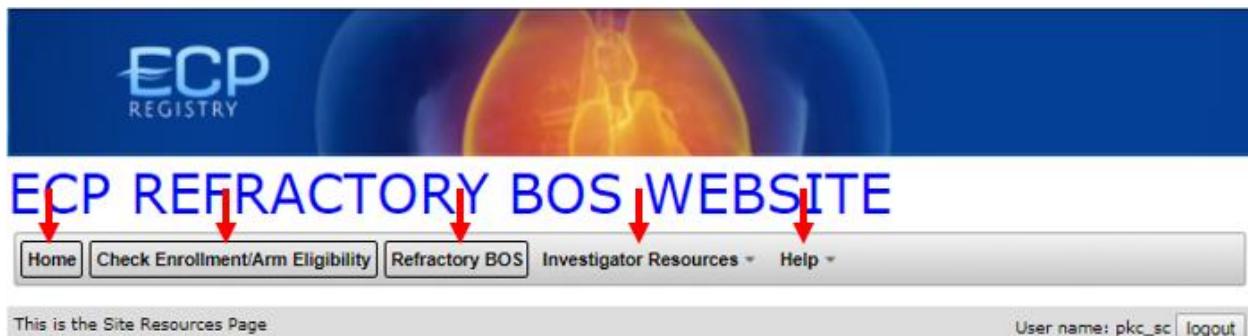
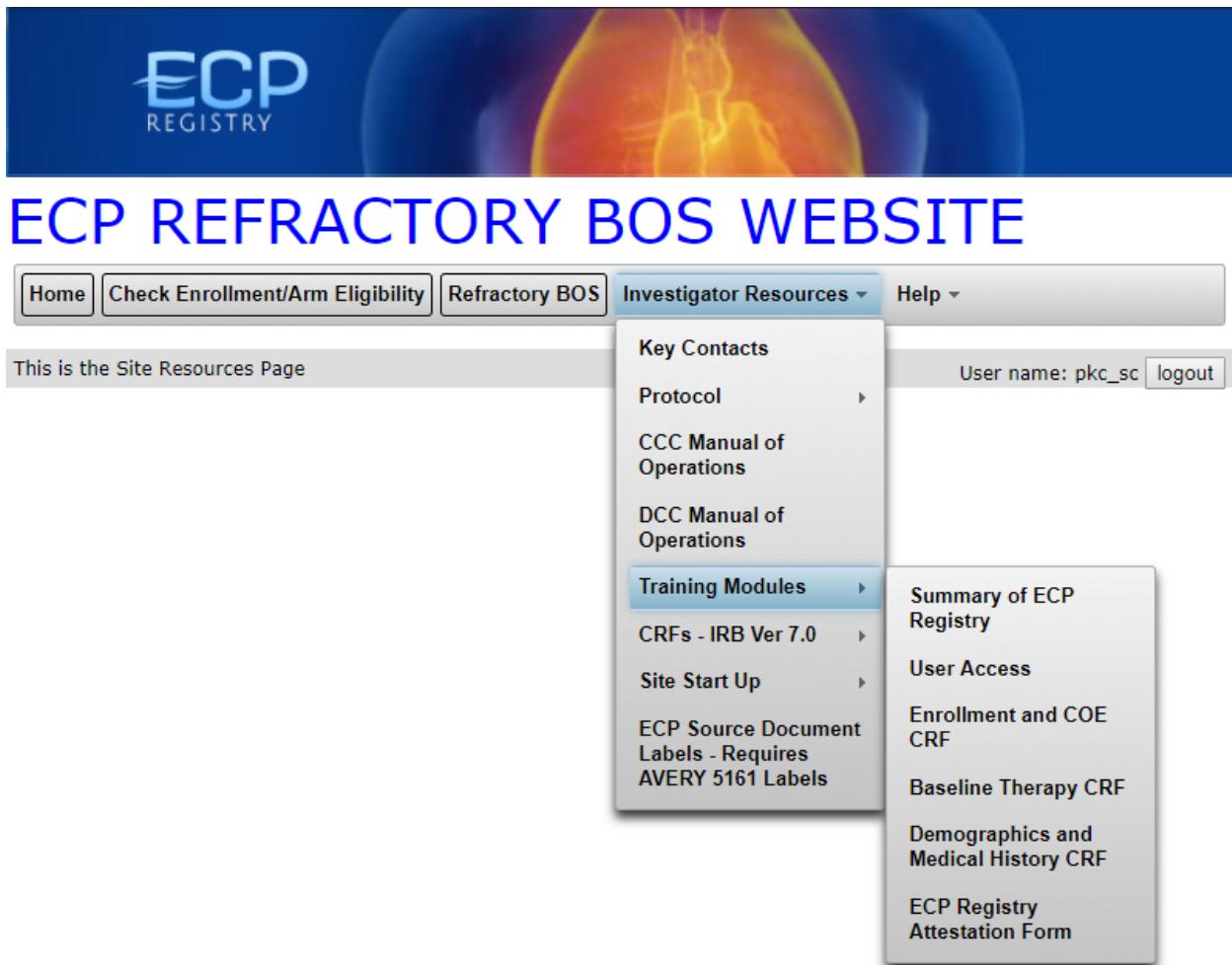


Figure 3

- 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 **Refractory BOS** 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, Not Required and Missed Visit. See Section 5.0 for detailed information.
- The **Investigator Resources** menu item contains a drop down menu (see **Figure 4**) with links to various site documents: Key Contacts, Protocol, Manual of Operations, Training Modules (see **Figure 5**), Case Report Forms(see **Figure 5**), Site Start Up (see **Figure 6**), and Source Document Labels.
- Help – The help menu item contains a drop down menu with links to the Support Staff and About pages. The Support Staff page contains a list of ECP Registry personnel at the Clinical Coordinating Center and their Responsible Areas and the About page contains information about the ECP Registry software.



**Figure 4**

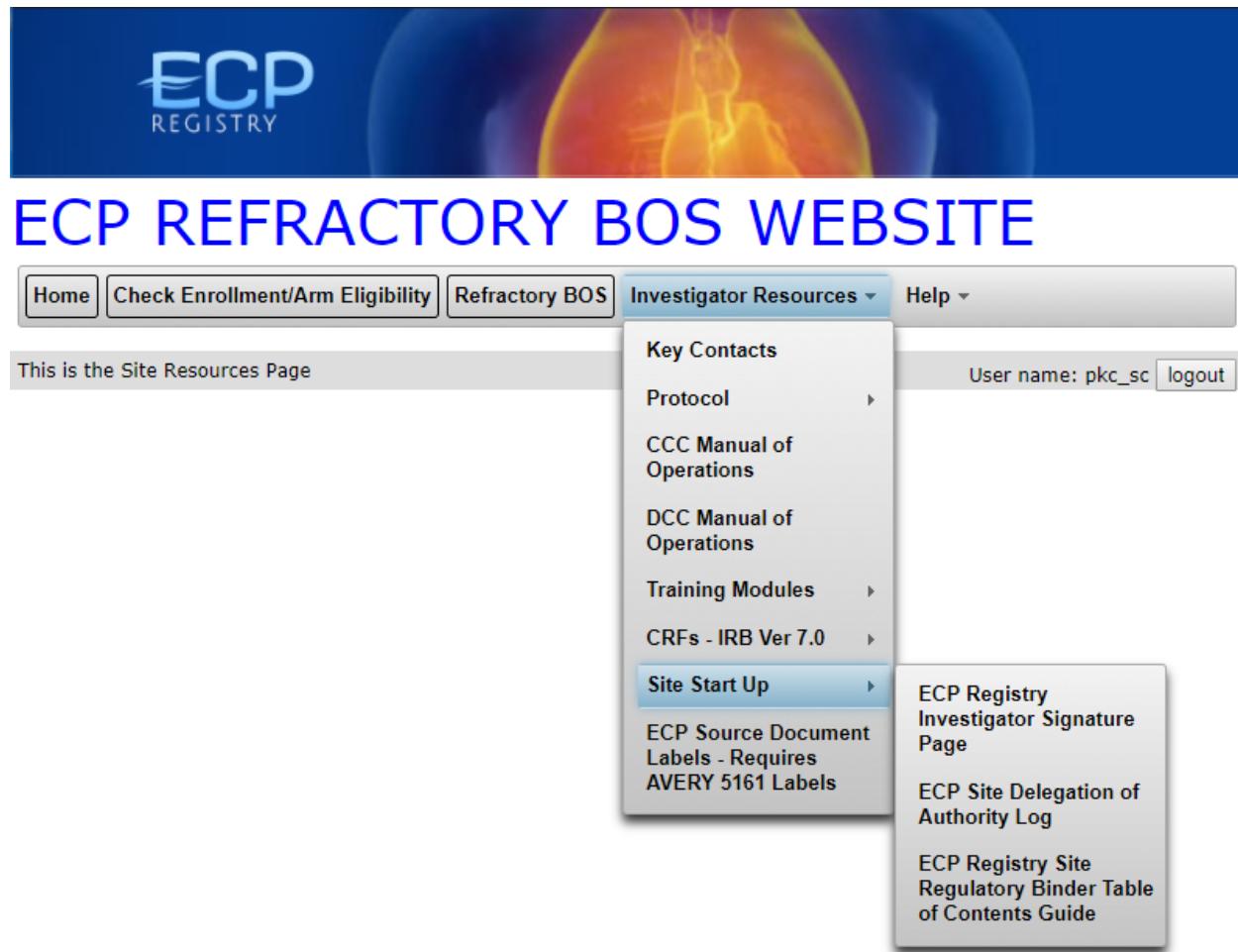
The screenshot shows the ECP Refractory BOS Website. At the top, there is a blue header bar with the ECP Registry logo on the left and a background image of a human torso with internal organs on the right. Below the header, the title "ECP REFRAC TORY BOS WEBSITE" is displayed in large blue letters. A navigation bar with buttons for "Home", "Check Enrollment/Arm Eligibility", "Refractory BOS", "Investigator Resources", and "Help" is visible. The "Investigator Resources" button is highlighted with a blue background. A dropdown menu for "Investigator Resources" is open, showing the following options:

- Key Contacts
- Protocol
- CCC Manual of Operations
- DCC Manual of Operations
- Training Modules
- CRFs - IRB Ver 7.0
- Site Start Up
- ECP Source Document Labels - Requires Avery 5161 Labels

On the right side of the page, there is a sidebar with the text "User name: pkc\_sc" and a "logout" button. Below the sidebar, a list of CRFs is displayed:

- Confirmation Of Eligibility CRF
- Demographics CRF
- Baseline Therapy CRF
- ECP Treatment Visit CRF
- Pulmonary Function Testing CRF
- Change In Therapy CRF
- Observational Arm Pulmonary Evaluation Log
- Crossover Safety Check CRF
- Quality of Life CRF
- Adverse Event Worksheet SAE CRF
- End Of Study CRF

*Figure 5*

**Figure 6**

## 5.0 Site Summary Page

**5.1** The **Refractory BOS** button directs you to the **Site Summary** page that displays the enrolled participants for the site. In **Figure 7**, there are four participants shown to be 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
- rBOS Study Arm – Either in the 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 death
- Missed Visit – The number of CRFs which the subject missed a visit.

**ECP REFRACTORY BOS WEBSITE**

Participant ID	Enrolled Date	rBOS Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	Missed Visit	
100001	04-10-2015	ECP Treatment Arm	ENROLLED	40	1	1	0	2	0	0	0	<a href="#">View</a>
100002	04-14-2015	ECP Treatment Arm	ENROLLED	36	1	2	0	1	0	0	0	<a href="#">View</a>
100003	04-14-2015	Observational Arm	ENROLLED	0	2	0	0	3	0	0	0	<a href="#">View</a>
100004	05-27-2015	Observational Arm	ENROLLED	3	0	0	0	1	0	0	0	<a href="#">View</a>

**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 ECP Treatment Arm the following Events and worksheets will appear on the Participant Summary page:
- Confirmation of Eligibility
  - Demographics / Medical History
  - Baseline Therapy
  - ECP Treatment

- Quality of Life
- Pulmonary Evaluation
- Change in Therapy
- End of Study

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

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

The Event 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.

**6.3** 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

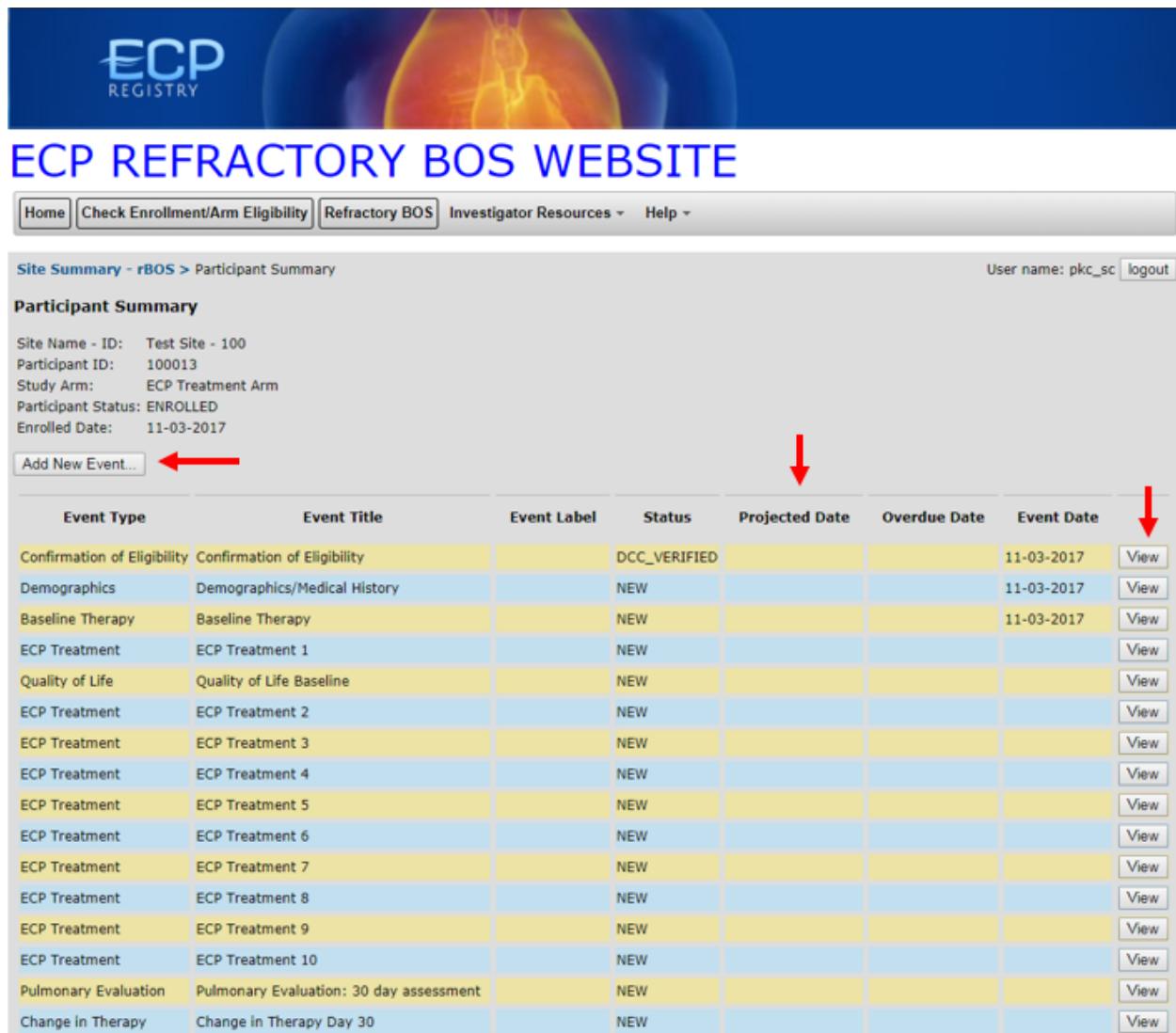
For the Observation Arm the following events and worksheets may be selected by adding a new event:

- Pulmonary Evaluation
- Change in Therapy
- Adverse Event Worksheet
- End of Study

**6.4** The **Participant Summary** page also includes an **Add New Event** button, found in the upper left corner. See *Figure 9*.

- 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](#)
- 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](#)
  - Change in Therapy – See [Section 13.6](#)
  - End of Study – See [Section 13.7](#)
  - 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.



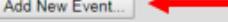
**ECP REFRACATORY BOS WEBSITE**

Home Check Enrollment/Arm Eligibility Refractory BOS Investigator Resources Help

Site Summary - rBOS > Participant Summary User name: pkc\_sc logout

**Participant Summary**

Site Name - ID: Test Site - 100  
Participant ID: 100013  
Study Arm: ECP Treatment Arm  
Participant Status: ENROLLED  
Enrolled Date: 11-03-2017

Add New Event... 

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Confirmation of Eligibility	Confirmation of Eligibility	DCC_VERIFIED			11-03-2017		
Demographics	Demographics/Medical History	NEW			11-03-2017		
Baseline Therapy	Baseline Therapy	NEW			11-03-2017		
ECP Treatment	ECP Treatment 1	NEW					
Quality of Life	Quality of Life Baseline	NEW					
ECP Treatment	ECP Treatment 2	NEW					
ECP Treatment	ECP Treatment 3	NEW					
ECP Treatment	ECP Treatment 4	NEW					
ECP Treatment	ECP Treatment 5	NEW					
ECP Treatment	ECP Treatment 6	NEW					
ECP Treatment	ECP Treatment 7	NEW					
ECP Treatment	ECP Treatment 8	NEW					
ECP Treatment	ECP Treatment 9	NEW					
ECP Treatment	ECP Treatment 10	NEW					
Pulmonary Evaluation	Pulmonary Evaluation: 30 day assessment	NEW					
Change in Therapy	Change in Therapy Day 30	NEW					

Figure 8 (continued below)

ECP Treatment	ECP Treatment 11	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 12	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 13	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 14	NEW					<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 60 day assessment	NEW					<a href="#">View</a>
Change in Therapy	Change in Therapy Day 60	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 15	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 16	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 17	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 18	NEW					<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 90 day assessment	NEW					<a href="#">View</a>
Change in Therapy	Change in Therapy Day 90	NEW					<a href="#">View</a>
Quality of Life	Quality of Life Day 90	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 19	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 20	NEW					<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 120 day assessment	NEW					<a href="#">View</a>
Change in Therapy	Change in Therapy Day 120	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 21	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 22	NEW					<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 150 day assessment	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 23	NEW					<a href="#">View</a>
ECP Treatment	ECP Treatment 24	NEW					<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 180 day assessment	NEW					<a href="#">View</a>
Change in Therapy	Change in Therapy Day 180	NEW					<a href="#">View</a>
Quality of Life	Quality of Life Day 180	NEW					<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 210 day assessment	NEW					<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 240 day assessment	NEW					<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 270 day assessment	NEW					<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 300 day assessment	NEW					<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 330 day assessment	NEW					<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 365 day assessment	NEW					<a href="#">View</a>
End of Study	End Of Study	NEW					<a href="#">View</a>

[Add New Event...](#)

**Figure 9 - The Participant Summary page for the ECP Treatment Arm displays the status of all Events for a participant.**



## ECP REFRACtORY BOS WEBSITE

Home Check Enrollment/Arm Eligibility Refractory BOS Investigator Resources Help

Site Summary - rBOS > Participant Summary

### Participant Summary

Site Name - ID: Test Site - 100  
 Participant ID: 100015  
 Study Arm: Observational Arm  
 Participant Status: ENROLLED  
 Enrolled Date: 11-07-2017

Add New Event...

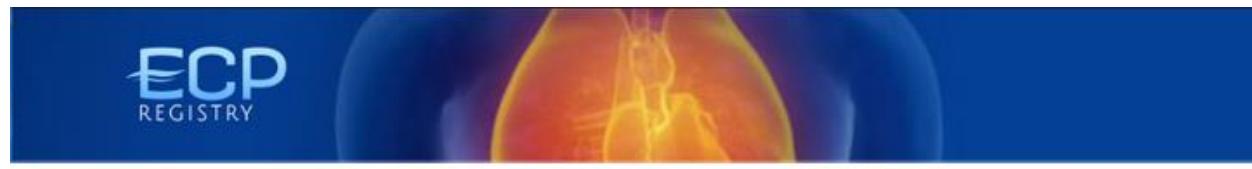
Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED		11-07-2017	<a href="#">View</a>
Demographics	Demographics/Medical History		NEW		11-07-2017	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		NEW		11-07-2017	<a href="#">View</a>
Observation Pulmonary Evaluation Log	Observation Pulmonary Evaluation Log		NEW		11-07-2017	<a href="#">View</a>
Quality of Life	Quality of Life Baseline		NEW			<a href="#">View</a>
Change in Therapy	Change in Therapy Day 30		NEW			<a href="#">View</a>
Change in Therapy	Change in Therapy Day 60		NEW			<a href="#">View</a>
Change in Therapy	Change in Therapy Day 90		NEW			<a href="#">View</a>
Quality of Life	Quality of Life Day 90		NEW			<a href="#">View</a>
Change in Therapy	Change in Therapy Day 120		NEW			<a href="#">View</a>
Change in Therapy	Change in Therapy Day 180		NEW			<a href="#">View</a>
Quality of Life	Quality of Life Day 180		NEW			<a href="#">View</a>

Add New Event...

**Figure 9 - The Participant Summary page for the Observational Arm displays the status of all Events for a participant.**

## 7.0 Event Summary Page

- 7.1** The **Event Summary** page, **Figure** , 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** , 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.



## ECP REFRACTORY BOS WEBSITE

Home Check Enrollment/Arm Eligibility Refractory BOS Investigator Resources Help

**Site Summary - rBOS > Participant Summary > Event Summary**

**Event Summary**

Site Name - ID:	Test Site - 100	Event Type:	Confirmation of Eligibility
Participant ID:	100015	Event Title:	Confirmation of Eligibility
Study Arm:	Observational Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	DCC_VERIFIED
Enrolled Date:	11-07-2017	Event Date:	11-07-2017

Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date
Confirmation of Eligibility	Confirmation of Eligibility Form	DCC_VERIFIED	11-07-2017	11-07-2017

**View**

**Figure – Event Summary**

## 8.0 CRF Data Entry and Navigation

- 8.1** An example CRF is shown in **Figure 11** (Top portion of the Confirmation of Eligibility CRF). The Electronic Data Capture system will log a user out after two hours if the user has not had any 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 Refractory BOS server 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 radio button) 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 a numerical value is outside the allowable range.
- 8.8** Note the line of text near the top of each page, circled in **Figure** above. 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.

**Form Summary**

Site Name - ID: Test Site - 100	Event Type: Confirmation of Eligibility	Form Type: Confirmation of Eligibility
Participant ID: 100013	Event Title: Confirmation of Eligibility	Form Title: Confirmation of Eligibility Form
Study Arm: ECP Treatment Arm	Event Label:	Form Creation Date: 11-03-2017
Participant Status: ENROLLED	Event Status: DCC_VERIFIED	Form Status: DCC_VERIFIED
Enrolled Date: 11-03-2017	Event Date: 11-03-2017	Last Submitted Date: 11-03-2017

**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)**

**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 de-identified 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.

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)
5. Complete Blood Count (CBC) Report
6. Source or FEV1 noting date BOS diagnosed and Refractory BOS diagnosed

Source Document Type	Document Name	Submission Date	
History and Physical or Consultation Note	ECP Registry Attestation Form_6-18-15.pdf	11-03-2017	<input type="button" value="View"/>
History and Physical or Consultation Note	ECP Pre-Procedure Assessment Form.pdf	11-03-2017	<input type="button" value="View"/>
Select Source Document Type A Signed Confirmation of Eligibility Form must be uploaded			
Attach Source Document: <input type="button" value="Browse..."/> No file selected.		<input type="button" value="Upload"/>	

**SECTION A. TRANSPLANT AND BASELINE**

1. Date of lung transplantation: 08/01/2013

2. ISHLT BASELINE MEASUREMENTS - The system will calculate the baseline pulmonary function testing results using the ISHLT definition = the average of the two highest FEV1 measurements obtained 3 weeks apart after transplantation. Please provide the results of the two component PFT assessments to be used for this calculation:

a. First component assessment:

i. Date: 05/04/2014

ii. FEV1 (pre-bronchodilator): 2.4 liters

iii. FVC (pre-bronchodilator): 3.19 liters

b. Second component assessment:

i. Date: 11/19/2013

**Figure – Example CRF**

## 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 12**. After verification, all of the data fields are grayed out (**Figure 13 - 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	<input type="button" value="View"/>

**Figure 12**

### SECTION E. PULMONARY EVALUATIONS

1. Please enter all available FEV1 measurements for the patient collected in the past year.
2. Please enter the FEV1 values from the oldest date at the top to the newest date at the bottom.
3. Five or more FEV1 values must have been obtained within the six months prior to study enrollment and must be at least two weeks apart.
4. FEV1 values must have been obtained regularly for four months preceding enrollment, with no interval between FEV1 measurements exceeding eight weeks in this time period.
5. The most recent FEV1 must have been obtained within two weeks prior to enrollment and must be greater than 900 mL.

<b>A. Date</b> <input type="text" value="05/20/2017"/>	<b>FEV1</b> <input type="text" value="1.56"/> liters	<b>FVC</b> <input type="text" value="1.95"/> liters
<b>B. Date</b> <input type="text" value="06/28/2017"/>	<b>FEV1</b> <input type="text" value="1.62"/> liters	<b>FVC</b> <input type="text" value="1.9"/> liters
<b>C. Date</b> <input type="text" value="07/28/2017"/>	<b>FEV1</b> <input type="text" value="1.51"/> liters	<b>FVC</b> <input type="text" value="2.02"/> liters
<b>D. Date</b> <input type="text" value="08/28/2017"/>	<b>FEV1</b> <input type="text" value="1.5"/> liters	<b>FVC</b> <input type="text" value="2.0"/> liters
<b>E. Date</b> <input type="text" value="09/28/2017"/>	<b>FEV1</b> <input type="text" value="1.4"/> liters	<b>FVC</b> <input type="text" value="1.8"/> liters
<b>F. Date</b> <input type="text" value="10/28/2017"/>	<b>FEV1</b> <input type="text" value="1.3"/> liters	<b>FVC</b> <input type="text" value="1.94"/> liters

**Figure 13 - 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 10**.

2. Gender:  Male  Female

Q2: VERIFICATION STATUS CRF Query

DCC Query Comment: Notes report participant as female

**Figure 10** - 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 11** and **Figure 12** –

B. Date 08/07/2017

B. Date: VERIFICATION STATUS Source Missing

DCC Query Comment:

B. FEV1: VERIFICATION STATUS Source Missing

DCC Query Comment:

B. FVC: VERIFICATION STATUS Source Missing

DCC Query Comment:

**Figure 11** - Verification status of data values marked Source Missing by DCC

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	History and Physical or Consultation Note		

**Figure 12** – Uploaded source documents used for verifying the data values

- 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 13**.

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		CRF_QUERY		11-10-2017	<input type="button" value="View"/>

**Figure 13**

- 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 (See **Figure 14**). When reviewing queries, the location and reference of each query must be carefully noted.

## SECTION E. PULMONARY EVALUATIONS

1. Please enter all available FEV1 measurements for the patient collected in the past year.
2. Please enter the FEV1 values from the oldest date at the top to the newest date at the bottom.
3. Five or more FEV1 values must have been obtained within the six months prior to study enrollment and must be at least two weeks apart.
4. FEV1 values must have been obtained regularly for four months preceding enrollment, with no interval between FEV1 measurements exceeding eight weeks in this time period.
5. The most recent FEV1 must have been obtained within two weeks prior to enrollment and must be greater than 900 mL.

**Figure 14**

- Circled, in **Figure 15**, are the four individual queries, as seen in **Figure 14**.
  - 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.

## SECTION E. PULMONARY EVALUATIONS

1. Please enter all available FEV1 measurements for the patient collected in the past year.
2. Please enter the FEV1 values from the oldest date at the top to the newest date at the bottom.
3. Five or more FEV1 values must have been obtained within the six months prior to study enrollment and must be at least two weeks apart.
4. FEV1 values must have been obtained regularly for four months preceding enrollment, with no interval between FEV1 measurements exceeding eight weeks in this time period.
5. The most recent FEV1 must have been obtained within two weeks prior to enrollment and must be greater than 900 mL.

A. Date 07/07/2017  FEV1 2.5 liters FVC 3.0 liters  
A. Date: VERIFICATION STATUS CRF Query  
Source doc date reads 7/8/2017  
DCC Query Comment:

B. Date 08/07/2017  FEV1 2.4 liters FVC 3.0 liters  
B. Date: VERIFICATION STATUS Source Missing  
Source doc not uploaded  
DCC Query Comment:

B. FEV1: VERIFICATION STATUS Source Missing

B. FVC: VERIFICATION STATUS Source Missing

DCC Query Comment:

**Figure 15**

- Click the drop down box at each data field as it is corrected and select **Unverified**, **Figure** .
- 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**.

A. Date 07/07/2017

FEV1 2.5 liters FVC 3.0 liters

A. Date: VERIFICATION STATUS CRF Query  
Source d Unverified 7/8/2017

DCC Query Comment: CRF Query  
Source Missing

B. Date 08/07/2017

FEV1 2.5 liters FVC 3.0 liters

Figure 20

- 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
- Change in 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
Complete Blood Count (CBC) Report	CBC_xxxxxx_mmddyyyy.pdf
Source or FEV1 noting date BOS diagnosed and Refractory BOS diagnosed	BOSDX_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.  All other forms should use the date on the uploaded document.	xxxxxx = Participant ID mm = 2-digit month 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 “Select Source Document Type” drop down menu, **Figure 216**.

**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)**

**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 de-identified 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.**

**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)
5. Complete Blood Count (CBC) Report
6. Source or FEV1 noting date BOS diagnosed and Refractory BOS diagnosed

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..."/>	No file selected.
		<input type="button" value="Upload"/>

**Figure 216**

**10.6** Select the **Source Document Type** from the drop down menu for the PDF, **Figure 16**.

**10.7** Click the **Browse** button, **Figure 17**.

**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 right of the **Browse** button.

**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)
5. Complete Blood Count (CBC) Report
6. Source or FEV1 noting date BOS diagnosed and Refractory BOS diagnosed

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 style="background-color: #0070C0; color: white; border: none; padding: 2px; margin-right: 10px;" type="button" value="A Signed Confirmation of Eligibility Form must be uploaded"/> History and Physical or Consultation Note Operative Report of Transplant Procedure Pulmonary Function Test Reports (for each FEV-1 submitted) Complete Blood Count (CBC) Report Source or FEV1 noting date BOS diagnosed and Refractory BOS diagnosed	
SECTION A. TRANSPLANT		
1. Date of lung transplant		

*Figure 22 – Source Documents Types from 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)
5. Complete Blood Count (CBC) Report
6. Source or FEV1 noting date BOS diagnosed and Refractory BOS diagnosed

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..."/>	No file selected.	<input type="button" value="Upload"/>

*Figure 17– Browse to PDF file and Upload for the 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 184*.

**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)
5. Complete Blood Count (CBC) Report
6. Source or FEV1 noting date BOS diagnosed and Refractory BOS diagnosed

Source Document Type	Document Name	Submission Date	
A Signed Confirmation of Eligibility Form must be uploaded	COE_101001_11082017.pdf	11-11-2017	<b>View</b> <b>Delete</b>
Select Source Document Type: A Signed Confirmation of Eligibility Form must be uploaded 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"/>			

**Figure 18– Signed COE pdf file uploaded for Confirmation of Eligibility 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.

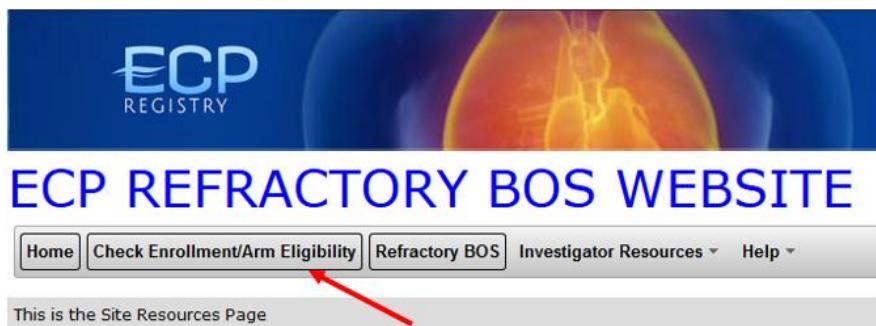
**10.15** Continue until all source document PDF files have been uploaded for the CRF. Select the correct “**Source Document Type**” for each document uploaded.

**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 Refractory BOS study, and to which study arm he/she will be assigned, click the **Check Enrollment/Arm Eligibility** button, **Figure 19** on the Site Resources page.



**Figure 19**

- 11.2** The Enrollment Assessment and Study Arm Eligibility worksheet displays. The current date is automatically populated, as shown in **Figure 20**. Use the tab key or mouse to navigate to answer all questions.

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:** 11/08/2017

**SECTION A. TRANSPLANT AND BASELINE**

1. Date of lung transplantation:

2. ISHLT BASELINE MEASUREMENTS - The system will calculate the baseline pulmonary function testing results using the ISHLT definition = the average of the two highest FEV1 measurements obtained 3 weeks apart after transplantation. Please provide the results of the two component PFT assessments to be used for this calculation:

a. First component assessment:

i. Date:

ii. FEV1 (pre-bronchodilator):  liters

iii. FVC (pre-bronchodilator):  liters

**Figure 20**

- 11.3** The Enrollment Assessment and Study Arm Eligibility worksheet is divided into seven sections.

- The Transplant and Baseline section is shown in **Figure 22**.
  - Enter the dates for the lung transplantation and 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 pre-bronchodilator values of each recorded FEV1 and FVC obtained at baseline after the lung transplantation. NOTE: the “c. Baseline FEV1...” value will automatically be calculated for you based on the numerical values you enter.

**SECTION A. TRANSPLANT AND BASELINE**

1. Date of lung transplantation:

2. ISHLT BASELINE MEASUREMENTS - The system will calculate the baseline pulmonary function testing results using the ISHLT definition = the average of the two highest FEV1 measurements obtained 3 weeks apart after transplantation. Please provide the results of the two component PFT assessments to be used for this calculation:

a. First component assessment:

i. Date:

ii. FEV1 (pre-bronchodilator):  liters

iii. FVC (pre-bronchodilator):  liters

b. Second component assessment:

i. Date:

ii. FEV1 (pre-bronchodilator):  liters

iii. FVC (pre-bronchodilator):  liters

c. Baseline FEV1 (pre-bronchodilator)(mean FEV1 values above):  liters

**Figure 21 - Confirmation of Eligibility Transplant and Baseline Section**

- The Inclusion Criteria section is shown in **Figure 22**. Answer all inclusion questions by clicking the appropriate radio button. All answers must be "YES" to be eligible for the ECP Refractory BOS study.

**SECTION B. INCLUSION CRITERIA - all answers must be "YES" for subject to be eligible:**

- YES    NO   Age 18 years or older
- YES    NO   Medicare-eligible (i.e. patients with both Part A and B) status
- YES    NO   Lung transplant recipient (combined organ transplant recipients, e.g. heart-lung or liver-lung recipients, are eligible)
- YES    NO   Refractory BOS defined as ongoing decline in FEV1 despite at least one of the following treatments: azithromycin, high dose steroid, anti-thymocyte globulin, total lymphoid irradiation, sirolimus, or everolimus
- YES    NO   Patients with a diagnosis of BOS using at least two laboratory based FEV1 values obtained at least three weeks apart that are both at least 20% lower than baseline FEV1 using the ISHLT definition (the average of the two highest FEV1 measurements obtained at least three weeks apart after transplantation)
- YES    NO   At minimum five recorded FEV1 measurements obtained at intervals at least two weeks apart over the six months preceding study enrollment, of which one FEV1 must be within two weeks of enrollment
- YES    NO   History of frequent spirometry monitoring, defined as having had regular FEV1 measurements during the preceding four months to enrollment with no time interval between FEV1 measurements that exceeds eight weeks
- YES    NO   A documented clinical assessment including a physical assessment and CBC with WBC within two weeks prior to enrollment

**Figure 22 - Confirmation of Eligibility Inclusion Criteria Section**

- The **Exclusion Criteria** section is shown in **Figure 23**. Answer all Exclusion questions by clicking the appropriate radio button. All answers must be “NO” for the participant to be eligible.

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

- |                                  |                                 |   |
|----------------------------------|---------------------------------|---|
| <input type="radio"/> <b>YES</b> | <input type="radio"/> <b>NO</b> | Current participation in another clinical treatment trial with an investigational agent   |
| <input type="radio"/> <b>YES</b> | <input type="radio"/> <b>NO</b> | Any condition that may interfere with subject's ability to perform pulmonary function testing   |
| <input type="radio"/> <b>YES</b> | <input type="radio"/> <b>NO</b> | Known allergy or hypersensitivity to pharmacologic agents used during ECP   |
| <input type="radio"/> <b>YES</b> | <input type="radio"/> <b>NO</b> | Has a) acute contraindication to receiving ECP due to any acute condition such as new or evolving myocardial infarction or central nervous system disorder, hemodynamic instability or hypovolemia, acute bleeding, respiratory distress; b) lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyrin, variegate porphyria, xeroderma pigmentosum, albinism, or other dermatologic or ocular condition that contraindicates the use of methoxsalen or markedly enhances photosensitivity in the investigator's judgment; or c) other condition that poses unacceptable risk for study-related complications as judged by the referring clinician |
| <input type="radio"/> <b>YES</b> | <input type="radio"/> <b>NO</b> | Any condition that would significantly affect the participant's ability to adhere to the protocol or affect interpretability of the study results   |
| <input type="radio"/> <b>YES</b> | <input type="radio"/> <b>NO</b> | Aphakia or absence of ocular lenses   |
| <input type="radio"/> <b>YES</b> | <input type="radio"/> <b>NO</b> | Pregnancy (confirmed by a positive pregnancy test)  |
| <input type="radio"/> <b>YES</b> | <input type="radio"/> <b>NO</b> | Inability to provide informed consent or to comply with study treatments or assessments (e.g. due to cognitive impairment or geographic distance)   |
| <input type="radio"/> <b>YES</b> | <input type="radio"/> <b>NO</b> | Recent (i.e., within two weeks prior to enrollment) leukopenia (white blood cell count less than 3,000 cells/mm <sup>3</sup> )  |
| <input type="radio"/> <b>YES</b> | <input type="radio"/> <b>NO</b> | Decline in lung function (FEV1) is related to either Restrictive CLAD or other causes that do not represent BOS such as pneumonia, heart failure, etc   |
| <input type="radio"/> <b>YES</b> | <input type="radio"/> <b>NO</b> | Patient's most recent FEV1 is equal to or less than 900 mL  |

**Figure 23 - Confirmation of Eligibility Exclusion Criteria Section**

- The **BOS Diagnosis Information** section is shown in **Figure** .
  - Enter the dates for the diagnosis of post-transplantation BOS (new BOS), diagnosis for ECP Refractory BOS, and 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 pre-bronchodilator values of each recorded FEV1 and FVC obtained at diagnosis of post-transplantation BOS (new BOS) and diagnosis for ECP Refractory BOS.

## SECTION D. BOS DIAGNOSIS INFORMATION

1. Date of diagnosis of post-transplantation BOS:  

2. Laboratory-based FEV1 values used to confirm the initial diagnosis of BOS:

a. First component assessment:

i. Date:  

ii. FEV1 (pre-bronchodilator):  liters

iii. FVC (pre-bronchodilator):  liters

b. Second component assessment:

i. Date:  

ii. FEV1 (pre-bronchodilator):  liters

iii. FVC (pre-bronchodilator):  liters

c. Third component assessment (if needed):

i. Date:  

ii. FEV1 (pre-bronchodilator):  liters

iii. FVC (pre-bronchodilator):  liters

3. Date of diagnosis of refractory BOS:  

4. Laboratory-based FEV1 values used to confirm the diagnosis of refractory BOS:

a. First component assessment:

i. Date:  

ii. FEV1 (pre-bronchodilator):  liters

iii. FVC (pre-bronchodilator):  liters

b. Second component assessment:

i. Date:  

ii. FEV1 (pre-bronchodilator):  liters

iii. FVC (pre-bronchodilator):  liters

c. Third component assessment (if needed):

i. Date:  

ii. FEV1 (pre-bronchodilator):  liters

iii. FVC (pre-bronchodilator):  liters

*Figure 30 - Confirmation of Eligibility BOS Diagnosis Information*

- The **Pulmonary Evaluations** section is shown in *Figure* .
  - 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 26) obtained within the last 12 months. If more than 26 FEV1s are available in the last 12 months, record only the most recent 26 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 two weeks apart.
  - The most recent FEV1 value must be from within the two weeks of enrollment.
  - Enter FEV1 and FVC values in chronological order beginning with the oldest date first starting in A. Date and proceeding down the list of dates.

#### **SECTION E. PULMONARY EVALUATIONS**

- 1. Please enter all available FEV1 measurements for the patient collected in the past year.**
- 2. Please enter the FEV1 values from the oldest date at the top to the newest date at the bottom.**
- 3. Five or more FEV1 values must have been obtained within the six months prior to study enrollment and must be at least two weeks apart.**
- 4. FEV1 values must have been obtained regularly for four months preceding enrollment, with no interval between FEV1 measurements exceeding eight weeks in this time period.**
- 5. The most recent FEV1 must have been obtained within two weeks prior to enrollment and must be greater than 900 mL.**

<b>A. Date</b> <input type="text"/> 	<b>FEV1</b> <input type="text"/> liters	<b>FVC</b> <input type="text"/> liters
<b>B. Date</b> <input type="text"/> 	<b>FEV1</b> <input type="text"/> liters	<b>FVC</b> <input type="text"/> liters
<b>C. Date</b> <input type="text"/> 	<b>FEV1</b> <input type="text"/> liters	<b>FVC</b> <input type="text"/> liters
<b>D. Date</b> <input type="text"/> 	<b>FEV1</b> <input type="text"/> liters	<b>FVC</b> <input type="text"/> liters
<b>E. Date</b> <input type="text"/> 	<b>FEV1</b> <input type="text"/> liters	<b>FVC</b> <input type="text"/> liters
<b>F. Date</b> <input type="text"/> 	<b>FEV1</b> <input type="text"/> liters	<b>FVC</b> <input type="text"/> liters
<b>G. Date</b> <input type="text"/> 	<b>FEV1</b> <input type="text"/> liters	<b>FVC</b> <input type="text"/> liters
<b>H. Date</b> <input type="text"/> 	<b>FEV1</b> <input type="text"/> liters	<b>FVC</b> <input type="text"/> liters

*Figure 31 - Confirmation of Eligibility Pulmonary Evaluations Section*

- Clinical Assessment section is shown in *Figure* .
  - Enter the date for the physical exam and the CBC. Both the physical exam and CBC date must be within two weeks of the enrollment date.
  - Enter the CBC values.

**SECTION F. CLINICAL ASSESSMENTS**

1. Date of most recent physical exam  

2. Most Recent Complete Blood Count (CBC)

Date of CBC:  

WBCs:  (K/cumm)

RBCs:  (M/cumm)

Hemoglobin:  (g/dl)

Hematocrit:  (%)

Platelets:  (K/cumm)

*Figure 32 - Confirmation of Eligibility Clinical Assessment Section*

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

**SECTION G. CONFIRMATION OF ENROLLMENT**

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

B. Informed Consent Form Version Date  



*Figure 33 - Confirmation of Eligibility Confirmation of Enrollment Section*

- 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* .

Critical Note: Eligibility and study arm determination are based upon the data entered into 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 that may contain one of the following three pages for: (1) the **ECP Treatment Arm Results**, *Figure* , (2) the **Observation Arm Results**, *Figure 35*, or (3) a **participant excluded from enrollment**, *Figure 36*.

NOTE: **Figure 35** 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* .
- 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* .
- If the inclusion/exclusion criteria or the slope calculation is too great are not met, then the individual is not eligible to participate in the study, *Figure 24a and 36b*. You will have the option to review the data to make sure this determination is not due to incorrect data entry by clicking the "Review Data Entry" button.

**Enrollment Determination Results**

This patient is now ENROLLED into the Study. 

**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 34* - Shows the Enrollment Determination Results page for the ECP Treatment Arm

### Enrollment Determination Results

This patient is now ENROLLED into the Study.

### 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  $\geq -30$  when the minimum FEV1  $\geq 1200$  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 35 - Shows the Enrollment Determination Results page for the Observation Arm

### Enrollment Determination Results

This patient MAY NOT be enrolled at this time. To be eligible for study enrollment, the patient must meet all study Inclusion Criteria and no study Exclusion Criteria.

All of the Inclusion Criteria questions must be marked YES and all of the Exclusion Criteria questions must be marked NO to be eligible for study enrollment.

[Review Data Entry](#)

[Return to Site Page](#)

Figure 24a- Shows the Enrollment Determination Results for a participant excluded from enrollment based on wrong answer for an inclusion or exclusion criteria

### Enrollment Determination Results

**This patient MAY NOT be enrolled at this time because the most recent physical assessment is older than two weeks.**

**To be eligible for study enrollment, the patient must meet all study Inclusion Criteria and no study Exclusion Criteria.**

[Review Data Entry](#) [Return to Site Page](#)

**Figure 25b-** Shows the Enrollment Determination Results for a participant excluded from enrollment based on a calculated date or measurement range (a specific reason will be given)

- 11.7** If eligible for enrollment into the ECP Refractory BOS study, 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 (See **Figures 34 or 35**). 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** button 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 26**  
- 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**.

## SECTION H. 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 26 - 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 Case Report Form (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
  - Complete Blood Count (CBC) Report
  - Source or FEV1 noting date BOS diagnosed and Refractory BOS diagnosed
- 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
  - Complete Blood Count
  - BOS diagnosis and refractory BOS diagnosis
- To complete the **Confirmation of Eligibility** CRF:
- Click the **Refractory BOS** button to be directed to the **Site Summary** page, *Figure 27*.



*Figure 27 – Refractory BOS button*

- On the **Site Summary** page find the assigned **Participant ID** and click **View**. *Figure 28*.

Site Summary - Refractory BOS (rBOS)												User name: pkc_sc	logout	
Site Summary - rBOS														
Site Name - ID: Test Site - 100														
Participant ID	Enrolled Date	rBOS Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	Missed Visit			
100016	11-08-2017	ECP Treatment Arm	ENROLLED	1	0	0	0	0	0	0	0			

*Figure 28*

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

Site Summary - rBOS > Participant Summary 

**Participant Summary**

Site Name - ID: Test Site - 100  
 Participant ID: 100016  
 Study Arm: ECP Treatment Arm  
 Participant Status: ENROLLED  
 Enrolled Date: 11-08-2017

[Add New Event...](#)

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Confirmation of Eligibility	Confirmation of Eligibility		NEW			11-08-2017	<a href="#">View</a>

[Add New Event...](#)



**Figure 40**

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

Site Summary - rBOS > Participant Summary > Event Summary 

**Event Summary**

Site Name - ID: Test Site - 100      Event Type: Confirmation of Eligibility  
 Participant ID: 100016      Event Title: Confirmation of Eligibility  
 Study Arm: ECP Treatment Arm      Event Label:  
 Participant Status: ENROLLED      Event Status: NEW  
 Enrolled Date: 11-08-2017      Event Date: 11-08-2017

Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date	
Confirmation of Eligibility	Confirmation of Eligibility Form	NEW	11-08-2017	11-08-2017	<a href="#">View</a>



**Figure 41**

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

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

**Form Summary**

Site Name - ID:	Test Site - 100	Event Type:	Confirmation of Eligibility	Form Type:	Confirmation of Eligibility
Participant ID:	100016	Event Title:	Confirmation of Eligibility	Form Title:	Confirmation of Eligibility Form
Study Arm:	ECP Treatment Arm	Event Label:		Form Creation Date:	11-08-2017
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	11-08-2017	Event Date:	11-08-2017	Last Submitted Date:	11-08-2017

**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 42*

- 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**.
- **Figure** shows an example of the top portion of a Confirmation of Eligibility CRF with many of the 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.

Figure 43

- In Section H, answer question D, "Has the signed Confirmation of Eligibility CRF been uploaded?" **Figure .**

## SECTION G. CONFIRMATION OF ELIGIBILITY

<b>A. Date eligibility status confirmed</b>	11/08/2017
<b>B. Date the approved Informed Consent Form was signed by the subject</b>	11/08/2017
<b>C. Informed Consent Form Version Date</b>	11/08/2017
<b>D. Has the signed Confirmation of Eligibility CRF been uploaded?</b>	<input checked="" type="radio"/> YES <input type="radio"/> NO

Figure 44

- 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,

#### SECTION H. 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 .*

#### SECTION H. 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 45*

- 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 29*.

Site Summary - rBOS > Participant Summary

**Participant Summary**

Site Name - ID: Test Site - 100  
 Participant ID: 100016  
 Study Arm: ECP Treatment Arm  
 Participant Status: ENROLLED  
 Enrolled Date: 11-08-2017

[Add New Event...](#)

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		SUBMITTED		11-08-2017	<a href="#">View</a>

[Add New Event...](#)

**Figure 29**

**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 Refractory BOS study.**

- 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 CRF

- The **Demographics/Medical History** 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 **Refractory BOS** button, which will direct you to the **Site Summary** page, *Figure 30*.
- On the **Site Summary** page locate the correct participant using the assigned **Participant ID** and click **View**. *Figure 30*.



**ECP REFRACTORY BOS WEBSITE**

Site Summary - Refractory BOS (rBOS) User name: pkc\_sc logout

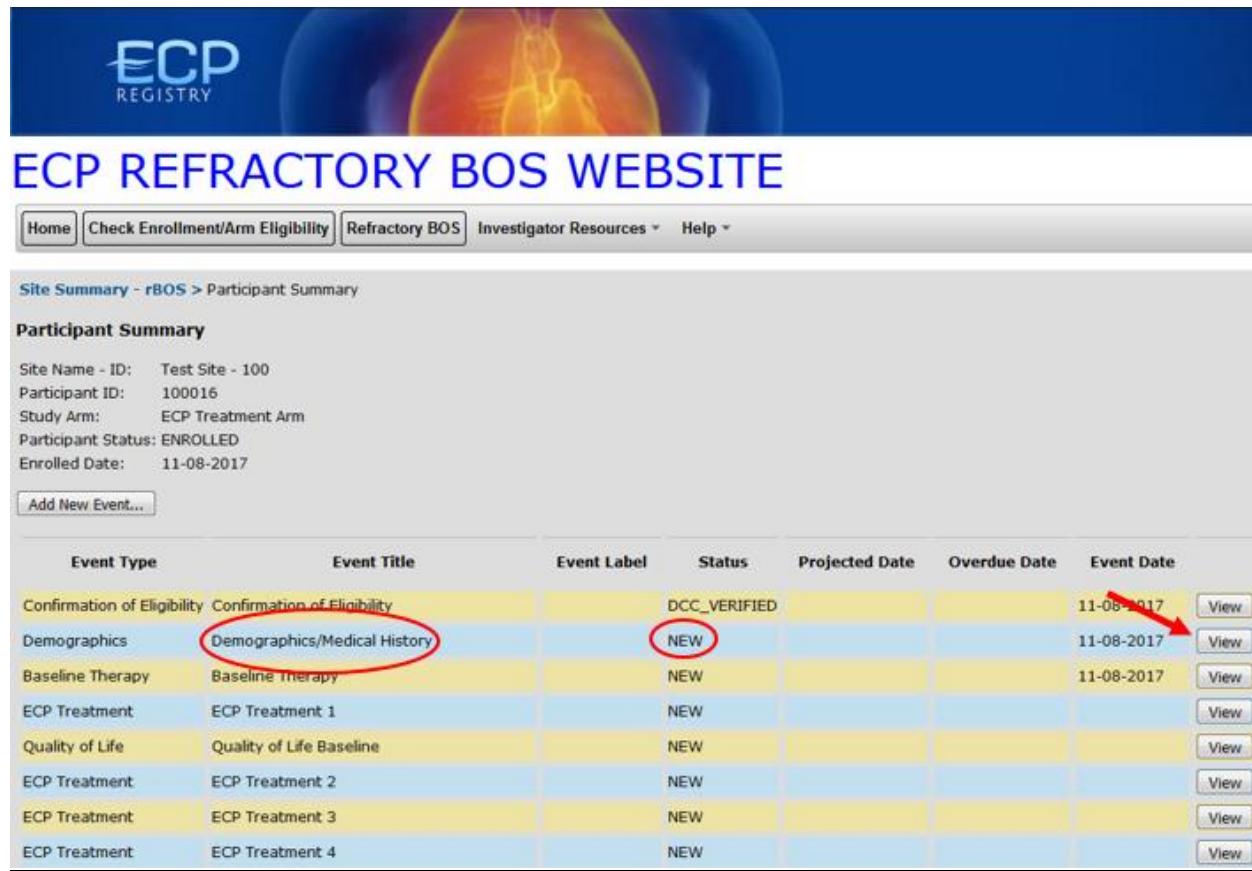
**Site Summary - rBOS**

Site Name - ID: Test Site - 100

Participant ID	Enrolled Date	rBOS Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	Missed Visit
100015	11-07-2017	Observational Arm	ENROLLED	11	0	0	0	1	0	0	<a href="#">View</a>
100016	11-08-2017	ECP Treatment Arm	ENROLLED	47	0	0	0	1	0	0	<a href="#">View</a>

**Figure 30**

- The **Participant Summary** page is displayed, *Figure 31*.
- If the **Demographics/Medical History** event **Status** column reads **NEW**, then this CRF has not been started or submitted, click **View**, *Figure 31*.
- The columns for the **Projected Date** and the **Overdue Date** are populated after the first ECP treatment CRF is submitted.



**ECP REFRACATORY BOS WEBSITE**

Home Check Enrollment/Arm Eligibility Refractory BOS Investigator Resources Help

Site Summary - rBOS > Participant Summary

**Participant Summary**

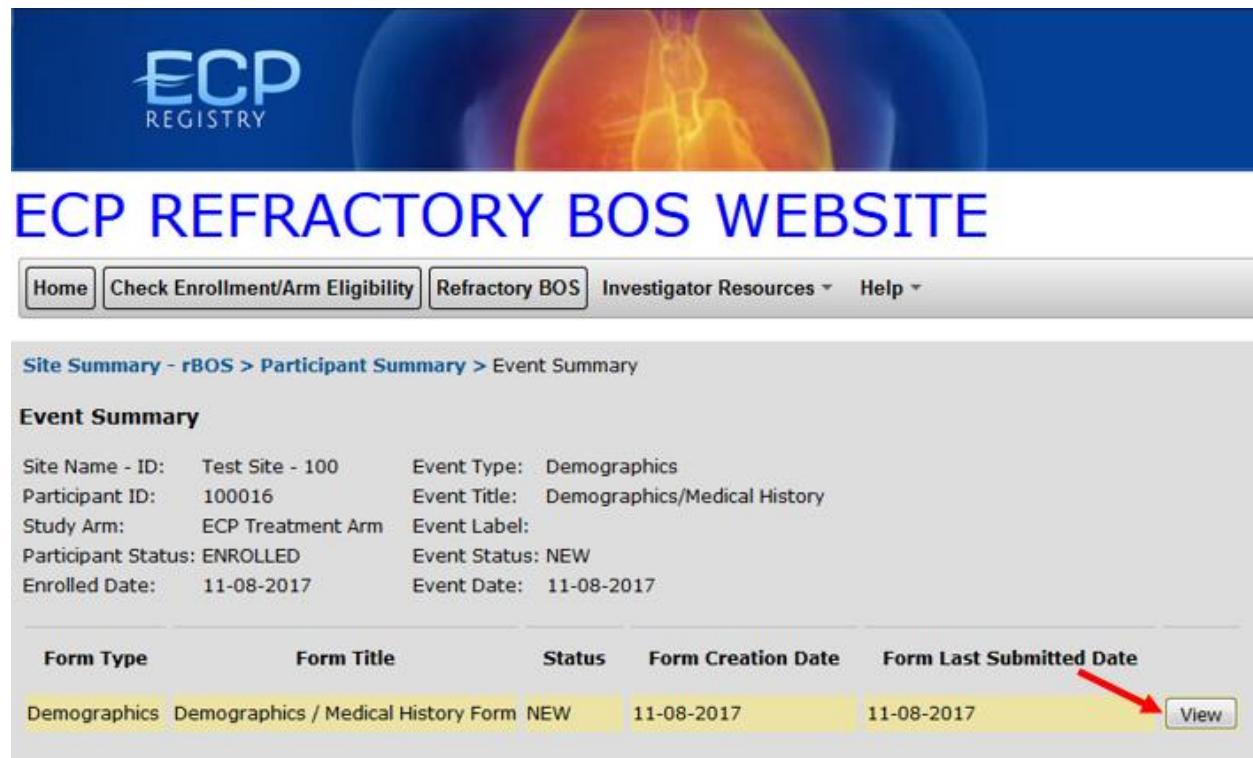
Site Name - ID: Test Site - 100  
 Participant ID: 100016  
 Study Arm: ECP Treatment Arm  
 Participant Status: ENROLLED  
 Enrolled Date: 11-08-2017

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED		11-08-2017	<a href="#">View</a>
Demographics	Demographics/Medical History		NEW		11-08-2017	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		NEW		11-08-2017	<a href="#">View</a>
ECP Treatment	ECP Treatment 1		NEW			<a href="#">View</a>
Quality of Life	Quality of Life Baseline		NEW			<a href="#">View</a>
ECP Treatment	ECP Treatment 2		NEW			<a href="#">View</a>
ECP Treatment	ECP Treatment 3		NEW			<a href="#">View</a>
ECP Treatment	ECP Treatment 4		NEW			<a href="#">View</a>

**Figure 31**

- Clicking **View** directs you to the **Event Summary** page. The **Demographics/Medical History** event is listed here, click **View**, **Figure 32**.



**ECP REFRACtORY BOS WEBSITE**

Site Summary - rBOS > Participant Summary > Event Summary

**Event Summary**

Site Name - ID:	Test Site - 100	Event Type:	Demographics
Participant ID:	100016	Event Title:	Demographics/Medical History
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	11-08-2017	Event Date:	11-08-2017

Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date	
Demographics	Demographics / Medical History Form	NEW	11-08-2017	11-08-2017	<a href="#">View</a>

**Figure 32**

- 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 the **Demographics/Medical History** CRF, **Figure** .



# ECP REFRACTORY BOS WEBSITE

Home | Check Enrollment/Arm Eligibility | Refractory BOS | Investigator Resources | Help

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

**Form Summary**

Site Name - ID:	Test Site - 100	Event Type:	Demographics	Form Type:	Demographics
Participant ID:	100016	Event Title:	Demographics/Medical History	Form Title:	Demographics / Medical History Form
Study Arm:	ECP Treatment Arm	Event Label:		Form Creation Date:	11-08-2017
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	11-08-2017	Event Date:	11-08-2017	Last Submitted Date:	11-08-2017

**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"/>	
<b>Date of Participant Enrollment in Study:</b> <input type="text" value="11/08/2017"/>		

Figure 50

- The entire Demographics/Medical History CRF is shown in **Figure 51a - Demographics/Medical History**.

<b>Form Summary</b>					
Site Name - ID:	Test Site - 100	Event Type:	Demographics	Form Type:	Demographics
Participant ID:	100016	Event Title:	Demographics/Medical History	Form Title:	Demographics / Medical History Form
Study Arm:	ECP Treatment Arm	Event Label:		Form Creation Date:	11-08-2017
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	11-08-2017	Event Date:	11-08-2017	Last Submitted Date:	11-08-2017

**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:**

**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:

**Figure 51a - Demographics/Medical History**

7. Operation performed:

Single  
 Bilateral  
 Heart-lung  
 Other

If other, please describe:

8. Weight at time of transplant:  kilograms  Not Available

9. Height:  centimeters  Not Available

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 Azathioprine  
 YES  NO Cyclosporine A  
 YES  NO Methotrexate  
 YES  NO Macrolide Antibiotic, Azithromycin  
 YES  NO Mycophenolate Mofetil (Cellcept or Myfortic)  
 YES  NO Anti-Thymocyte Globulin - ATG (Thymoglobulin or Altgam)

Figure 33- Demographics/Medical History

<p><input type="radio"/> YES <input type="radio"/> NO      Total Lymphoid Irradiation</p> <p><input type="radio"/> YES <input type="radio"/> NO      Other Drug(s)</p> <p>If YES for Other Drug(s), please provide the drug name(s)</p> <div style="border: 1px solid black; height: 40px; margin-top: 5px;"></div>												
<p>13. Check all drugs that were <u>previously used as active treatment of BOS</u> in this participant:</p> <p><input type="radio"/> YES <input type="radio"/> NO      Tacrolimus</p> <p><input type="radio"/> YES <input type="radio"/> NO      Prednisone</p> <p><input type="radio"/> YES <input type="radio"/> NO      Alemtuzumab</p> <p><input type="radio"/> YES <input type="radio"/> NO      Sirolimus (Rapamycin)</p> <p><input type="radio"/> YES <input type="radio"/> NO      Everolimus</p> <p><input type="radio"/> YES <input type="radio"/> NO      Azathioprine</p> <p><input type="radio"/> YES <input type="radio"/> NO      Cyclosporine A</p> <p><input type="radio"/> YES <input type="radio"/> NO      Methotrexate</p> <p><input type="radio"/> YES <input type="radio"/> NO      Macrolide Antibiotic, Azithromycin</p> <p><input type="radio"/> YES <input type="radio"/> NO      Mycophenolate Mofetil (Cellcept or Myfortic)</p> <p><input type="radio"/> YES <input type="radio"/> NO      Anti-Thymocyte Globulin - ATG (Thymoglobulin or Atgam)</p> <p><input type="radio"/> YES <input type="radio"/> NO      Total Lymphoid Irradiation</p> <p><input type="radio"/> YES <input type="radio"/> NO      Other Drug(s)</p> <p>If YES for Other Drug(s), please provide the drug name(s)</p> <div style="border: 1px solid black; height: 40px; margin-top: 5px;"></div>												
<p>14. Has the participant received prednisone therapy within the last 6 months?    <input type="radio"/> YES    <input type="radio"/> NO</p> <p>If yes, daily starting dose: <input type="text"/> mg</p> <p>15. During the last 6 months, has the patient required a prednisone dose escalation for any period of greater than 5 days?    <input type="radio"/> YES    <input type="radio"/> NO</p> <p>If yes, to what daily dose: <input type="text"/> mg</p> <p>Estimate average daily dose over 6 months: <input type="text"/> mg</p> <p>16. Date of diagnosis of post-transplantation BOS: <input type="text" value="11/29/2016"/> <input type="button" value=""/></p> <p>17. Post-transplant BOS stage at diagnosis:    <input type="radio"/> 0    <input type="radio"/> 0-p    <input type="radio"/> 1    <input type="radio"/> 2    <input type="radio"/> 3</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center; padding: 2px;">Stage</th> <th style="text-align: center; padding: 2px;">Definition</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; padding: 2px;">BOS Stage 0</td> <td style="text-align: center; padding: 2px;">FEV1 &gt; 90% and FEF 25%-75% &gt; 75% of baseline</td> </tr> <tr> <td style="text-align: center; padding: 2px;">BOS Stage 0-p</td> <td style="text-align: center; padding: 2px;">FEV1 = 81% to 90% of baseline and/or FEF 25%-75% &gt; 75% of baseline</td> </tr> <tr> <td style="text-align: center; padding: 2px;">BOS Stage 1</td> <td style="text-align: center; padding: 2px;">FEV1 = 66% to 80% of baseline</td> </tr> <tr> <td style="text-align: center; padding: 2px;">BOS Stage 2</td> <td style="text-align: center; padding: 2px;">FEV1 = 51% to 65% of baseline</td> </tr> <tr> <td style="text-align: center; padding: 2px;">BOS Stage 3</td> <td style="text-align: center; padding: 2px;">FEV1 less than or equal to 50% of baseline</td> </tr> </tbody> </table> <p>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:</p> <p>a. Baseline FEV1 (pre-bronchodilator)(mean FEV1 values below): 4.0    liters</p> <p>b. First component assessment:</p> <p>i. Date: <input type="text" value="11/05/2015"/> <input type="button" value=""/></p>	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
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											

Figure 34- Demographics/Medical History

ii. FEV1 (pre-bronchodilator): 4.0 liters

iii. FVC (pre-bronchodilator): 5.0 liters

c. Second component assessment:

i. Date: 11/29/2015

ii. FEV1 (pre-bronchodilator): 4.0 liters

iii. FVC (pre-bronchodilator): 5.0 liters

**SECTION C. Clinical Status at or Within Two Weeks 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 two weeks 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? \_\_\_\_\_ Select delivery method: \_\_\_\_\_

28. Comments: \_\_\_\_\_

**Figure 35- Demographics/Medical History**

- Complete Sections A, B, and C of the CRF, **Figure 51a - 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** . For help uploading the required source documents as PDFs, see [Section 10.0 Uploading Scanned Source Document PDF files](#).

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	
History and Physical or Consultation Note	HX_101000_01072015.pdf	2015-01-13	<a href="#">View</a>
Operative Report of Transplant Procedure	ORTP_101000_05132014.pdf	2015-01-13	<a href="#">View</a>
Pulmonary Function Test Reports (for each FEV-1 submitted)	PFT_101000_06132014.pdf	2015-01-13	<a href="#">View</a>
Pulmonary Function Test Reports (for each FEV-1 submitted)	PFT_101000_07062014.pdf	2015-01-13	<a href="#">View</a>
Select Source Document Type	History and Physical or Consultation Note		
Attach Source Document:	<input type="button" value="Browse..."/>	<input type="button" value="Upload"/>	

**Figure 52**

- 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 53**.

27. Is the participant receiving supplemental oxygen?  YES  NO

If yes, how much?  liters/minute

28. Comments:



**Figure 53**

- 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 36**.

**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"/>		
<b>Date of Participant Enrollment in Study:</b> <input type="text" value="11/08/2017"/>		
<b><u>SECTION A. Demographic Information</u></b>		
1. Age: <input type="text"/> <input checked="" type="checkbox"/> Validation Error: Age ranges between 18 and 99 years		

**Figure 36**

- 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 37**.

**Participant Summary**

Site Name - ID: Test Site - 100  
 Participant ID: 100016  
 Study Arm: ECP Treatment Arm  
 Participant Status: ENROLLED  
 Enrolled Date: 11-08-2017

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED		11-08-2017	<input type="button" value="View"/>
Demographics	Demographics/Medical History		SUBMITTED		11-08-2017	<input type="button" value="View"/>
Baseline Therapy	Baseline Therapy		NEW		11-08-2017	<input type="button" value="View"/>
ECP Treatment	ECP Treatment 1		NEW			<input type="button" value="View"/>
Quality of Life	Quality of Life Baseline		NEW			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 2		NEW			<input type="button" value="View"/>
ECP Treatment	ECP Treatment 3		NEW			<input type="button" value="View"/>

**Figure 37**

### 12.3 Baseline Therapy CRF

- The **Baseline Therapy** CRF is completed for both ECP Treatment and Observation Arm participants.
- The following source documents are required to complete this online CRF:
  - Clinical Note or Medication Record Form
- To Complete the CRF:
  - Click the **Refractory BOS** button, which will direct you to the **Site Summary** page.
  - On the **Site Summary** page locate the correct patient by assigned **Participate ID** and click **View**.
  - The **Participant Summary** page is now displayed, *Figure 38*.
  - The **Baseline Therapy** event **Status** column reads **NEW**, because the CRF has not been started or submitted, *Figure 38*.
  - 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.

**Participant Summary**

Site Name - ID:	Test Site - 100					
Participant ID:	100016					
Study Arm:	ECP Treatment Arm					
Participant Status:	ENROLLED					
Enrolled Date:	11-08-2017					
<a href="#">Add New Event...</a>						
Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED		11-08-2017	<a href="#">View</a>
Demographics	Demographics/Medical History		SUBMITTED		11-08-2017	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		NEW		11-08-2017	<a href="#">View</a>
ECP Treatment	ECP Treatment 1		NEW			<a href="#">View</a>
Quality of Life	Quality of Life Baseline		NEW			<a href="#">View</a>
ECP Treatment	ECP Treatment 2		NEW			<a href="#">View</a>
ECP Treatment	ECP Treatment 3		NEW			<a href="#">View</a>

*Figure 38*

- Clicking **View** directs you to the **Event Summary** page, *Figure 39*, where the **Baseline Therapy** event is listed. Click **View**.

Event Summary				
Site Name - ID:	Test Site - 100	Event Type:	Baseline Therapy	
Participant ID:	100016	Event Title:	Baseline Therapy	
Study Arm:	ECP Treatment Arm	Event Label:		
Participant Status:	ENROLLED	Event Status:	NEW	
Enrolled Date:	11-08-2017	Event Date:	11-08-2017	
Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date
Baseline Therapy	Baseline Therapy Form	NEW	11-08-2017	11-08-2017
				<a href="#">View</a>

**Figure 39**

- 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 40**.

Form Summary					
Site Name - ID:	Test Site - 100	Event Type:	Baseline Therapy	Form Type:	Baseline Therapy
Participant ID:	100016	Event Title:	Baseline Therapy	Form Title:	Baseline Therapy Form
Study Arm:	ECP Treatment Arm	Event Label:		Form Creation Date:	11-08-2017
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	11-08-2017	Event Date:	11-08-2017	Last Submitted Date:	11-08-2017
<b>Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts</b>					
<b>BASELINE THERAPY - Case Report Form (CRF)</b>					
<b>Please include the following types of source documents:</b>					
<b>1. Clinical Note or Medication Record Form</b>					
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..."/>	No file selected.	<input type="button" value="Upload"/>		
<input type="button" value="Save"/>	<input type="button" value="Submit"/>				
<b>Baseline Therapy Date:</b> <span style="border: 1px solid green; padding: 2px;">11/08/2017</span>					

**Figure 40**

- 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 Event and Form **Status** of the CRF will be changed to **Started**. You may then return to the document later and complete it or make changes, **Figure 41**.

<b>Event Summary</b>					
Site Name - ID:	Test Site - 100	Event Type:	Baseline Therapy	Event Title:	Baseline Therapy
Participant ID:	100016	Event Label:		Event Status:	STARTED
Study Arm:	ECP Treatment Arm	Event Date:	11-08-2017	Form Creation Date:	11-08-2017
Participant Status:	ENROLLED	Form Last Submitted Date:		Form Type:	Baseline Therapy
Enrolled Date:	11-08-2017			Form Title:	Baseline Therapy Form

Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date	
Baseline Therapy	Baseline Therapy Form	STARTED	11-08-2017	11-08-2017	<b>View</b>

**Figure 41**

- 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 60**.

**Baseline Therapy Date:** 11/08/2017

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

YES  NO Tacrolimus  
 YES  NO Alemtuzumab  
 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 Anti-Thymocyte Globulin - ATG (Thymoglobulin or Atgam)  
 YES  NO Total Lymphoid Irradiation  
 YES  NO Other Drug(s)

If YES for Other Drug(s), please provide the drug name(s):

2. Is the patient taking prednisone?  YES  NO

If yes, enter daily dose: \_\_\_\_\_ mg (input range: 0-150)

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

If yes, list drugs:

Name anticoagulant 1: \_\_\_\_\_

Name anticoagulant 2: \_\_\_\_\_

Name anticoagulant 3: \_\_\_\_\_

4. 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: \_\_\_\_\_

5. Comments:

Save  

Figure 60

- 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* . 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 61

- 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* .

ECP REGISTRY

## ECP REFRACtORY BOS WEBSITE

Home Check Enrollment/Arm Eligibility Refractory BOS Investigator Resources Help

Site Summary - rBOS > Participant Summary

**Participant Summary**

Site Name - ID: Test Site - 100  
 Participant ID: 100016  
 Study Arm: ECP Treatment Arm  
 Participant Status: ENROLLED  
 Enrolled Date: 11-08-2017

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED		11-08-2017	<a href="#">View</a>
Demographics	Demographics/Medical History		SUBMITTED		11-08-2017	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		SUBMITTED		11-08-2017	<a href="#">View</a>
ECP Treatment	ECP Treatment 1		NEW			<a href="#">View</a>

Figure 62

## 12.4 ECP Treatment Visit CRF

- The following source documents are required to complete the **ECP Treatment Visit CRF**:
  - Photopheresis Procedure Note/Report
  - CBC - Lab Report
  - Progress Note or Clinical Note describing complications, if any
  - **NOTE:** In case the whole blood processing was not completed, the following source document is required: Source describing why whole blood processing not completed as required (if applicable)
- One form must be completed per ECP treatment visit.
- To Complete the **ECP Treatment Visit CRF**:
  - Click the **Refractory BOS** 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 42*.



**ECP REFRACTORY BOS WEBSITE**

Participant ID	Enrolled Date	rBOS Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PT Approved	Not Required	Missed Visit
100015	11-07-2017	Observational Arm	ENROLLED	11	0	0	0	1	0	0	0
100016	11-08-2017	ECP Treatment Arm	ENROLLED	47	0	0	0	1	0	0	0

*Figure 42*

- The **Participant Summary** page is now displayed, *Figure 43*.
- If the **ECP Treatment Visit** event **Status** column reads **New**, the CRF has not been started or submitted, click **View**, *Figure 43*.
- 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.

**Participant Summary**

Site Name - ID:	Test Site - 100																																																	
Participant ID:	100016																																																	
Study Arm:	ECP Treatment Arm																																																	
Participant Status:	ENROLLED																																																	
Enrolled Date:	11-08-2017																																																	
<a href="#">Add New Event...</a> 																																																		
<table border="1"> <thead> <tr> <th>Event Type</th> <th>Event Title</th> <th>Event Label</th> <th>Status</th> <th>Projected Date</th> <th>Overdue Date</th> <th>Event Date</th> </tr> </thead> <tbody> <tr> <td>Confirmation of Eligibility</td> <td>Confirmation of Eligibility</td> <td></td> <td>DCC_VERIFIED</td> <td></td> <td></td> <td>11-08-2017 <a href="#">View</a></td> </tr> <tr> <td>Demographics</td> <td>Demographics/Medical History</td> <td></td> <td>SUBMITTED</td> <td></td> <td></td> <td>11-08-2017 <a href="#">View</a></td> </tr> <tr> <td>Baseline Therapy</td> <td>Baseline Therapy</td> <td></td> <td>SUBMITTED</td> <td></td> <td></td> <td>11-08-2017 <a href="#">View</a></td> </tr> <tr> <td>ECP Treatment</td> <td>ECP Treatment 1</td> <td></td> <td>NEW </td> <td></td> <td></td> <td>11-08-2017 <a href="#">View</a> </td> </tr> <tr> <td>Quality of Life</td> <td>Quality of Life Baseline</td> <td></td> <td>NEW</td> <td></td> <td></td> <td>11-08-2017 <a href="#">View</a></td> </tr> <tr> <td>ECP Treatment</td> <td>ECP Treatment 2</td> <td></td> <td>NEW</td> <td></td> <td></td> <td>11-08-2017 <a href="#">View</a></td> </tr> </tbody> </table>		Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			11-08-2017 <a href="#">View</a>	Demographics	Demographics/Medical History		SUBMITTED			11-08-2017 <a href="#">View</a>	Baseline Therapy	Baseline Therapy		SUBMITTED			11-08-2017 <a href="#">View</a>	ECP Treatment	ECP Treatment 1		NEW 			11-08-2017 <a href="#">View</a> 	Quality of Life	Quality of Life Baseline		NEW			11-08-2017 <a href="#">View</a>	ECP Treatment	ECP Treatment 2		NEW			11-08-2017 <a href="#">View</a>
Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date																																												
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			11-08-2017 <a href="#">View</a>																																												
Demographics	Demographics/Medical History		SUBMITTED			11-08-2017 <a href="#">View</a>																																												
Baseline Therapy	Baseline Therapy		SUBMITTED			11-08-2017 <a href="#">View</a>																																												
ECP Treatment	ECP Treatment 1		NEW 			11-08-2017 <a href="#">View</a> 																																												
Quality of Life	Quality of Life Baseline		NEW			11-08-2017 <a href="#">View</a>																																												
ECP Treatment	ECP Treatment 2		NEW			11-08-2017 <a href="#">View</a>																																												

**Figure 43**

- Clicking **View** directs you to the **Event Summary** page.
- The **ECP Treatment Visit** event is listed here, click **View**, **Figure 44**.

**Event Summary**

Site Name - ID:	Test Site - 100	Event Type:	ECP Treatment										
Participant ID:	100016	Event Title:	ECP Treatment 1										
Study Arm:	ECP Treatment Arm	Event Label:											
Participant Status:	ENROLLED	Event Status:	NEW										
Enrolled Date:	11-08-2017	Event Date:											
<table border="1"> <thead> <tr> <th>Form Type</th> <th>Form Title</th> <th>Status</th> <th>Form Creation Date</th> <th>Form Last Submitted Date</th> </tr> </thead> <tbody> <tr> <td>ECP Treatment</td> <td>ECP Treatment Visit 1 Form</td> <td>NEW</td> <td>11-08-2017</td> <td>11-08-2017 <a href="#">View</a> </td> </tr> </tbody> </table>				Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date	ECP Treatment	ECP Treatment Visit 1 Form	NEW	11-08-2017	11-08-2017 <a href="#">View</a> 
Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date									
ECP Treatment	ECP Treatment Visit 1 Form	NEW	11-08-2017	11-08-2017 <a href="#">View</a> 									

**Figure 44**

- Clicking **View** directs you to the **ECP Treatment Visit CRF** page, **Figure 45**.
- Enter the **ECP Treatment Visit** date or use the calendar icon to select the date.



# ECP REFRACTORY BOS WEBSITE

Home | Check Enrollment/Arm Eligibility | Refractory BOS | Investigator Resources | Help

Site Summary - rBOS > Participant Summary > Event Summary > ECP Treatment Visit 1 Form

**Form Summary**

Site Name - ID:	Test Site - 100	Event Type:	ECP Treatment	Form Type:	ECP Treatment
Participant ID:	100016	Event Title:	ECP Treatment 1	Form Title:	ECP Treatment Visit 1 Form
Study Arm:	ECP Treatment Arm	Event Label:		Form Creation Date:	11-08-2017
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	11-08-2017	Event Date:		Last Submitted Date:	11-08-2017

**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)**

**ECP Treatment Visit 1 Form**

**Please include the following types of source documents:**

1. Photopheresis Procedure Note/Report
2. CBC - Lab Report
3. Pre-Procedure Assessment Form
4. Progress Note or Clinical Note describing complication (if applicable)
5. Source describing why whole blood processing not completed as required (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..."/> No file selected.	<input type="button" value="Upload"/>
<input type="button" value="Save"/> <input type="button" value="Submit"/>		
<b>ECP Treatment Visit Date:</b> <input type="text"/> <input type="button"/>		

Figure 45

- 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 46**. For help uploading the required source documents as PDFs, see **10.0 Uploading Scanned Source Document PDF files**.

**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	<a href="#">View</a>
CBC - Lab Report	CBC_101001_01242015.pdf	2015-01-26	<a href="#">View</a>
Select Source Document Type	Photopheresis Procedure Note/Report		
Attach Source Document:	<input type="button" value="Browse..."/>	<input type="button" value="Upload"/>	

**Figure 46**

- Note data item #6 **Complete Blood Count (CBC)** on **Figure 47**. You will need to select one of the four options such as: “**CBC Collected with Differential on the Day of ECP**”. If two ECP Treatment are scheduled on consecutive days and a CBC was not obtained on the second day, check “**CBC Collected with ECP Treatment Yesterday**” on the ECP Treatment CRF that is completed for the second day’s treatment. If the CBC or Differential was missed, select the appropriate one and upload a note to file. 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 47**, the **WBCs** entry requires K/cumm (thousands per cubic millimeter), the **RBCs** require M/cumm (millions per cubic millimeter), **Hemoglobin** requires g/dl (grams per deciliter) and **Hematocrit** requires %.
- Note Section A #7 **Type of hemocytometer used to measure the CBC**. 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.

**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. A. Resting oxygen saturation:  %

B. Is the participant receiving supplemental oxygen?  YES  NO

C. If yes, how much?  Select delivery method:

6. Complete blood count (CBC):

CBC Collected with Differential on the Day of ECP  
 CBC Collected with ECP Treatment Yesterday  
 CBC Missed (Please provide note to file.)  
 Differential missed (Please provide note to file.)

Date of CBC:

WBCs:  (K/cumm)

RBCs:  (M/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

Figure 47

- 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 48*.

**ECP Treatment Visit Date:** 11/08/2017

**SECTION A. Pre-Treatment Assessment**

1. Weight: 84.0 kilograms

2. Blood pressure: systolic 125 mmHg diastolic 15 mmHg

Validation Error: Diastolic ranges between 30 and 150 mmHg.

3. Heart rate: 77 beats per minute

4. Respiratory rate: 22 breaths per minute

5. A. Resting oxygen saturation: 95 %

B. Is the participant receiving supplemental oxygen?  YES  NO

C. If yes, how much?  Select delivery method:

6. Complete blood count (CBC):

CBC Collected with Differential on the Day of ECP  
 CBC Collected with ECP Treatment Yesterday  
 CBC Missed (Please provide note to file.)  
 Differential missed (Please provide note to file.)

Date of CBC: 11/08/2017

WBCs:  (K/cumm) ← Missing Data

Validation Error: WBC ranges between 1.0 and 40.0.

RBCs: 8.0 (M/cumm)

Hemoglobin: 15.0 (g/dl)

Hematocrit: 29.0 (%)

Platelets: 19 (K/cumm) ← Data out of Range

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

Neutrophils:  (%) ← Missing Data

Validation Error: Neutrophils range between 0 and 100%.

Figure 48

- After submitting the **ECP Treatment Visit** CRF, you will be directed back to the **Participant Summary** page.
- NOTE: The **Projected Date** column now has dates added based on the date of the first ECP Treatment Visit date.
- The **Status** of the event in the **Participant Summary** page has changed to **SUBMITTED**, *Figure* .
- 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.

**Participant Summary**

Site Name - ID: Test Site - 100  
 Participant ID: 100016  
 Study Arm: ECP Treatment Arm  
 Participant Status: ENROLLED  
 Enrolled Date: 11-08-2017

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
ECP Treatment	ECP Treatment 1		SUBMITTED	11-08-2017		11-08-2017	<a href="#">View</a>
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			11-08-2017	<a href="#">View</a>
Demographics	Demographics/Medical History		SUBMITTED			11-08-2017	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		SUBMITTED			11-08-2017	<a href="#">View</a>
Quality of Life	Quality of Life Baseline		NEW	11-08-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 2		NEW	11-11-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 3		NEW	11-15-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 4		NEW	11-18-2017			<a href="#">View</a>

*Figure 70*

## 12.5 Pulmonary Evaluation CRF

- To Complete a **Pulmonary Evaluation** CRF:
  - Click the **Refractory BOS** 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* .
  - The data in the columns for the **Projected Date** and the **Overdue Date** of the Pulmonary Evaluation CRFs were populated when the first ECP Treatment CRF was 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* .

- 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 71*.

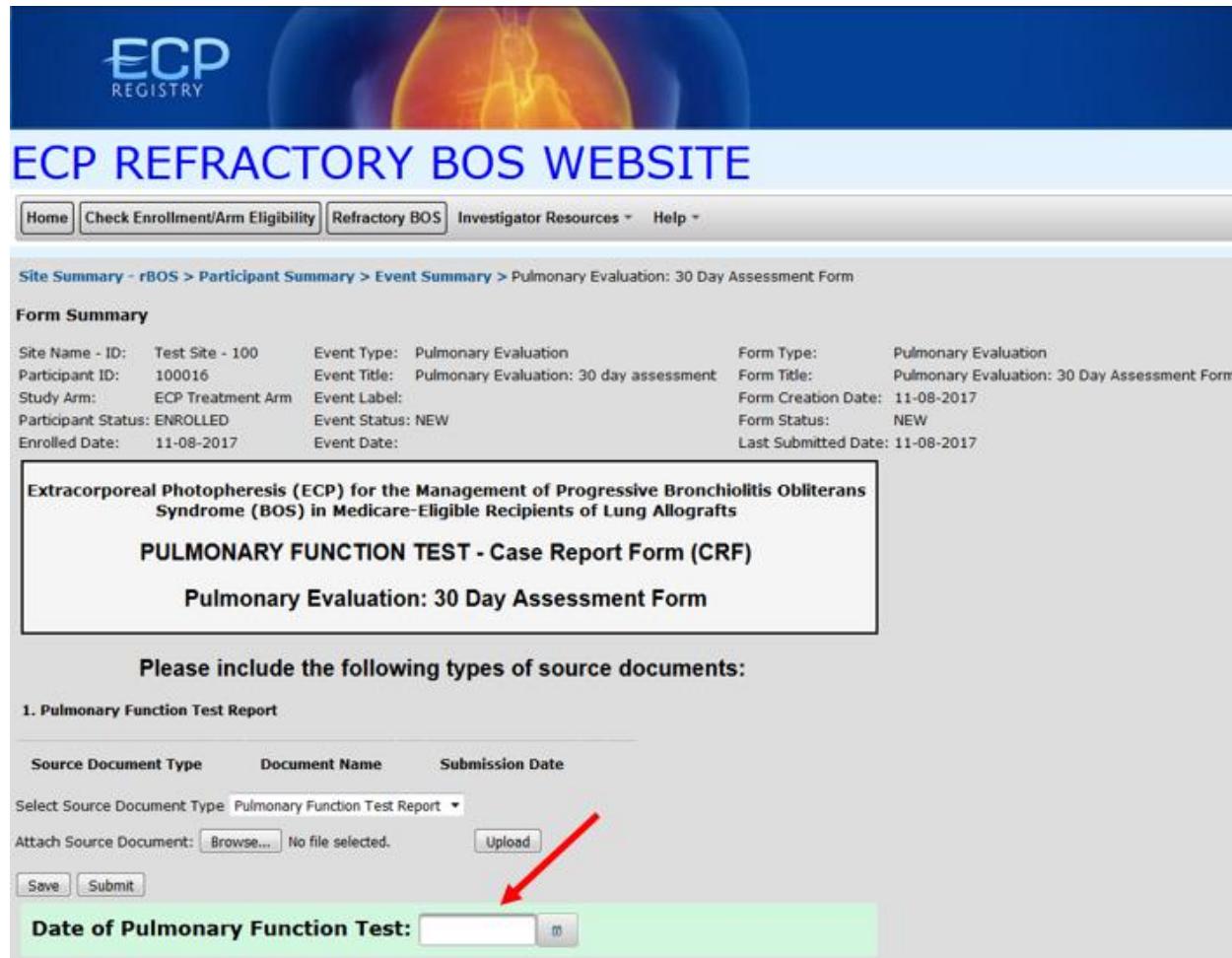
Participant Summary							
Event Type		Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
ECP Treatment	ECP Treatment 1		SUBMITTED	11-08-2017		11-08-2017	<a href="#">View</a>
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			11-08-2017	<a href="#">View</a>
Demographics	Demographics/Medical History		SUBMITTED			11-08-2017	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		SUBMITTED			11-08-2017	<a href="#">View</a>
Quality of Life	Quality of Life Baseline		NEW	11-08-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 2		NEW	11-11-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 3		NEW	11-15-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 4		NEW	11-18-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 5		NEW	11-22-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 6		NEW	11-25-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 7		NEW	11-29-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 8		NEW	12-02-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 9		NEW	12-05-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 10		NEW	12-08-2017			<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 30 day assessment		NEW	12-08-2017	12-16-2017		<a href="#">View</a>
Change in Therapy	Change in Therapy Day 30		NEW	12-08-2017			<a href="#">View</a>

*Figure 71*

Event Summary							
Form Type		Form Title	Status	Form Creation Date	Form Last Submitted Date		
Site Name - ID:	Test Site - 100	Event Type:	Pulmonary Evaluation				
Participant ID:	100016	Event Title:	Pulmonary Evaluation: 30 day assessment				
Study Arm:	ECP Treatment Arm	Event Label:					
Participant Status:	ENROLLED	Event Status:	NEW				
Enrolled Date:	11-08-2017	Event Date:					
Pulmonary Evaluation	Pulmonary Evaluation: 30 Day Assessment Form	NEW	11-08-2017	11-08-2017	<a href="#">View</a>		

*Figure 72*

- 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 49*.



**ECP REFRACTORY BOS WEBSITE**

Home | Check Enrollment/Arm Eligibility | Refractory BOS | Investigator Resources | Help

Site Summary - rBOS > Participant Summary > Event Summary > Pulmonary Evaluation: 30 Day Assessment Form

**Form Summary**

Site Name - ID:	Test Site - 100	Event Type:	Pulmonary Evaluation	Form Type:	Pulmonary Evaluation
Participant ID:	100016	Event Title:	Pulmonary Evaluation: 30 day assessment	Form Title:	Pulmonary Evaluation: 30 Day Assessment Form
Study Arm:	ECP Treatment Arm	Event Label:		Form Creation Date:	11-08-2017
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	11-08-2017	Event Date:		Last Submitted Date:	11-08-2017

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

**PULMONARY FUNCTION TEST - Case Report Form (CRF)**

**Pulmonary Evaluation: 30 Day Assessment 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:	Browse...	No file selected.
<input type="button" value="Upload"/> <input type="button" value="Save"/> <input type="button" value="Submit"/>		
<b>Date of Pulmonary Function Test:</b> <input type="text" value=""/> <input type="button" value="m"/>		

Figure 49

- Complete the CRF, Error! Reference source not found.. 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 50*.
- 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 50*.

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

**PULMONARY FUNCTION TEST - Case Report Form (CRF)**

**Pulmonary Evaluation: 30 Day Assessment 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 <input style="border: 1px solid #ccc; padding: 2px 10px;" type="button" value="Pulmonary Function Test Report"/>		
Attach Source Document: <input style="border: 1px solid #ccc; padding: 2px 10px;" type="button" value="Browse..."/> <input style="border: 1px solid #ccc; padding: 2px; width: 150px;" type="text" value="No file selected."/> <input style="border: 1px solid #ccc; padding: 2px 10px;" type="button" value="Upload"/>		
<input style="border: 1px solid #ccc; padding: 2px 10px;" type="button" value="Save"/> <input style="border: 1px solid #ccc; padding: 2px 10px;" type="button" value="Submit"/>		

**Date of Pulmonary Function Test:**

**1. A. Resting oxygen saturation:**  %

**B. Is the participant receiving supplemental oxygen?**  YES  NO

**C. If yes, how much?**  **Select delivery method:**

✖ Validation Error: Resting oxygen saturation ranges from 60% to 100%.

**2. FEV1 (pre-bronchodilator):**  liters

**3. FVC (pre-bronchodilator):**  liters

**4. FEV1/FVC Ratio:**  %

**5. Comments:**

**Figure 50**

- 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 CRF

- The **Change in Therapy** CRF is completed for both ECP Treatment and Observation Arm participants.
- The following source documents are required to complete this online CRF:
  - Clinical Note or Medication Record Form
- To Complete the CRF:
  - Click the **Refractory BOS** button, which will direct you to the **Site Summary** page.
  - On the **Site Summary** page locate the correct patient by assigned **Participate ID** and click **View**.
  - The **Participant Summary** page is now displayed, *Figure 38*.
  - The **Change in Therapy Day 30** event **Status** column reads **NEW**, because the CRF has not been started or submitted, *Figure 38*.

Participant Summary							
Site Name - ID: Test Site - 100 Participant ID: 100016 Study Arm: ECP Treatment Arm Participant Status: ENROLLED Enrolled Date: 11-08-2017							
<a href="#">Add New Event...</a> <span style="color: red;">(arrow pointing to this button)</span>							
Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
ECP Treatment	ECP Treatment 1		SUBMITTED	11-08-2017		11-08-2017	<a href="#">View</a>
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			11-08-2017	<a href="#">View</a>
Demographics	Demographics/Medical History		SUBMITTED			11-08-2017	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		SUBMITTED			11-08-2017	<a href="#">View</a>
Quality of Life	Quality of Life Baseline		NEW	11-08-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 2		NEW	11-11-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 3		NEW	11-15-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 4		NEW	11-18-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 5		NEW	11-22-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 6		NEW	11-25-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 7		NEW	11-29-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 8		NEW	12-02-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 9		NEW	12-05-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 10		NEW	12-08-2017			<a href="#">View</a>
Pulmonary Evaluation	Pulmonary Evaluation: 30 day assessment		NEW	12-08-2017	12-16-2017		<a href="#">View</a>
Change in Therapy	Change in Therapy Day 30		NEW	12-08-2017			<a href="#">View</a> <span style="color: red;">(arrow pointing to this button)</span>
ECP Treatment	ECP Treatment 11		NEW	12-20-2017			<a href="#">View</a>

Figure 51

- In case new **Change in Therapy** CRF is needed, select the **Add New Event** button and the **Add New Event** selection box appears which lists **Change in Therapy** among the selections, **Figure 52**.
- Click **Change in Therapy** and click **Submit**, **Figure 52**.

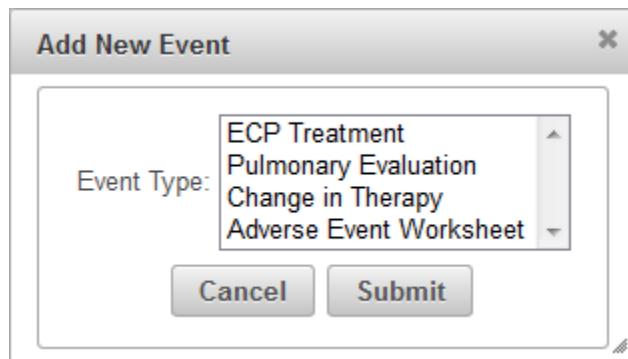


Figure 52

- An Event Summary page for the new **Change in Therapy** CRF is now displayed.
- Note that the Event Title, in this case of adding a new **Change in Therapy** CRF, 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 using **Add New Event**.
- Select **View**, *Figure 53*, to display the **Change in Therapy** CRF, *Figure 54*.

Event Summary				
Site Name - ID:	Test Site - 100	Event Type:	Change in Therapy	
Participant ID:	100016	Event Title:	Change in Therapy Day 30	
Study Arm:	ECP Treatment Arm	Event Label:		
Participant Status:	ENROLLED	Event Status:	NEW	
Enrolled Date:	11-08-2017	Event Date:		
Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date
Change in Therapy	Change in Therapy Day 30 Form	NEW	11-08-2017	11-08-2017
<input type="button" value="View"/>				

**Figure 53**

- Data fields #1, 3 and 4, **Figure 54a and 78b**, 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 and 4.
- Data field 2 and 5 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 Control Arm, *Figure 54*.
- 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**.

**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 Day 30 Form**

**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.**

**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:	Browse... No file selected.	<input type="button" value="Upload"/>
<input type="button" value="Save"/>	<input type="button" value="Submit"/>	

**Change in Therapy Date:**

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

- |                                      |                                     |  |         |                                 |                                 |                                 |
|--------------------------------------|-------------------------------------|--|---------|---------------------------------|---------------------------------|---------------------------------|
| <input checked="" type="radio"/> YES | <input type="radio"/> NO            | Tacrolimus   | Dosage: | <input type="radio"/> Increased | <input type="radio"/> Decreased | <input type="radio"/> No Change |
| <input checked="" type="radio"/> YES | <input type="radio"/> NO            | Alemtuzumab  | Dosage: | <input type="radio"/> Increased | <input type="radio"/> Decreased | <input type="radio"/> No Change |
| <input type="radio"/> YES            | <input checked="" type="radio"/> NO | Sirolimus (Rapamycin)                                  | Dosage: | <input type="radio"/> Increased | <input type="radio"/> Decreased | <input type="radio"/> No Change |
| <input type="radio"/> YES            | <input checked="" type="radio"/> NO | Everolimus   | Dosage: | <input type="radio"/> Increased | <input type="radio"/> Decreased | <input type="radio"/> No Change |
| <input type="radio"/> YES            | <input checked="" type="radio"/> NO | Azathioprine   | Dosage: | <input type="radio"/> Increased | <input type="radio"/> Decreased | <input type="radio"/> No Change |
| <input type="radio"/> YES            | <input checked="" type="radio"/> NO | Cyclosporine A   | Dosage: | <input type="radio"/> Increased | <input type="radio"/> Decreased | <input type="radio"/> No Change |
| <input type="radio"/> YES            | <input checked="" type="radio"/> NO | Methotrexate   | Dosage: | <input type="radio"/> Increased | <input type="radio"/> Decreased | <input type="radio"/> No Change |
| <input type="radio"/> YES            | <input checked="" type="radio"/> NO | Macrolide Antibiotic, Azithromycin                     | Dosage: | <input type="radio"/> Increased | <input type="radio"/> Decreased | <input type="radio"/> No Change |
| <input type="radio"/> YES            | <input checked="" type="radio"/> NO | Mycophenolate Mofetil (Cellcept or Myfortic)           | Dosage: | <input type="radio"/> Increased | <input type="radio"/> Decreased | <input type="radio"/> No Change |
| <input type="radio"/> YES            | <input checked="" type="radio"/> NO | Anti-Thymocyte Globulin - ATG (Thymoglobulin or Atgam) | Dosage: | <input type="radio"/> Increased | <input type="radio"/> Decreased | <input type="radio"/> No Change |
| <input type="radio"/> YES            | <input checked="" type="radio"/> NO | Total Lymphoid Irradiation                             |         |                                 |                                 |                                 |
| <input type="radio"/> YES            | <input checked="" type="radio"/> NO | Other Drug(s)  |         |                                 |                                 |                                 |

If YES for Other Drug(s), please provide the drug name(s) and whether the dosage went up or down:

**Figure 54a – Change in Therapy**

2. Is the patient taking prednisone?  YES  NO

A. If yes, enter daily dose:  mg (input range: 0-150)

B. Number of changes in dose:

C. If dose changed, dose range:  
Lowest Dose:  mg (input range: 0-150)

Highest Dose:  mg (input range: 0-150)

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

If yes, list drugs:

Name anticoagulant 1:

Name anticoagulant 2:

Name anticoagulant 3:

4. 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:

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

a. If yes, date of discontinuation

b. If yes, reason for discontinuation:

6. Comments:

Figure 55b – Change in Therapy

- 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 56*.

**Participant Summary**

Site Name - ID: Test Site - 100  
 Participant ID: 100016  
 Study Arm: ECP Treatment Arm  
 Participant Status: ENROLLED  
 Enrolled Date: 11-08-2017

[Add New Event...](#)

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
ECP Treatment	ECP Treatment 1		SUBMITTED	11-08-2017		11-08-2017	<a href="#">View</a>
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			11-08-2017	<a href="#">View</a>
Demographics	Demographics/Medical History		SUBMITTED			11-08-2017	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		SUBMITTED			11-08-2017	<a href="#">View</a>
Change in Therapy	Change in Therapy Day 30		SUBMITTED	12-08-2017		11-30-2017	<a href="#">View</a>
Quality of Life	Quality of Life Baseline		NEW	11-08-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 2		NEW	11-11-2017			<a href="#">View</a>

**Figure 56**

## 12.7 Quality of Life CRF

- **NOTE:** the **Quality of Life** CRF will not be filled out by the Site Coordinator. A Quality of Life CRF will be populated with the data the participant entered into the Android Tablet when the participant took the Quality of Life CRF. The Quality of Life CRF will not contain the results from the participant's entries immediately. A delay of approximately 24 to 48 hours will be normal before the Quality of Life CRF has been automatically populated from the Android Tablet database. If the Quality of Life CRF has not been populated within 48 hours, the Android Tablet may need to be turned on and connected to Wifi to allow the participant's Quality of Life CRF to be uploaded to the database.
  - To view the Quality of Life CRF, click the **New BOS** 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, **Figure 80**.
  - For the EPI Arm or Control Arm, locate the **Quality of Life Baseline** CRF, found on the **Participant Summary** page. Click view to display the Event Summary page, **Figure** .

**Participant Summary**

Site Name - ID: Test Site - 100  
 Participant ID: 100016  
 Study Arm: ECP Treatment Arm  
 Participant Status: ENROLLED  
 Enrolled Date: 11-08-2017

[Add New Event...](#)

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
ECP Treatment	ECP Treatment 1		SUBMITTED	11-08-2017		11-08-2017	<a href="#">View</a>
Confirmation of Eligibility	Confirmation of Eligibility		STARTED			11-08-2017	<a href="#">View</a>
Demographics	Demographics/Medical History		SUBMITTED			11-08-2017	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		SUBMITTED			11-08-2017	<a href="#">View</a>
Change in Therapy	Change in Therapy Day 30		SUBMITTED	12-08-2017		11-30-2017	<a href="#">View</a>
Quality of Life	Quality of Life Baseline		NEW	11-08-2017			<a href="#">View</a>
ECP Treatment	ECP Treatment 2		NEW	11-11-2017			<a href="#">View</a>

**Figure 80**

- On the Event Summary page, click **View**, **Figure**, to display the **Quality of Life Baseline** CRF, **Figure 57**.

**Event Summary**

Site Name - ID: Test Site - 100      Event Type: Quality of Life  
 Participant ID: 100016      Event Title: Quality of Life Baseline  
 Study Arm: ECP Treatment Arm      Event Label:  
 Participant Status: ENROLLED      Event Status: NEW  
 Enrolled Date: 11-08-2017      Event Date:

Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date	
Quality of Life	Quality of Life Baseline Form	NEW	11-08-2017	11-08-2017	<a href="#">View</a>

**Figure 80**

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

**QUALITY OF LIFE - Case Report Form (CRF)**

**Save** **Submit**

**Quality of Life Date:**

**SECTION 1 Modified Medical Research Council Dyspnea Scale**

**Please circle the grade that best fits your usual condition these days. Only circle one grade.**  
Grade Symptoms

**Grade Symptoms**

- 0 Not troubled with breathlessness except with strenuous exercise
- 1 Troubled by shortness of breath when hurrying on the level or walking up a slight hill
- 2 Walks slower than people of the same age on the level because of breathlessness or has to stop for breath when walking at own pace on the level
- 3 Stop for breath after walking about 100 yards or after a few minutes on the level
- 4 Too breathless to leave the house or breathless when dressing or undressing

**SECTION 2 ST. GEORGE'S RESPIRATORY QUESTIONNAIRE For COPD patients (SGRQ-C)**

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life.

We are using it to find out which aspects of your illness cause you most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

**Please select one to show how you describe your current health:**

- Very good**
- Good**
- Fair**
- Poor**
- Very poor**

**Questions about how much respiratory trouble you have.**

**Please check ONE box for each question:**

**1. I cough:**

- most days a week**
- several days a week**
- only with respiratory infections**
- not at all**

**Figure 81**

## 12.8 End of Study CRF

- To Complete the CRF:
  - Click the **Refractory BOS** 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. Click view to display the Event Summary page, *Figure* .
  - For the Observation arm, the **End of Study** CRF is created by clicking the **Add New Event** button, *Figure 69*. Click End of Study in the drop down box and select the Submit button. The Event Summary page then displays, *Figure* .
  - On the Event Summary page, click **View**, *Figure* , to display the **End of Study** CRF, *Figure 57*.

Event Summary				
Site Name - ID:	Test Site - 100	Event Type:	End of Study	
Participant ID:	100016	Event Title:	End Of Study	
Study Arm:	ECP Treatment Arm	Event Label:		
Participant Status:	ENROLLED	Event Status:	NEW	
Enrolled Date:	11-08-2017	Event Date:		
Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date
End of Study	End of Study Form	NEW	11-08-2017	11-08-2017
				<input type="button" value="View"/>

*Figure 82*

**Add New Event**

Event Type:

Pulmonary Evaluation  
 End of Study  
 Change in Therapy  
 Adverse Event Worksheet

*Figure 83*

- Complete the **End of Study** 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.**
- Select **Submit** at the bottom of the CRF when the data are correct and complete, *Figure 57*.

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

**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	Document Name	Submission Date
Select Source Document Type	Clinical or Progress 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 Termination from Study:**

**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:**

**2. Comments:**

**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 that prompt you to correct or enter the values, **Figure 58**.

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

**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	Document Name	Submission Date
Select Source Document Type	Clinical or Progress 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 Termination from Study:**

Please enter date of termination from study.

**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:**

Please enter reason for termination from study.

**2. Comments:**

**Figure 58**

- 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**.

## 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 59**:
  - Demographics/Medical History
  - Baseline Therapy
  - Observation Pulmonary Evaluation Log – See [Section 13.4](#) for further information
  - Quality of Life
  - Change in Therapy



**ECP REFRACTORY BOS WEBSITE**

Site Summary - rBOS > Participant Summary

**Participant Summary**

Site Name - ID: Test Site - 100  
 Participant ID: 100015  
 Study Arm: Observational Arm  
 Participant Status: ENROLLED  
 Enrolled Date: 11-07-2017

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			11-07-2017	<a href="#">View</a>
Demographics	Demographics/Medical History		NEW			11-07-2017	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		NEW			11-07-2017	<a href="#">View</a>
Observation Pulmonary Evaluation Log	Observation Pulmonary Evaluation Log		NEW			11-07-2017	<a href="#">View</a>
Quality of Life	Quality of Life Baseline		NEW				<a href="#">View</a>
Change in Therapy	Change in Therapy Day 30		NEW				<a href="#">View</a>
Change in Therapy	Change in Therapy Day 60		NEW				<a href="#">View</a>
Change in Therapy	Change in Therapy Day 90		NEW				<a href="#">View</a>
Quality of Life	Quality of Life Day 90		NEW				<a href="#">View</a>
Change in Therapy	Change in Therapy Day 120		NEW				<a href="#">View</a>
Change in Therapy	Change in Therapy Day 180		NEW				<a href="#">View</a>
Quality of Life	Quality of Life Day 180		NEW				<a href="#">View</a>

Add New Event...

**Figure 59**

**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 **Observation Pulmonary Evaluation Log**:
  - Click the **Refractory BOS** 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 60**. Click view to display the **Event Summary** page, **Figure 61**.
  - Clicking **View** directs you to the **Observation Pulmonary Evaluation Log**, **Figure 62**.

Participant Summary						
Site Name - ID: Test Site - 100 Participant ID: 100015 Study Arm: Observational Arm Participant Status: ENROLLED Enrolled Date: 11-07-2017						
<a href="#">Add New Event...</a>						
Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility	DCC_VERIFIED			11-07-2017	<a href="#">View</a>
Demographics	Demographics/Medical History	NEW			11-07-2017	<a href="#">View</a>
Baseline Therapy	Baseline Therapy	NEW			11-07-2017	<a href="#">View</a>
Observation Pulmonary Evaluation Log	Observation Pulmonary Evaluation Log	NEW			11-07-2017	<a href="#">View</a>
Quality of Life	Quality of Life/Baseline	NEW				<a href="#">View</a>
Change in Therapy	Change in Therapy Day 30	NEW				<a href="#">View</a>
Change in Therapy	Change in Therapy Day 60	NEW				<a href="#">View</a>
Change in Therapy	Change in Therapy Day 90	NEW				<a href="#">View</a>
Quality of Life	Quality of Life Day 90	NEW				<a href="#">View</a>
Change in Therapy	Change in Therapy Day 120	NEW				<a href="#">View</a>
Change in Therapy	Change in Therapy Day 180	NEW				<a href="#">View</a>
Quality of Life	Quality of Life Day 180	NEW				<a href="#">View</a>
<a href="#">Add New Event...</a>						

**Figure 60**

Event Summary					
Site Name - ID:	Test Site - 100	Event Type:	Observation Pulmonary Evaluation Log		
Participant ID:	100015	Event Title:	Observation Pulmonary Evaluation Log		
Study Arm:	Observational Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	NEW		
Enrolled Date:	11-07-2017	Event Date:	11-07-2017		
Form Type	Form Title	Status	Form Creation Date	Form Last Submitted Date	
Pulmonary Evaluation Log	Observation Pulmonary Evaluation Log	NEW	11-07-2017	11-07-2017	<a href="#">View</a>

Figure 61

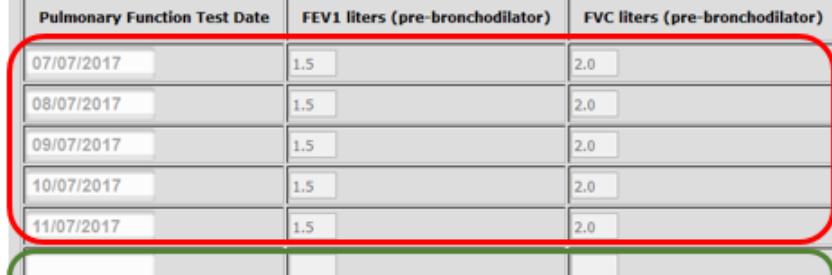
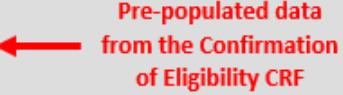
Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts					
OBSERVATION PULMONARY EVALUATION LOG					
Observation Pulmonary Evaluation Log					
<a href="#">Save</a>	<a href="#">Check ECP Treatment Eligibility</a>				
Pulmonary Function Test Date	FEV1 liters (pre-bronchodilator)	FVC liters (pre-bronchodilator)			
07/07/2017	1.5	2.0			
08/07/2017	1.5	2.0			
09/07/2017	1.5	2.0			
10/07/2017	1.5	2.0			
11/07/2017	1.5	2.0			
 					
 					

Figure 62

- Log Description
  - The log is pre-populated with the PFTs that were used to determine participant eligibility, **Figure 62**.
  - The log will be automatically populated with PFT values whenever a newly added 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. 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 into 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* .
    - Click the **Determine Study Arm Eligibility** button, *Figure* .

**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.



A. Date	<input type="text" value="11/10/2014"/>	FEV1	<input type="text" value="2.1"/>	liters	FVC	<input type="text"/>	liters
B. Date	<input type="text" value="12/08/2014"/>	FEV1	<input type="text" value="2.1"/>	liters	FVC	<input type="text"/>	liters
C. Date	<input type="text" value="01/05/2015"/>	FEV1	<input type="text" value="2.1"/>	liters	FVC	<input type="text"/>	liters
D. Date	<input type="text" value="02/02/2015"/>	FEV1	<input type="text" value="2.1"/>	liters	FVC	<input type="text"/>	liters
E. Date	<input type="text" value="03/06/2015"/>	FEV1	<input type="text" value="1.9"/>	liters	FVC	<input type="text"/>	liters
F. Date	<input type="text" value="03/13/2015"/>	FEV1	<input type="text" value="1.8"/>	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 90**

- 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 91 - 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 92 - Eligible for Crossover to ECP Treatment**. To begin the transfer to ECP treatment, click **Transfer Participant to ECP Treatment Arm**. To continue transfer, see Section 13.4.1.
- 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 63 - 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 **Override and Transfer Participant to ECP Treatment Arm, Figure 93**. Otherwise, click **Keep Participant in Observation Arm, Figure 93**. The participant will then be put in a 2-month holding period, see Section 13.4.2.

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

User name: test\_tc logout

CROSSOVER ELIGIBILITY OUTCOME

Participant ID: 101000

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.

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.

Rate of lung function decline (Slope) = 0.0 ml / month

Statistically significant rate of decline (P-Value less than 0.05) = NaN

The minimum FEV1 value = 2000.0 ml

[Return to Registry](#)

Result of ecp treatment eligibility test

Reason test failed ecp eligibility

**Figure 91 - Ineligible for Crossover to ECP Treatment**

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

CROSSOVER ELIGIBILITY OUTCOME

Participant ID: 101006

Cross Over Determination Results: The participant is eligible to cross over into the ECP Treatment Arm.

Eligibility either failed or passed based on the following criterion: The slope meets criteria and is significant.

Rate of lung function decline (Slope) = -60.20779 ml / month

Statistically significant rate of decline (P-Value less than 0.05) = 0.0018546728

The minimum FEV1 value = 800.0 ml

[Transfer Participant to ECP Treatment Arm...](#) [Cancel](#)

**Figure 92 - Eligible for Crossover to ECP Treatment**

User name: washu\_sc [logout](#)

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

**CROSSOVER ELIGIBILITY OUTCOME**

Participant ID: 101001

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?

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.

Eligibility either failed or passed based on the following criterion: 4 or more FEV1 values in the last 4 weeks and the slope is OK but not significant.

Rate of lung function decline (Slope) = -66.41933 ml / month

Statistically significant rate of decline (P-Value less than 0.05) = 0.10046359

The minimum FEV1 value = 1200.0 ml

[Override and Transfer Participant to ECP Treatment Arm...](#) [Keep Participant in Observation Arm...](#) [Cancel](#)

**Figure 63 - Ineligible for Crossover to ECP Treatment but Eligible for Clinical Override**

#### 13.4.1 Procedure to Cross Over to ECP Treatment Arm

- Click the Transfer Participant to ECP Treatment Arm button, **Figure 92 - Eligible for Crossover to ECP Treatment**.
- A Crossover Safety Check Form is then created, and an Event Summary page, **Figure 64**, displays. Click View on the Event Summary page to display the form.

**Event Summary**

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

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

[View](#)

**Figure 64**

- The Crossover Safety check Form must be completed before crossover can occur, **Figure 65**.

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 <input type="button" value="▼"/>		
Attach Source Document: <input type="button" value="Choose File"/> No file chosen <input type="button" value="Upload"/>		
<input type="button" value="Save"/> <input type="button" value="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: 01/09/2015	FEV1: 2.0	liters	FVC: 3.0	liters
B. Date: 01/08/2015	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: 04/29/2015	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: \_\_\_\_\_

**Figure 65**

- On the Crossover Safety Check form, answer the Safety Check question #1, **Figure 65**.

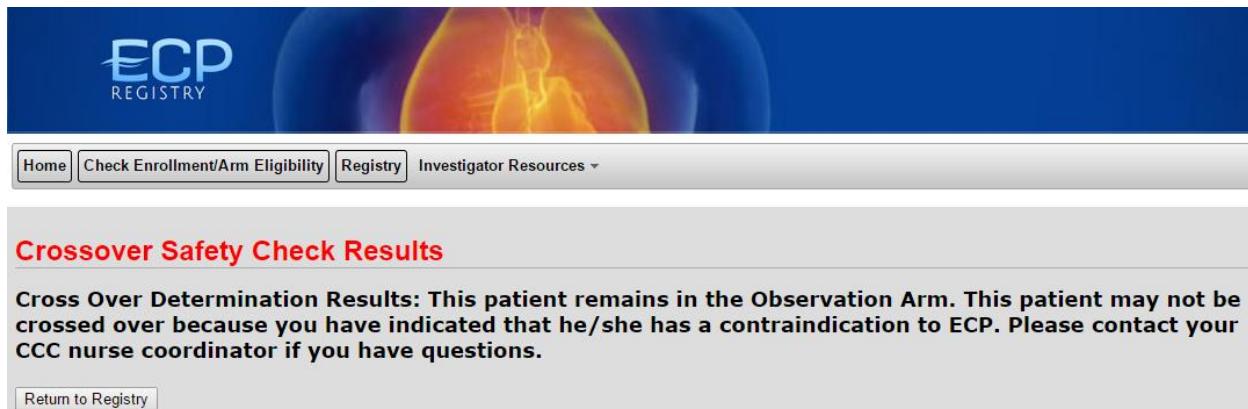
### **Safety Check**

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 66**

- 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 67**.



**Crossover Safety Check Results**

**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.

[Return to Registry](#)

**Figure 67**

- No – The participant may cross over to the ECP treatment arm. Do the following:
  - ◆ Save the Crossover Safety Check form, **Figure 65**.
  - ◆ 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 68**.
  - ◆ Answer question #2 on the Crossover Safety Check form, **Figure 68**.
  - ◆ 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 ECP Treatments CRFs, the Pulmonary Evaluation CRFs and the End of Study CRF.

**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
<input type="button" value="View"/> <input type="button" value="Delete"/>		

Select Source Document Type: A Signed Crossover Safety Check Form must be uploaded.

Attach Source Document:

**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: \_\_\_\_\_

**Figure 68**

**13.4.2 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** displays. Click the **Override and Transfer Participant to ECP Treatment Arm** button.
  - To continue with the override and transfer to ECP treatment, Section 13.4.1.

### 13.5 Pulmonary Evaluation CRF for Observation Arm

- A **Pulmonary Evaluation CRF** for every PFT that is dated after enrollment will need to be created. The PFTs should each be at least 7 days apart. The ECP Refractory BOS website will accept 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 69**.

**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	<a href="#">View</a>
Demographics	Demographics/Medical History		NEW		01-13-2015	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		NEW		01-13-2015	<a href="#">View</a>
Observation Pulmonary Evaluation Log	Observation Pulmonary Evaluation Log		NEW		01-13-2015	<a href="#">View</a>

[Add New Event](#)

**Figure 69**

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

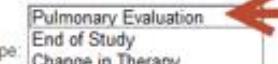
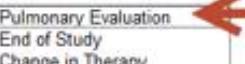
**Participant Summary**

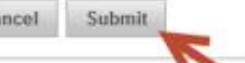
Site Name - ID:	WashU - 101
Participant ID:	101001
Study Arm:	Observational Arm
Participant Status:	ENROLLED
Enrolled Date:	01-13-2015

**Add New Event...**

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

**Add New Event**

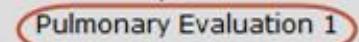
Event Type:  **Pulmonary Evaluation** 

**Submit** 

**Figure 100**

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

**Event Summary**

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

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



**Figure 101**

- Click **View, Figure** , to display the Pulmonary Evaluation Form, **Figure** .
- 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.

**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:**

1. Resting oxygen saturation:  %

2. FEV1 (pre-bronchodilator):  liters

3. FVC (pre-bronchodilator):  liters

4. FEV1/FVC Ratio:  %

5. Comments:

**Figure 102**

### 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 69**. For further information, see Section 12.6 – Change in Therapy.

### 13.7 Quality of Life

To view the **Quality of Life CRF**, see Section 12.7 – Quality of Life

### 13.8 End of Study

To create an **End of Study CRF**, click the **Add New Event** button found on the Participant Summary page, *Figure 69*. For further information, see [Section 12.8 – End of Study](#).

## 14.0 Adverse Event Worksheet

Please refer to the CCC Manual of Procedures.