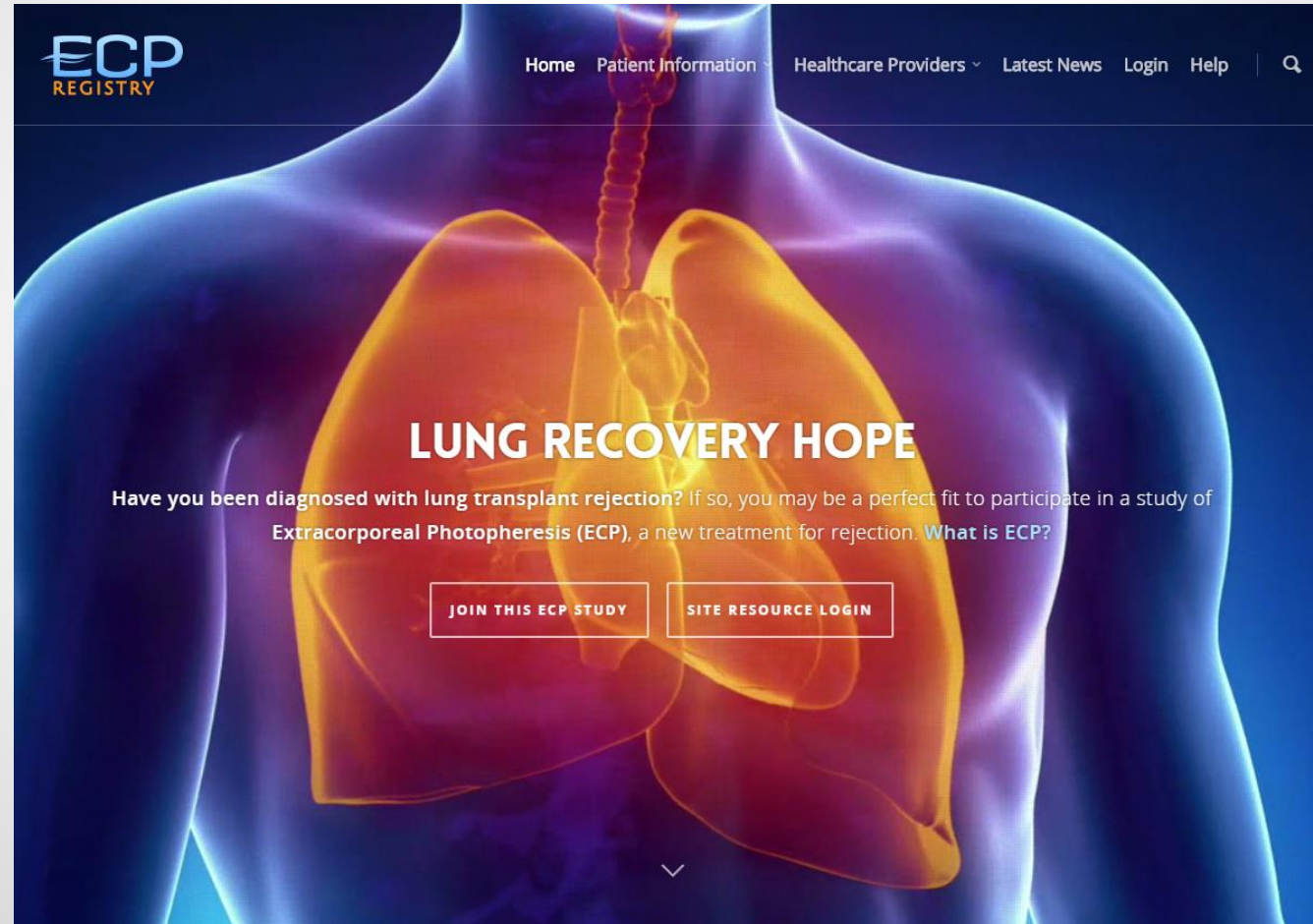


# Welcome to the Demographics/Medical History CRF Training Presentation

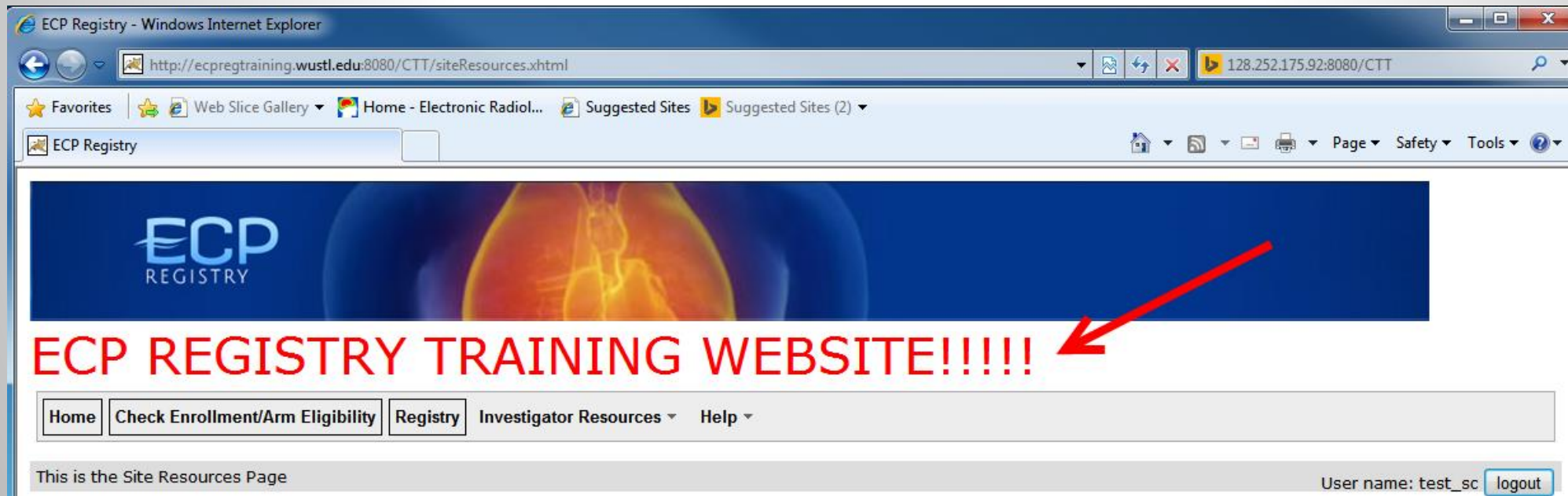


# Introduction

- This training presentation provides the staff at ECP-BOS enrollment sites with the process for completing a Demographics/Medical History Case Report Form (CRF) using the ECP Registry.
- Log in to the ECP Registry training Secure Website <http://ecpregtraining.wustl.edu/wordpress>

# Site Resources Page

- Following login, the ECP Training Site Resources Page displays.
- “Training Website” displays across the top of the page in Big Red Letters: **ECP REGISTRY TRAINING WEBSITE**



# Demographics/Medical History CRF Information

- The Demographics/Medical History CRF is one of the CRFs created for both the ECP Treatment and Observational Arm participants after the **COE CRF is DCC VERIFIED**.
- The following source documents are required to complete this CRF process:
  - A physical or physician's consultation note of the participant's medical history.
  - An Operative Report of Transplant procedure.
  - Pulmonary Function Test Reports to calculate the baseline pulmonary function test results using the ISHLT definition, which is equal to the average of the two highest FEV1 measurements obtained 3 weeks apart after transplantation.

# How to locate the participant's Demographics/Medical History CRF

1. Click the Registry button to be directed to your **Site Summary** page.

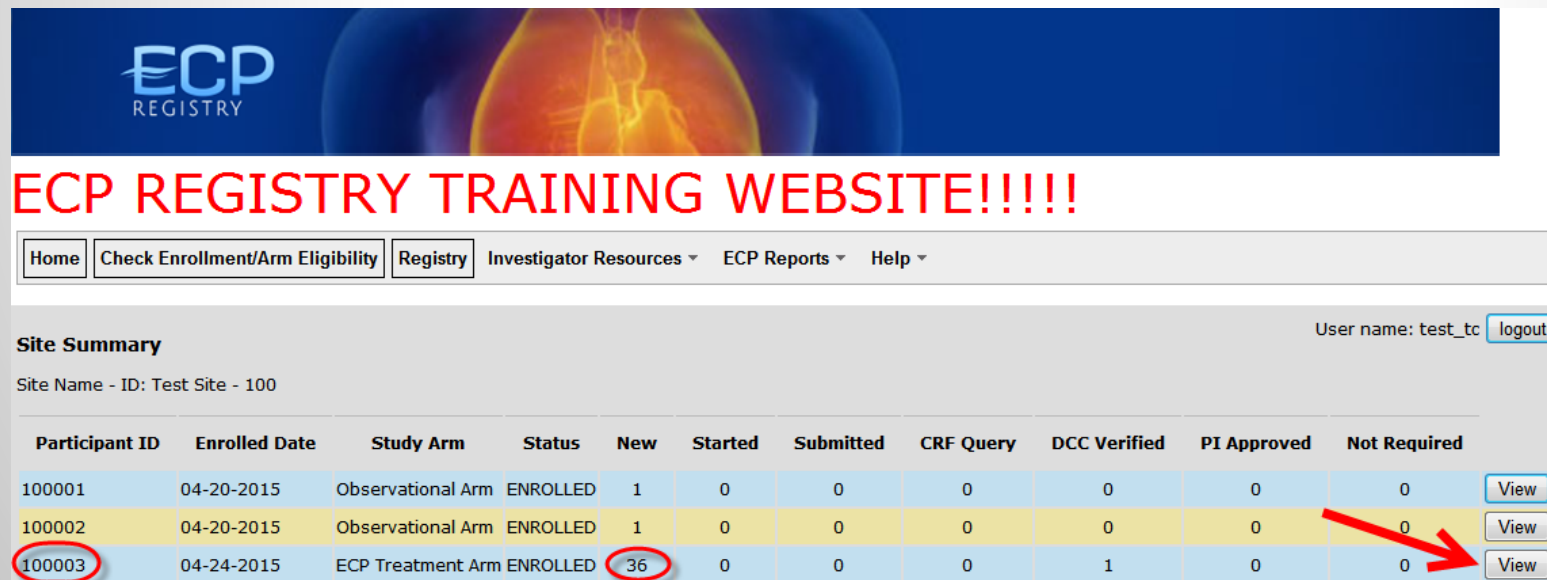


2. For training purpose, **Participant ID 100003** at **Test Site 100** will be used as an example.



# How to locate the participant's Demographics/Medical History CRF continued

3. On the **Site Summary** page, locate the assigned **Participate ID** and click the [View](#) button to be directed to the **Participant Summary** page.
4. Notice this participant is in the ECP Treatment Arm and 36 New CRFs were created after the **COE** CRF was DCC VERIFIED.



**ECP REGISTRY TRAINING WEBSITE!!!!**

Home Check Enrollment/Arm Eligibility Registry Investigator Resources ECP Reports Help


User name: test\_tc [logout](#)

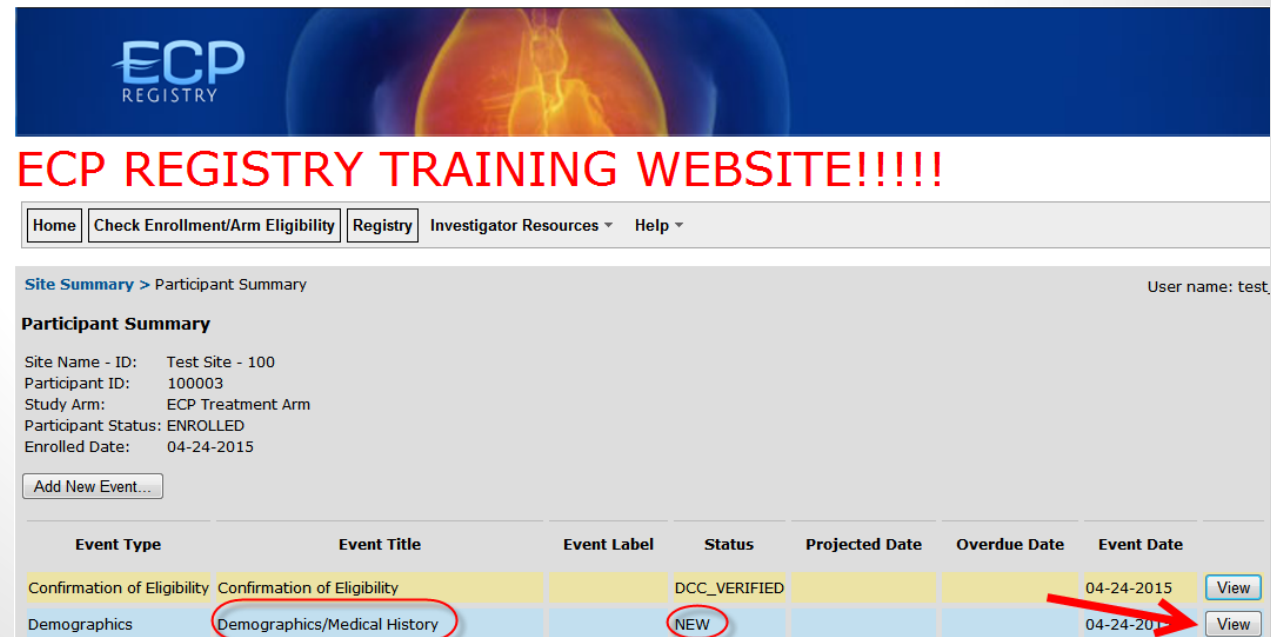
**Site Summary**

Site Name - ID: Test Site - 100

Participant ID	Enrolled Date	Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	
100001	04-20-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	<a href="#">View</a>
100002	04-20-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	<a href="#">View</a>
100003	04-24-2015	ECP Treatment Arm	ENROLLED	36	0	0	0	1	0	0	<a href="#">View</a>

# How to locate the participant's Demographics/Medical History CRF continued

5. The **Participant Summary** page is displayed with all 36 New CRFs.
6. Locate the **Demographics/Medical History** Event Type.
7. Notice the **Demographics/Medical History** event **Status** column reads **NEW**, because the CRF has not been started or submitted.
8. Click the  button to be directed to the participant's **Event Summary** page.



**ECP REGISTRY TRAINING WEBSITE!!!!**



Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary > Participant Summary User name: test


**Participant Summary**

Site Name - ID: Test Site - 100  
Participant ID: 100003  
Study Arm: ECP Treatment Arm  
Participant Status: ENROLLED  
Enrolled Date: 04-24-2015

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			04-24-2015	
Demographics	Demographics/Medical History		NEW			04-24-2015	

# How to locate the participant's Demographics/Medical History CRF continued

9. The **Event Summary** page displays with the **Demographics/Medical History** Form listed.
10. Click  button to be directed to the **Demographics/Medical History** CRF.



The screenshot shows the ECP Registry Training Website. At the top is a blue banner with the ECP Registry logo and a heart scan image. Below the banner is a red heading 'ECP REGISTRY TRAINING WEBSITE!!!!'. A navigation bar contains buttons for Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. The main content area shows a breadcrumb trail: Site Summary > Participant Summary > Event Summary. Under the 'Event Summary' heading, there is a table of participant information. Below this is a table of forms, with a red arrow pointing to the 'View' button for the 'Demographics / Medical History Form'.

**ECP REGISTRY TRAINING WEBSITE!!!!**

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

Site Summary > Participant Summary > Event Summary

**Event Summary**

Site Name - ID:	Test Site - 100	Event Type:	Demographics
Participant ID:	100003	Event Title:	Demographics/Medical History
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	04-24-2015	Event Date:	04-24-2015

Form Type	Form Title	Status	Date	
Demographics	Demographics / Medical History Form	NEW	04-24-2015	



# Completing the Demographics/Medical History CRF

1. The **Demographics/Medical History** CRF displays.
2. Note all forms on the training website have bright red banners to distinguish from the live website.
3. The **Date of Participant Enrollment in Study** is automatically populated by the system on this CRF with the same date as the **COE** CRF.

**ECP REGISTRY TRAINING WEBSITE!!!!**

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

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

**Form Summary**

Site Name - ID:	Test Site - 100	Event Type:	Demographics	Form Type:	Demographics
Participant ID:	100003	Event Title:	Demographics/Medical History	Form Title:	Demographics / Medical History Form
Study Arm:	ECP Treatment Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	04-24-2015	Event Date:	04-24-2015	Form Date:	04-24-2015

**Extracorporeal Photophoresis (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="text"/> Browse...	<input type="button" value="Upload"/>
<input type="button" value="Save"/>	<input type="button" value="Submit"/>	

**Date of Participant Enrollment in Study:** 04/24/2015

# Completing the Demographics/Medical History CRF continued

4. Complete Sections A, B, and C.
5. Use the mouse to navigate and click the appropriate radio button to answer the questions and fill in the boxes as required.
6. For training purpose, enter the values shown in Section A example below.

**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

# Completing the Demographics/Medical History CRF continued

7. For training purpose, enter the values shown in Section B examples below.

## 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: 09/17/2013

7. Operation performed:

- ☒ Single
- ☐ Bilateral
- ☐ Heart-lung
- ☐ Other

If other, please describe:

8. Weight at time of transplant: 79 kilograms

9. Height: 180 Centimeters

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

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

If other active conditions, please describe:

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

- ☐ YES ☒ NO Anti-Thrombotic
- ☐ YES ☒ NO Anti-Platelet Agent

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

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

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

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

14. Has the participant received prednisone therapy within the last 6 months? ☒ YES ☐ NO

If yes, daily starting dose: 10 mg

15. During the last 6 months, has the patient required a prednisone dose escalation for any period of greater than 5 days? ☒ YES ☐ NO

If yes, to what daily dose: 30 mg

Estimate average daily dose over 6 months: 10 mg

16. Date of diagnosis of post-transplantation BOS: 09/25/2014

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

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

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

a. Baseline FEV1 (pre-bronchodilator)(mean FEV1 values below): 2.35 liters

b. First component assessment:

i. Date: 05/10/2014

ii. FEV1 (pre-bronchodilator): 2.41 liters

iii. FVC (pre-bronchodilator): 3.19 liters

c. Second component assessment:

i. Date: 10/02/2013

ii. FEV1 (pre-bronchodilator): 2.29 liters

iii. FVC (pre-bronchodilator): 3.01 liters

# Completing the Demographics/Medical History CRF continued

- For training purpose, enter the values shown in Section C example below.
- If you wish to return to this document to complete it later, click **Save** button.

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

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


20. Is the participant on any anticoagulant or anti-platelet drugs? ☐ YES ☒ NO

If yes, list drugs:

Name drug 1:

Name drug 2:

Name drug 3:

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

22. Weight:  kilograms

23. Blood pressure: systolic  mmHg diastolic  mmHg

24. Heart rate:  beats per minute

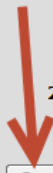
25. Respiratory rate:  breaths per minute

26. Resting oxygen saturation:  %

27. Is the participant receiving supplemental oxygen? ☒ YES ☐ NO

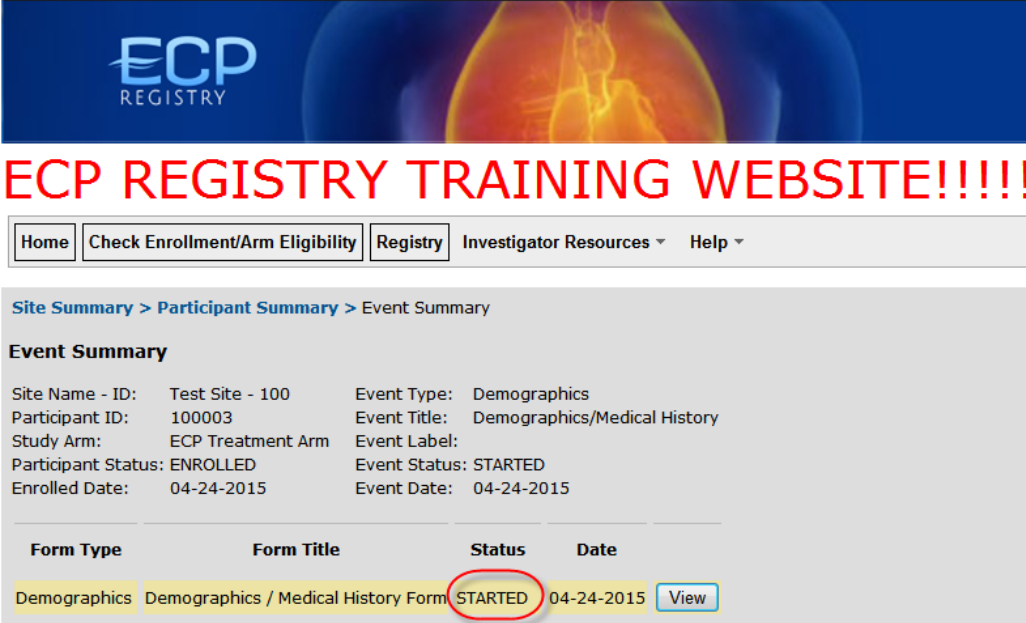
If yes, how much?  liters/minute

28. Comments:



# Completing the Demographics/Medical History CRF continued

10. Once the **Save** button is clicked, the **Status** of the CRF will be changed to **Started**. You may then return to the document later and complete it or make changes.



The screenshot shows the ECP Registry Training Website interface. At the top, there is a blue header with the ECP Registry logo and a heart graphic. Below the header, the text "ECP REGISTRY TRAINING WEBSITE!!!!" is displayed in red. A navigation bar contains links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. The main content area shows the "Event Summary" page, which includes a breadcrumb trail: Site Summary > Participant Summary > Event Summary. The Event Summary section displays the following information:

Site Name - ID:	Test Site - 100	Event Type:	Demographics
Participant ID:	100003	Event Title:	Demographics/Medical History
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	STARTED
Enrolled Date:	04-24-2015	Event Date:	04-24-2015

Below the summary, there is a table with the following columns: Form Type, Form Title, Status, and Date. The first row shows "Demographics" as the Form Type, "Demographics / Medical History Form" as the Form Title, "STARTED" as the Status (circled in red), and "04-24-2015" as the Date. A "View" button is located next to the Date.

11. Before submitting the CRF, scan and upload the required source documents. See slide #18 "Scan Source Documents into pdf Files" & slides #19-21 "Uploading PDF Files of Scanned Source Document".



# Completing the Demographics/Medical History CRF continued

12. Confirm that all data entered is accurate and that the required source document PDFs have been uploaded.
13. No changes can be made to this CRF once this **Submit** button is clicked.
14. Click the **Submit** button at either the top of or bottom of CRF.



**ECP REGISTRY TRAINING WEBSITE!!!!**

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

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

**Form Summary**

Site Name - ID:	Test Site - 100	Event Type:	Demographics	Form Type:	Demographics
Participant ID:	100003	Event Title:	Demographics/Medical History	Form Title:	Demographics / Medical History Form
Study Arm:	ECP Treatment Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	04-24-2015	Event Date:	04-24-2015	Form Date:	04-24-2015

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

**DEMOGRAPHICS/MEDICAL HISTORY - Case Report Form (CRF)**

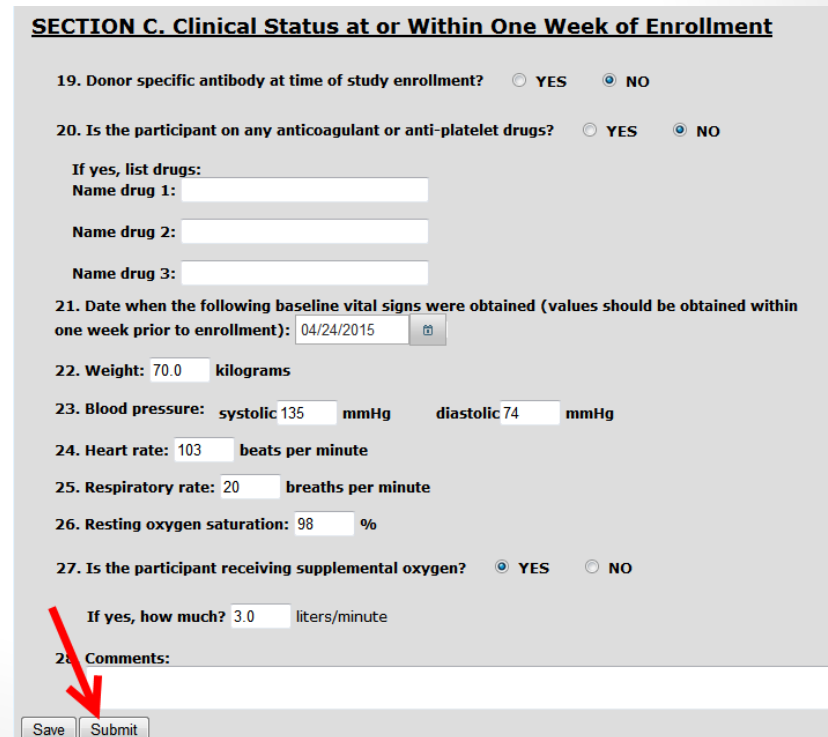
Please include the following types of source documents:

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

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

Attach Source Document:

Date of Participant Enrollment in Study:



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

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

20. Is the participant on any anticoagulant or anti-platelet drugs? ☐ YES ☒ NO

If yes, list drugs:

Name drug 1:

Name drug 2:

Name drug 3:

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

22. Weight:  kilograms

23. Blood pressure: systolic  mmHg diastolic  mmHg

24. Heart rate:  beats per minute

25. Respiratory rate:  breaths per minute

26. Resting oxygen saturation:  %

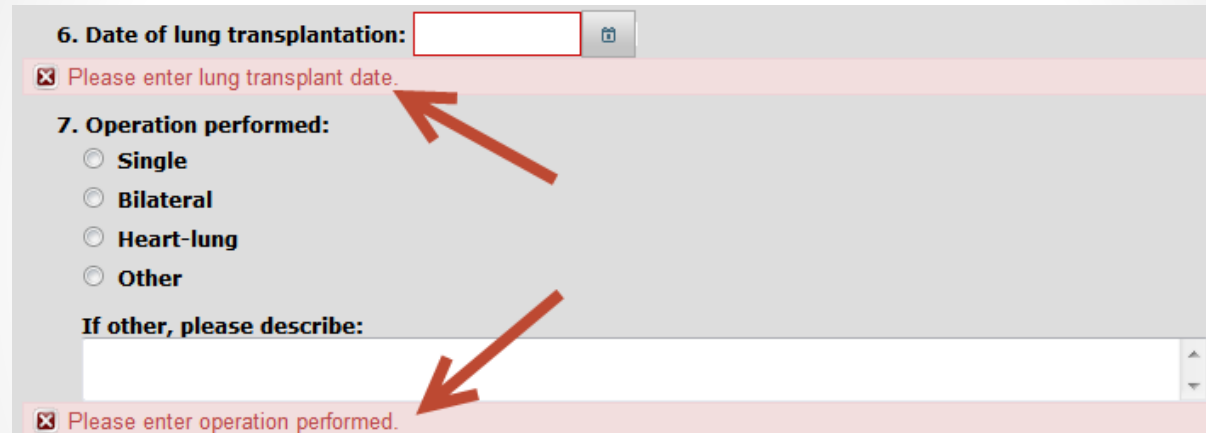
27. Is the participant receiving supplemental oxygen? ☒ YES ☐ NO

If yes, how much?  liters/minute

28. Comments:

# Completing the Demographics/Medical History CRF continued

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



The screenshot shows a portion of a Clinical Research Form (CRF) with two sections. Section 6, 'Date of lung transplantation:', has an empty date input field. Below it, a red error message reads 'Please enter lung transplant date.' with a red arrow pointing to the input field. Section 7, 'Operation performed:', has four radio button options: 'Single', 'Bilateral', 'Heart-lung', and 'Other'. Below these is a text input field labeled 'If other, please describe:'. A red error message at the bottom reads 'Please enter operation performed.' with a red arrow pointing to the text input field.

15. Complete and/or fix the out of range values and click the **Submit** button again.
16. After submitting the CRF, you are directed back to the **Participant Summary** page.

# Completing the Demographics/Medical History CRF

19. The **Status** of the CRF will be changed to **Submitted** on the **Participant Summary** page and the **Event Summary** page.

ECP REGISTRY TRAINING WEBSITE!!!!

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary > Participant Summary

Participant Summary

Site Name - ID: Test Site - 100  
Participant ID: 100003  
Study Arm: ECP Treatment Arm  
Participant Status: ENROLLED  
Enrolled Date: 04-24-2015

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			04-24-2015 View
Demographics	Demographics/Medical History		SUBMITTED			04-24-2015 View

ECP REGISTRY TRAINING WEBSITE!!!!

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary > Participant Summary > Event Summary

Event Summary

Site Name - ID: Test Site - 100  
Participant ID: 100003  
Study Arm: ECP Treatment Arm  
Participant Status: ENROLLED  
Enrolled Date: 04-24-2015

Event Type: Demographics  
Event Title: Demographics/Medical History  
Event Label:  
Event Status: SUBMITTED  
Event Date: 04-24-2015

Form Type	Form Title	Status	Date
Demographics	Demographics / Medical History Form	SUBMITTED	04-24-2015 View

15. After the CRF has been submitted, the DCC Staff may need to communicate with you using a CRF Data Verification process if data entry errors are found. Once the CRF is error free, the **Status** of the CRF is changed to **DCC VERIFIED**. See Data Verification slides #25-28 for more information.

# Completing the Demographics/Medical History CRF

Notice now that this CRF has been submitted, the **Site Summary** page displays for **Participant ID 100003** at **Test Site 100**:

- 35 **NEW** CRFs (still to do)
- 1 **Submitted** CRF (the Baseline Therapy just submitted)
- 1 **DCC Verified** (the COE CRF)



The screenshot shows the ECP Registry Training Website. At the top is a blue banner with the ECP Registry logo and a heart image. Below the banner, the text "ECP REGISTRY TRAINING WEBSITE!!!!!" is displayed in red. A navigation bar contains links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. On the right, it shows "User name: test\_sc" and a "logout" button. The "Site Summary" link is circled in red. Below it, the site name is "Test Site - 100". A table lists participant data with columns: Participant ID, Enrolled Date, Study Arm, Status, New, Started, Submitted, CRF Query, DCC Verified, PI Approved, and Not Required. The row for Participant ID 100003 is highlighted, with the values 35 in the "New" column, 1 in the "Submitted" column, and 1 in the "DCC Verified" column, all circled in red. Each row has a "View" button.

**ECP REGISTRY TRAINING WEBSITE!!!!!**

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

User name: test\_sc logout

**Site Summary**

Site Name - ID: Test Site - 100

Participant ID	Enrolled Date	Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	
100001	04-20-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View
100002	04-20-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View
100003	04-24-2015	ECP Treatment Arm	ENROLLED	35	0	1	0	1	0	0	View

# Scan Source Documents into pdf Files

- Source documents are required to support and verify subject data. The specific source documentation required is identified at the top of each CRF.
- To scan source documents into pdf format:
  - Copy the source document(s).
  - **Remove all personal identifiers on the source documents including name, date of birth, account or hospital number with a sharpie or china marker.**
  - **All de-identified source documents must include an ECP source document label available on the ECP Registry website <http://ecpregistry.wustl.edu> located under INVESTIGATOR RESOURCES drop down menu.**
  - Scan de-identified documents.
  - Save as a pdf file using these suggested naming convention.

Source Document Types	PDF file name
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



# Upload pdf Files of Scanned Source Documents

- A list of required source documents is provided on each CRF page and also listed in the **Select Source Document Type** drop down menu.

**ECP**  
REGISTRY

**ECP REGISTRY TRAINING WEBSITE!!!!**

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

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

**Form Summary**

Site Name - ID:	Test Site - 100	Event Type:	Demographics	Form Type:	Demographics
Participant ID:	100003	Event Title:	Demographics/Medical History	Form Title:	Demographics / Medical History Form
Study Arm:	ECP Treatment Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	SUBMITTED	Form Status:	SUBMITTED
Enrolled Date:	04-24-2015	Event Date:	04-24-2015	Form Date:	05-04-2015

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

**DEMOGRAPHICS/MEDICAL HISTORY - Case Report Form (CRF)**

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

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

Source Document Type	Document Name	Submission Date
Select Source Document Type	History and Physical or Consultation Note	
Attach Source Document:	History and Physical or Consultation Note	
	Operative Report of Transplant Procedure	
	Pulmonary Function Test Reports (for each FEV-1 submitted)	

**Date of Participant Enrollment in Study:** 04/24/2015

# Upload pdf Files of Scanned Source Documents

- For training purpose, the examples shown are for uploading pdfs to the **COE CRF**.
- If a source document has more than one page, only upload the page(s) that contain the data relevant for that specific CRF.
- Select the **Source Document Type** from the drop down menu for the pdf.

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	
	History and Physical or Consultation Note	
Attach Source Document:	Operative Report of Transplant Procedure	
	Pulmonary Function Test Reports (for each FEV-1 submitted)	

- Click the **Browse** button.
- Locate the saved source document in pdf format and double click it.
- You will be directed back to the CRF page and the path to the pdf file displays next to the **Browse** button.
- Click the **Upload** button.

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:	ECPVHX_101003_1120201	

# Upload pdf Files of Scanned Source Documents

- For training purpose, the example shown is for uploading pdfs to the **COE CRF**.
- Once uploaded, a highlighted entry displays for the source document with the name of the pdf.
- To confirm that the correct pdf has been uploaded, click the **View** button next to the highlighted entry.
- Click the **Delete** button next to the highlighted entry if it is the wrong pdf and re-upload the correct one.
- Continue this process until all pdfs files have been uploaded for that CRF.

Please include the following types of source documents:

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

Source Document Type	Document Name	Submission Date		
A Signed Confirmation of Eligibility Form must be uploaded	COE_101001_01072015.pdf	2015-01-07	<a href="#">View</a>	<a href="#">Delete</a>

Select Source Document Type A Signed Confirmation of Eligibility Form must be uploaded

Attach Source Document:  [Browse...](#) [Upload](#)

[Save](#) [Submit](#)

# Example of Demographics/Medical History CRF with PDF Uploaded



ECP REGISTRY TRAINING WEBSITE!!!!

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

[Site Summary](#) > [Participant Summary](#) > [Event Summary](#) > Demographics / Medical History Form

**Form Summary**

Site Name - ID:	Test Site - 100	Event Type:	Demographics	Form Type:	Demographics
Participant ID:	100003	Event Title:	Demographics/Medical History	Form Title:	Demographics / Medical History Form
Study Arm:	ECP Treatment Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	SUBMITTED	Form Status:	SUBMITTED
Enrolled Date:	04-24-2015	Event Date:	04-24-2015	Form Date:	05-04-2015

**Extracorporeal Photophoresis (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_100003_0401315.pdf	05-04-2015	<a href="#">View</a>
Operative Report of Transplant Procedure	ORTP_100003_05132013.pdf	05-04-2015	<a href="#">View</a>
Pulmonary Function Test Reports (for each FEV-1 submitted)	PFT_100003_12012014.pdf	05-04-2015	<a href="#">View</a>
Pulmonary Function Test Reports (for each FEV-1 submitted)	PFT_100003_04132015.pdf	05-04-2015	<a href="#">View</a>
Pulmonary Function Test Reports (for each FEV-1 submitted)	PFT_100003_03022015.pdf	05-04-2015	<a href="#">View</a>

Select Source Document Type [Pulmonary Function Test Reports \(for each FEV-1 submitted\)](#)

Attach Source Document:  [Browse...](#) [Upload](#)

# ECP Navigation

- If need to come back to a CRF, always click the  button at the top of the page to direct you to your **Site Summary** page.
- Click the  button next to the **Participant ID** to direct you to the **Participant Summary** page.
- Click the  button next to the **Event Type** of the CRF to direct you to the **Event Summary** page.
- Click the  button next to the **Form Type** of the CRF to direct you to the CRF page.



# ECP Navigation

- Another way to navigate to the **Site Summary** page or the **Participant Summary** page, is to use the breadcrumb displayed at the top of the page. (See circled item in image below.) The **Site Summary** page and the **Participant Summary** page are in blue. These pages are linked to take you back at any time.
- Always **SAVE** your work before clicking on a bread crumb link.



The screenshot shows the ECP Registry Training Website interface. At the top is a blue header with the ECP Registry logo and a medical illustration. Below the header, the title "ECP REGISTRY TRAINING WEBSITE" is displayed in red. A navigation bar contains links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources (with a dropdown arrow), and Help. Below this, a breadcrumb trail is shown: "Site Summary > Participant Summary > Event Summary". The "Site Summary" and "Participant Summary" links are highlighted in blue and circled in red. Under the breadcrumb, the "Event Summary" section displays details for a specific event, including Site Name, Participant ID, Study Arm, Participant Status, Enrolled Date, Event Type, Event Title, Event Label, Event Status, and Event Date. At the bottom, a table lists the event details with columns for Form Type, Form Title, Status, Date, and a View button.

**ECP REGISTRY TRAINING WEBSITE**

Home Check Enrollment/Arm Eligibility Registry Investigator Resources ▾ Help

[Site Summary](#) > [Participant Summary](#) > Event Summary

**Event Summary**

Site Name - ID: Test Site - 100 Event Type: Confirmation of Eligibility  
Participant ID: 100001 Event Title: Confirmation of Eligibility  
Study Arm: ECP Treatment Arm Event Label:  
Participant Status: ENROLLED Event Status: NEW  
Enrolled Date: 04-03-2015 Event Date: 04-03-2015

Form Type	Form Title	Status	Date	
Confirmation of Eligibility	Confirmation of Eligibility Form	NEW	04-03-2015	<a href="#">View</a>

# Data Verification – DCC Staff

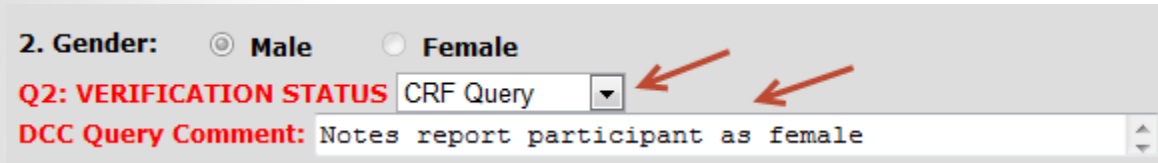
- The Data Coordinating Center (DCC) is responsible for validating CRF data after it has been submitted.
- When the status of a CRF becomes **SUBMITTED**, a technical coordinator from the DCC will examine the CRF's data and compare to the uploaded de-identified source documents.
- For each data field to be evaluated, the technical coordinator will make one of three possible determinations.
  - DCC Verified – The data on the CRF matches the corresponding de-identified source document.
  - CRF Query – The data on the CRF does not match the corresponding de-identified source document.
  - Source Missing – The source document(s) are missing.

# Data Verification – Site Coordinators

- Site coordinators must monitor the status of their site's CRFs on the **Site Summary** page looking for Events that are listed as **CRF Query**.
- CRF data fields with a status of **CRF Query** and **Source Missing** must be corrected and the CRF form re-submitted.
- Follow this process until the status of each CRF is **DCC VERIFIED**.

# Data Verification – examples from the CRF

- A CRF data field that is marked CRF Query will also have a comment explaining the nature of the discrepancy.



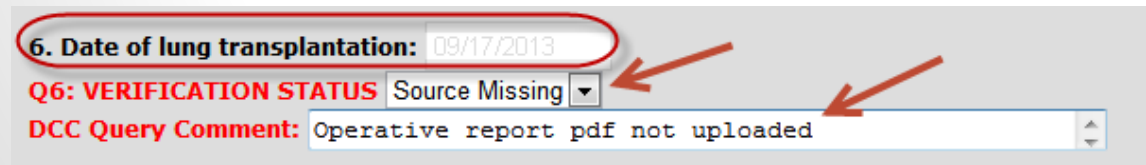
2. Gender: ☒ Male ☐ Female

Q2: VERIFICATION STATUS CRF Query

DCC Query Comment: Notes report participant as female

This screenshot shows a CRF form for gender data. The 'Gender' field has 'Male' selected. Below it, the 'Q2: VERIFICATION STATUS' is set to 'CRF Query'. A text box for 'DCC Query Comment' contains the text 'Notes report participant as female'. Two red arrows point to the 'CRF Query' dropdown and the comment text box.

- If a data field is marked Source Missing, the CRF does not have an uploaded source document to confirm the value in that field.



6. Date of lung transplantation: 09/17/2013

Q6: VERIFICATION STATUS Source Missing

DCC Query Comment: Operative report pdf not uploaded

This screenshot shows a CRF form for a date field. The 'Date of lung transplantation' is '09/17/2013'. Below it, the 'Q6: VERIFICATION STATUS' is set to 'Source Missing'. A text box for 'DCC Query Comment' contains the text 'Operative report pdf not uploaded'. A red oval highlights the date field, and two red arrows point to the 'Source Missing' dropdown and the comment text box.

# Data Verification – examples from the Site Summary page

- Example of an Event Status marked DCC Verified by the DCC staff.

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Demographics	Demographics/Medical History		CRF_QUERY			04-24-2015	<a href="#">View</a>

- Example of an Event Status marked CRF Query by the DCC staff.

Note: if several data fields are marked either CRF Query and Source Missing, the Status will only display CRF Query.

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Demographics	Demographics/Medical History		DCC_VERIFIED			04-24-2015	<a href="#">View</a>



# For Questions - DCC Contacts

Name	Role	Email	Phone
Joan Moulton	Technical Coordinator and Help Desk Manager	<a href="mailto:moultonj@mir.wustl.edu">moultonj@mir.wustl.edu</a>	314-362-7185
Mary Wolfsberger	Technical Coordinator and Help Desk Manager	<a href="mailto:wolfsbergerm@mir.wustl.edu">wolfsbergerm@mir.wustl.edu</a>	314-362-7194

# Attestation Form

- Thank you for taking the time to review the ECP Registry Electronic Data Capture (EDC) system
- Please sign the Attestation Form located on the ECP website <http://ecpregistry.wustl.edu> under Help drop down menu.
- Keep the original in your ECP Registry Binder.
- Forward a copy to [taylorlork@mir.wustl.edu](mailto:taylorlork@mir.wustl.edu)