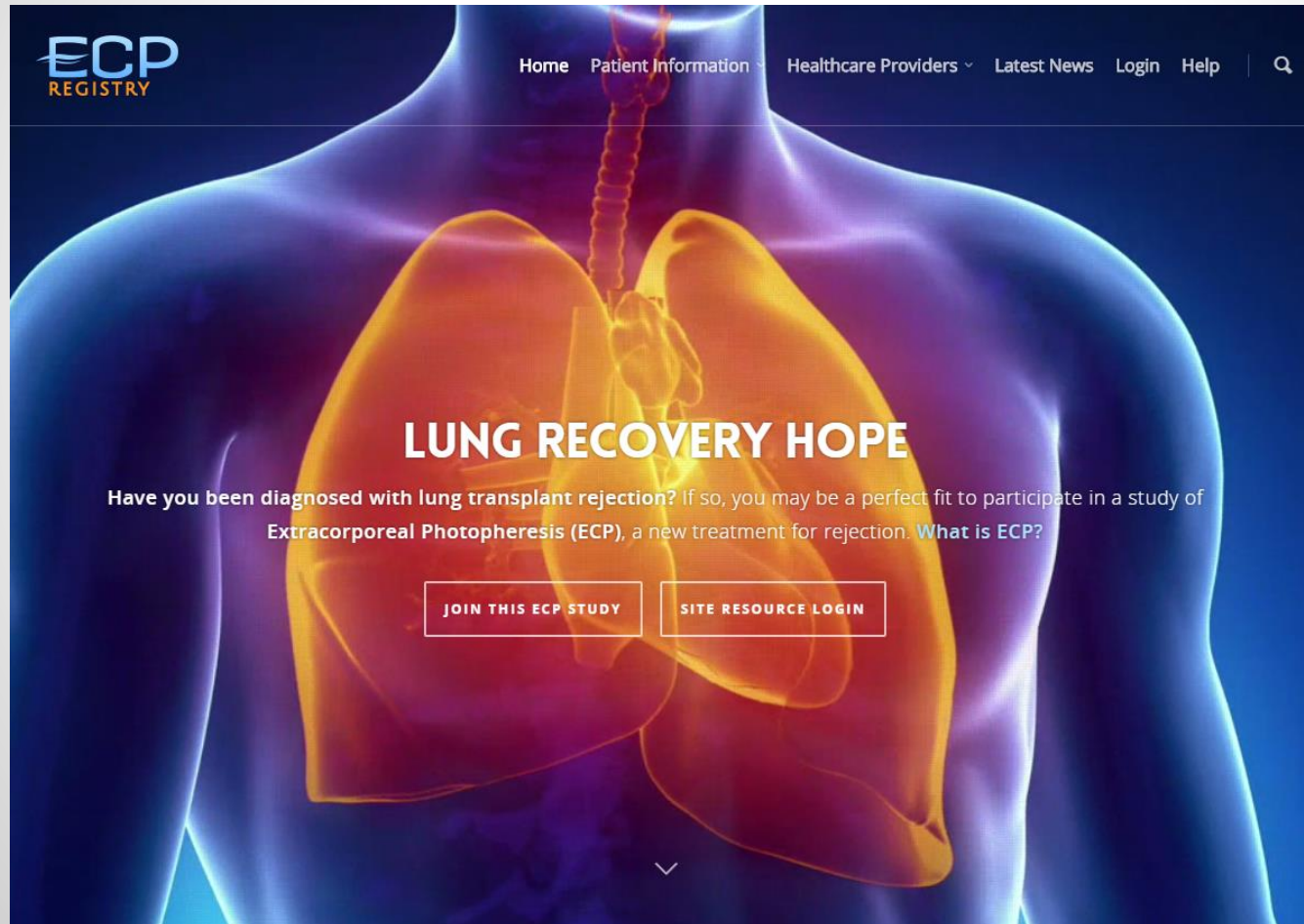


Welcome to the Enrollment and COE CRF Training Presentation



Introduction

- The Data Coordinating Center (DCC) for the ECP Registry is located at Washington University School of Medicine in St. Louis. The team is led by Dr. Fred Prior, Professor of Radiology and Director of the Electronic Radiology Lab.
- The DCC's primary function is to centrally coordinate the management of study data and to maintain the ECP Registry's public and secure website. The secure area contains the case report forms.
- This training presentation provides the staff at ECP-BOS enrollment sites with the processes for Enrollment and the Confirmation of Eligibility (COE) Case Report Form (CRF) using the ECP Registry .
- All site training will be done on an ECP Registry training website.

User Account and Password

- Each user is required to have their own account and password to log into the secure portion of the ECP Registry website.
- Do not share accounts and passwords.
- To obtain an account and password, you must be listed on your site's ECP Delegation of Authority (DOA) Log with the appropriate responsibility codes. The Clinical Coordinating Center (CCC) will assist with the DOA Log.

System Requirements for Using the ECP Registry

Operating Systems

- Windows 8
- Windows 7
- Windows XP
- MAC

Browsers

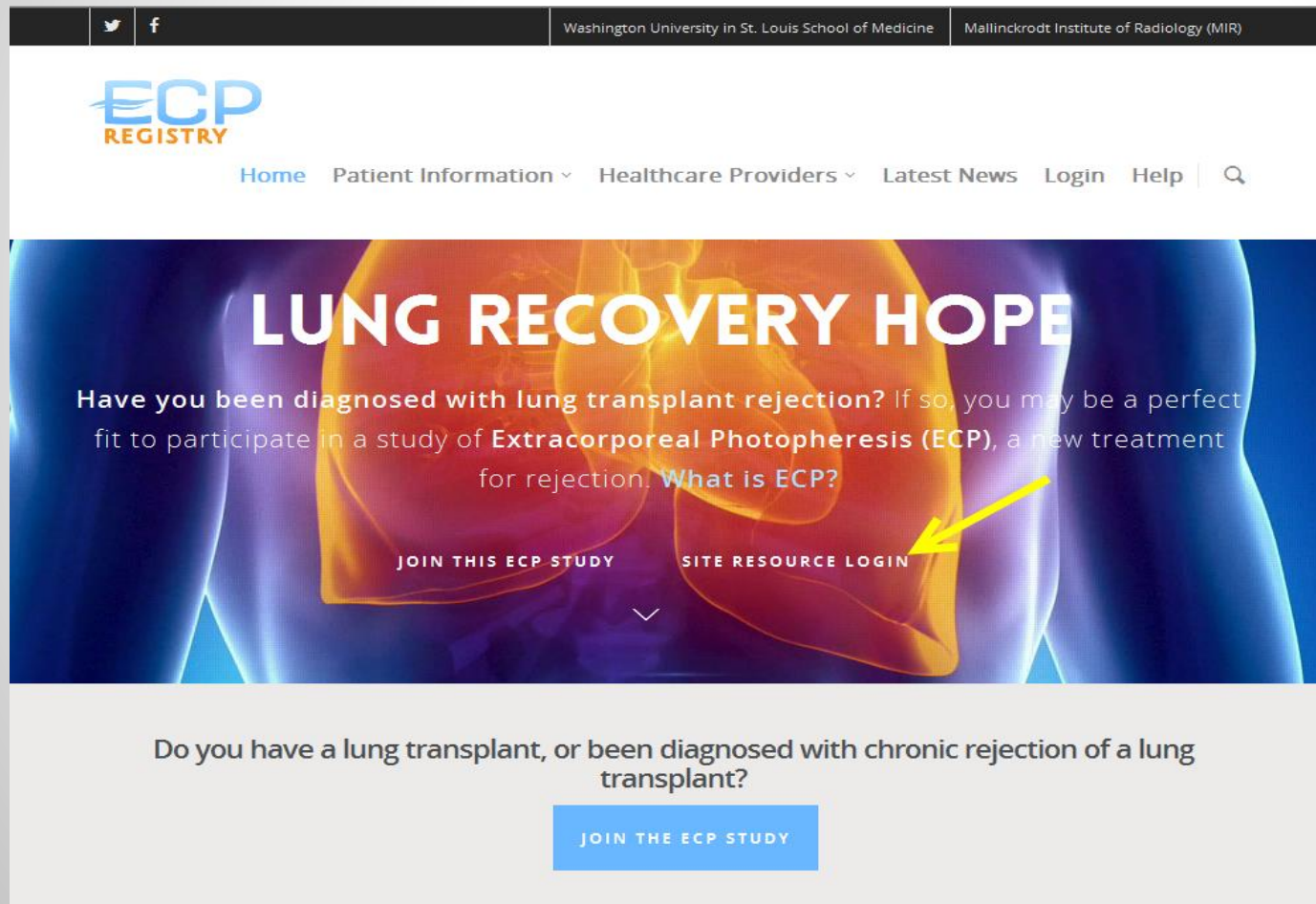
- Internet Explorer 8
- Internet Explorer 9
- Google Chrome

Please access the Training Website

- Open a browser window.
 - Internet Explorer 8 or 9 in Windows
 - Google Chrome in MAC
- Type the web address listed below.

<http://ecpregtraining.wustl.edu/wordpress>

- The **ECP** REGISTRY home page will display.
- Click on **SITE RESOURCE LOGIN** (see yellow arrow in image below) to access the ECP Registry Training Secure Website.



Logging into the Secure Website

- The **ECP Registry Training Site** Resources Login page is displayed.
- Login using your assigned username and password.

ECP Registry Site Resources Login

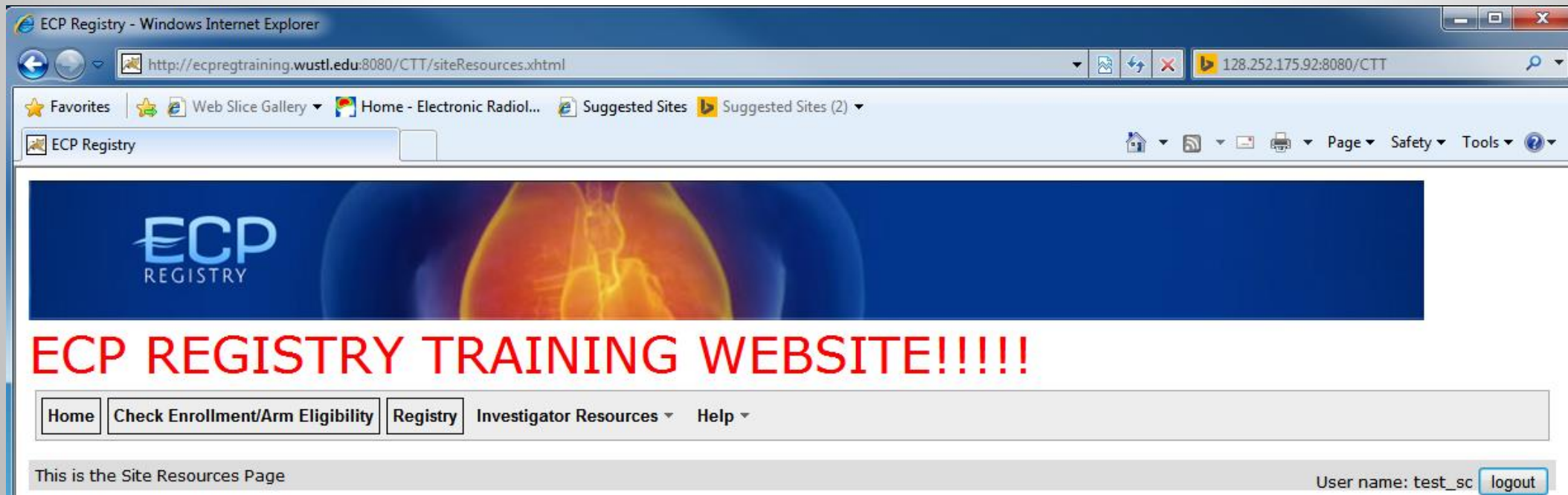
Username:

Password

Remember Me ☐

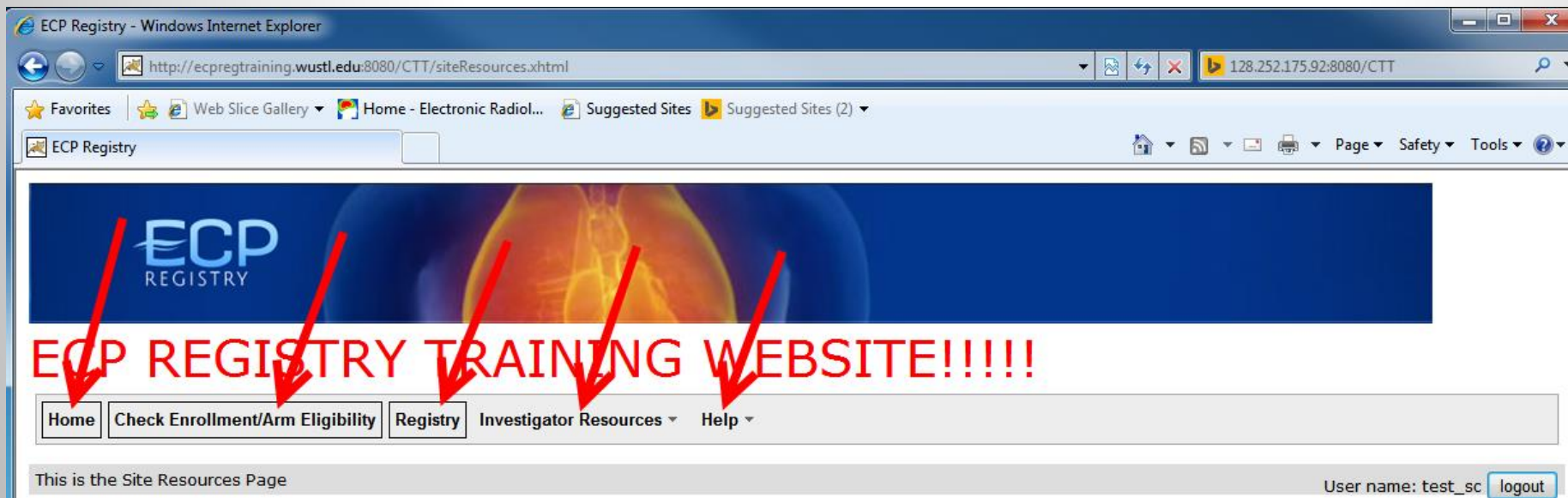
Site Resources Page

- 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**



Site Resources Page

- Note there are three menu buttons and two menu items at the top of the ECP Site Resources page. (see red arrows in image below)
- The [Home](#) button directs you back to the ECP Registry home page.
- The [Check Enrollment/Arm Eligibility](#) button opens the **Enrollment Assessment and Study Arm Eligibility** webpage.
- The [Registry](#) button directs you to the **Site Summary** page.
- The [Investigator Resources](#) menu item contains a drop down box that links to specific resources.
- The [Help](#) menu item contains a drop down box that links to ECP Registry resources.



Enrollment Eligibility and Study Arm Determination

- Click the **Check Enrollment/Arm Eligibility** button, this will start the Enrollment process.



- The **Enrollment Assessment and Study Arm Eligibility** worksheet will display.
- The current date is automatically populated by the system.
- Note all forms on the training website have bright red banners to distinguish the training website from the live website.

Extracorporeal Photophoresis (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: 04/03/2015

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

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

Enrollment Eligibility and Study Arm Determination

- The **Enrollment Assessment and Study Arm Eligibility** worksheet is divided into four sections.
- The first section is the **INCLUSION CRITERIA** section.
- Answer all inclusion questions by using your mouse to click the appropriate radio button.
- All answers must be “YES” for the participant to be eligible.

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

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

Enrollment Eligibility and Study Arm Determination

- The second section is the **EXCLUSION CRITERIA** section.
- Answer all exclusion questions by using your mouse to click the appropriate radio button.
- All answers must be “NO” for the participant to be eligible.

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

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

Enrollment Eligibility and Study Arm Determination

- The third section is the **PULMONARY EVALUATIONS** section.
- For training purpose, enter the values shown in the example below, except last date; E. use yesterday's date.

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


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

A. Date	<input type="text" value="03/01/2015"/>	FEV1	<input type="text" value="3.8"/>	liters	FVC	<input type="text" value="5.0"/>	liters
B. Date	<input type="text" value="03/10/2015"/>	FEV1	<input type="text" value="3.5"/>	liters	FVC	<input type="text" value="5.0"/>	liters
C. Date	<input type="text" value="03/17/2015"/>	FEV1	<input type="text" value="3.3"/>	liters	FVC	<input type="text" value="5.0"/>	liters
D. Date	<input type="text" value="03/24/2015"/>	FEV1	<input type="text" value="3.1"/>	liters	FVC	<input type="text" value="5.0"/>	liters
E. Date	<input type="text" value="03/31/2015"/>	FEV1	<input type="text" value="2.8"/>	liters	FVC	<input type="text" value="4.0"/>	liters

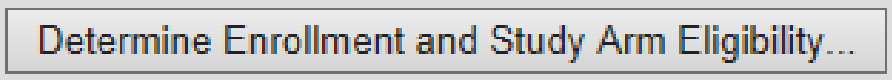
If additional FEV1 values have been obtained during the last 6 months, please provide:

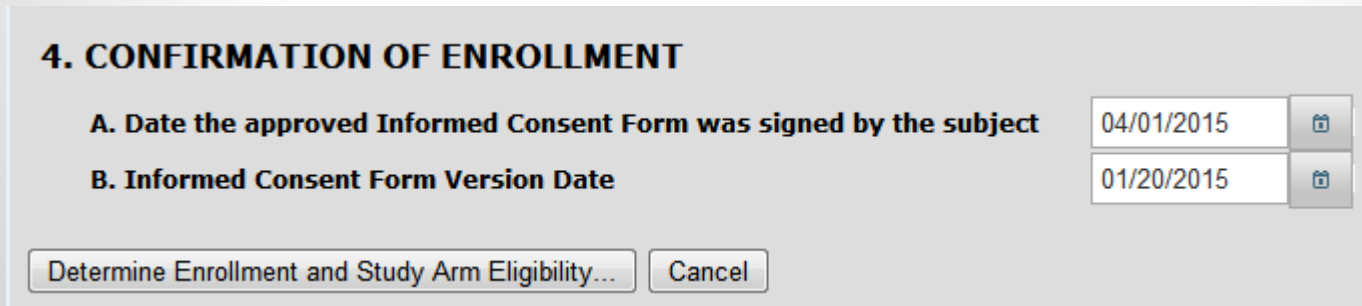
F. Date	<input type="text"/>	FEV1	<input type="text"/>	liters	FVC	<input type="text"/>	liters
G. Date	<input type="text"/>	FEV1	<input type="text"/>	liters	FVC	<input type="text"/>	liters
H. Date	<input type="text"/>	FEV1	<input type="text"/>	liters	FVC	<input type="text"/>	liters
I. Date	<input type="text"/>	FEV1	<input type="text"/>	liters	FVC	<input type="text"/>	liters
J. Date	<input type="text"/>	FEV1	<input type="text"/>	liters	FVC	<input type="text"/>	liters
K. Date	<input type="text"/>	FEV1	<input type="text"/>	liters	FVC	<input type="text"/>	liters
L. Date	<input type="text"/>	FEV1	<input type="text"/>	liters	FVC	<input type="text"/>	liters
M. Date	<input type="text"/>	FEV1	<input type="text"/>	liters	FVC	<input type="text"/>	liters
N. Date	<input type="text"/>	FEV1	<input type="text"/>	liters	FVC	<input type="text"/>	liters
O. Date	<input type="text"/>	FEV1	<input type="text"/>	liters	FVC	<input type="text"/>	liters

Enrollment Eligibility and Study Arm Determination

- Enter the date of each recorded FEV1 and FVC using the MM/DD/YYYY format, or click the  calendar icon and select date from the pop up calendar.
- Enter the **pre-bronchodilator** values of each recorded FEV1 and FVC (up to 15) obtained within the last 6 months.
- A minimum of 5 recorded **pre-bronchodilator** FEV1s and FVCs values post-transplant must be entered, all within the last 6 months.
- The recorded **pre-bronchodilator** FEV1 and FVC values must be at least one week apart, with the most recent one within the last week.
- Enter **pre-bronchodilator** FEV1 and FVC values in chronological date order **with the oldest date first in row A** and end with the newest date last.

Enrollment Eligibility and Study Arm Determination

- The fourth section is the **CONFIRMATION OF ENROLLMENT** section.
- For training purpose, enter the values in the example below.
- Enter the date the participant signed the Informed consent.
- Enter the Informed Consent form version date.
- Confirm all information entered is correct and accurate.
- Click the  button.
- NOTE no changes can be made to this form once this button is clicked.



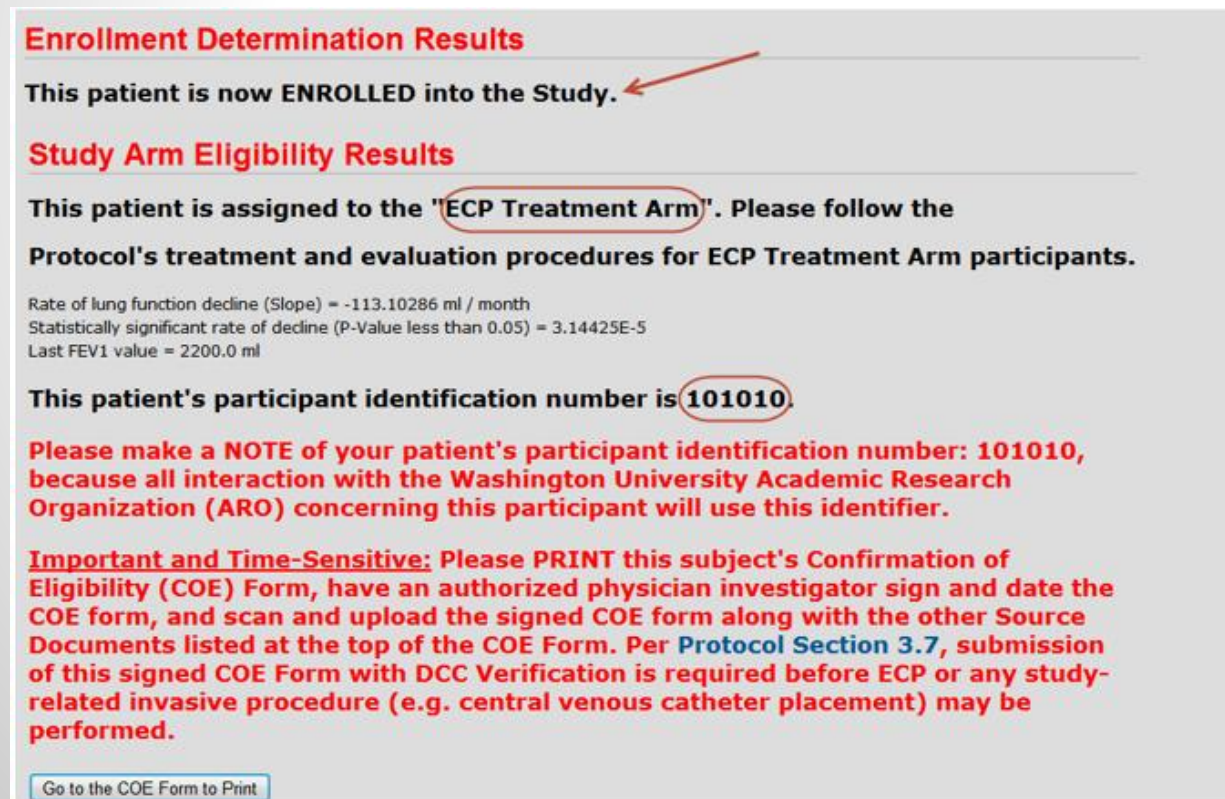
4. CONFIRMATION OF ENROLLMENT

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

B. Informed Consent Form Version Date

Enrollment Eligibility and Study Arm Determination

- After clicking the [Determine Enrollment and Study Arm Eligibility...](#) button, the **Enrollment Determination Results** page will display with the enrollment and study arm eligibility results.
- Three possible results will occur; 1) Participant enrolled in the ECP Treatment Arm, 2) Participant enrolled ECP Observational Arm or 3) Participant may not be enrolled at this time.
- In the example below, the participant was enrolled into the ECP Treatment Arm of the study and assigned Participant ID 101010.



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](#)

Enrollment Eligibility and Study Arm Determination

- In the example below, the participant was enrolled in the “Observational Arm” and assigned Participant ID 101009.

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 ≥ -30 when the minimum FEV1 ≥ 1200 ml

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

This patient’s participant identification number is **101009**.

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

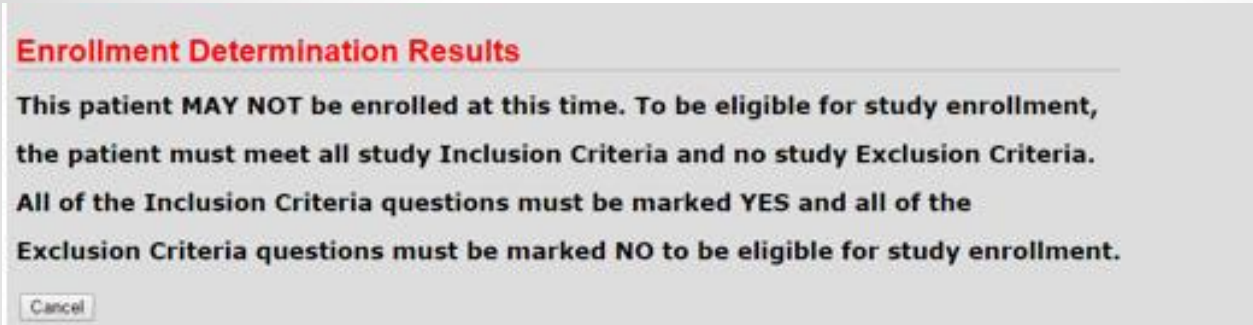
Please follow the Protocol’s treatment and evaluation procedures for Observation Arm patients, and enter all subsequent clinically obtained FEV-1 values into the Observation Pulmonary Evaluations Log. If your patient exhibits further decline and you wish him/her to receive ECP, you may enter up to 4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

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

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

Enrollment Eligibility and Study Arm Determination

- In the example below, the participant MAY NOT be enrolled at this time, but may be re-evaluated at another time.



- If enrolled, the participant will now be listed on the **Site Summary** page.
- All participants enrolled will be assigned a **Participant ID**.
- Keep a record of the assigned **Participant ID**, all interaction with Washington University DCC and CCC concerning participants will use this identifier.
- The Participant is now enrolled.

Printing the Confirmation of Eligibility CRF

- Click the [Go to the COE Form to Print](#) button at the bottom of the **Enrollment Determination Results** page to be directed to the COE CRF and print.

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](#)

- Clicking this button:
 - Populates the **COE** CRF with the participant data just entered into the **Enrollment Assessment and Study Arm Eligibility** worksheet.
 - Directs you to the **Site Summary** page where all eligible participants are listed for your site.

Printing the Confirmation of Eligibility CRF

- On the **Site Summary** page, locate the correct patient by assigned **Participant ID**.
- Click the [View](#) button on that line.

ECP REGISTRY TRAINING WEBSITE

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help


User name: test_sc [logout](#)

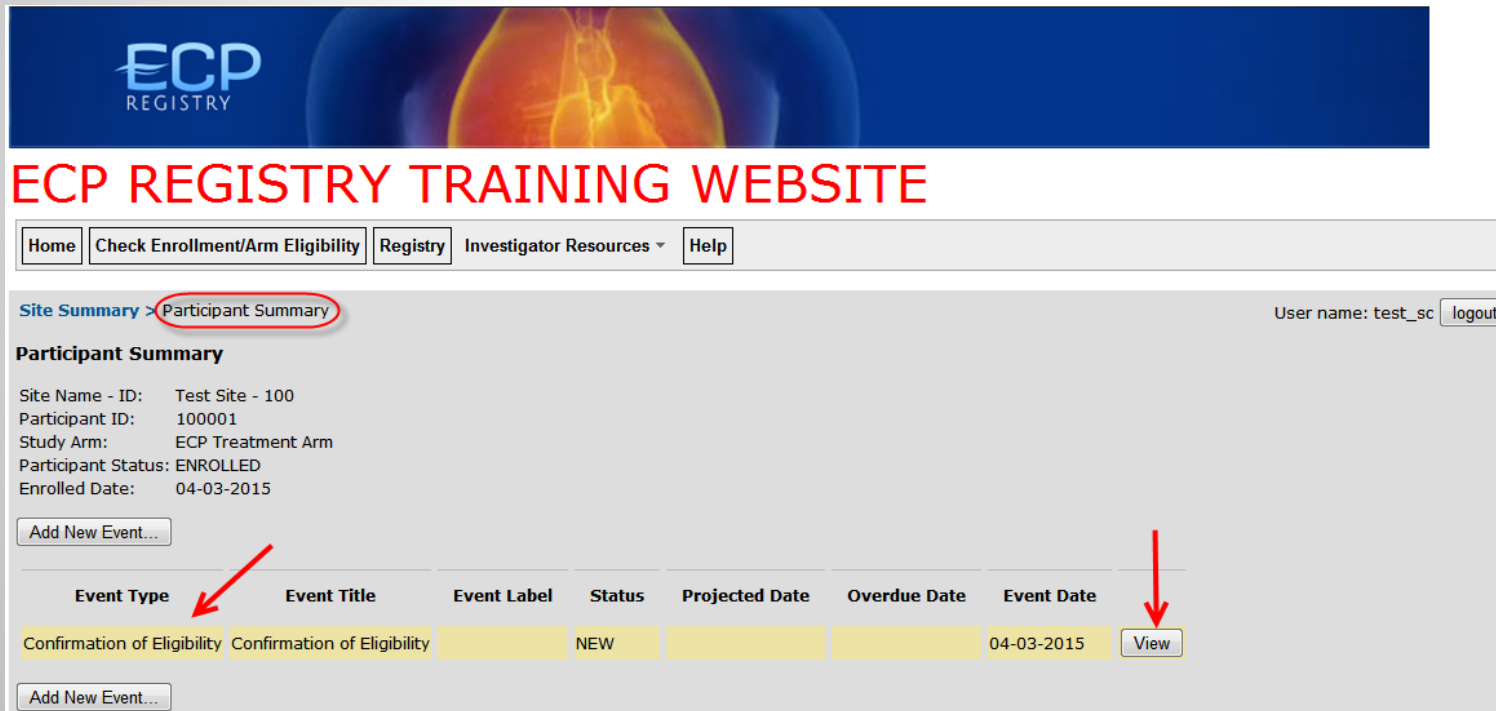
Site Summary

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	04-03-2015	ECP Treatment Arm	ENROLLED	1	0	0	0	0	0	0	View

Printing the Confirmation of Eligibility CRF


- The **Participant Summary** page is now displayed.
- In the example below, the **Confirmation of Eligibility** (COE) Event is listed.
- Click the  button to be directed to the **Event Summary** page.

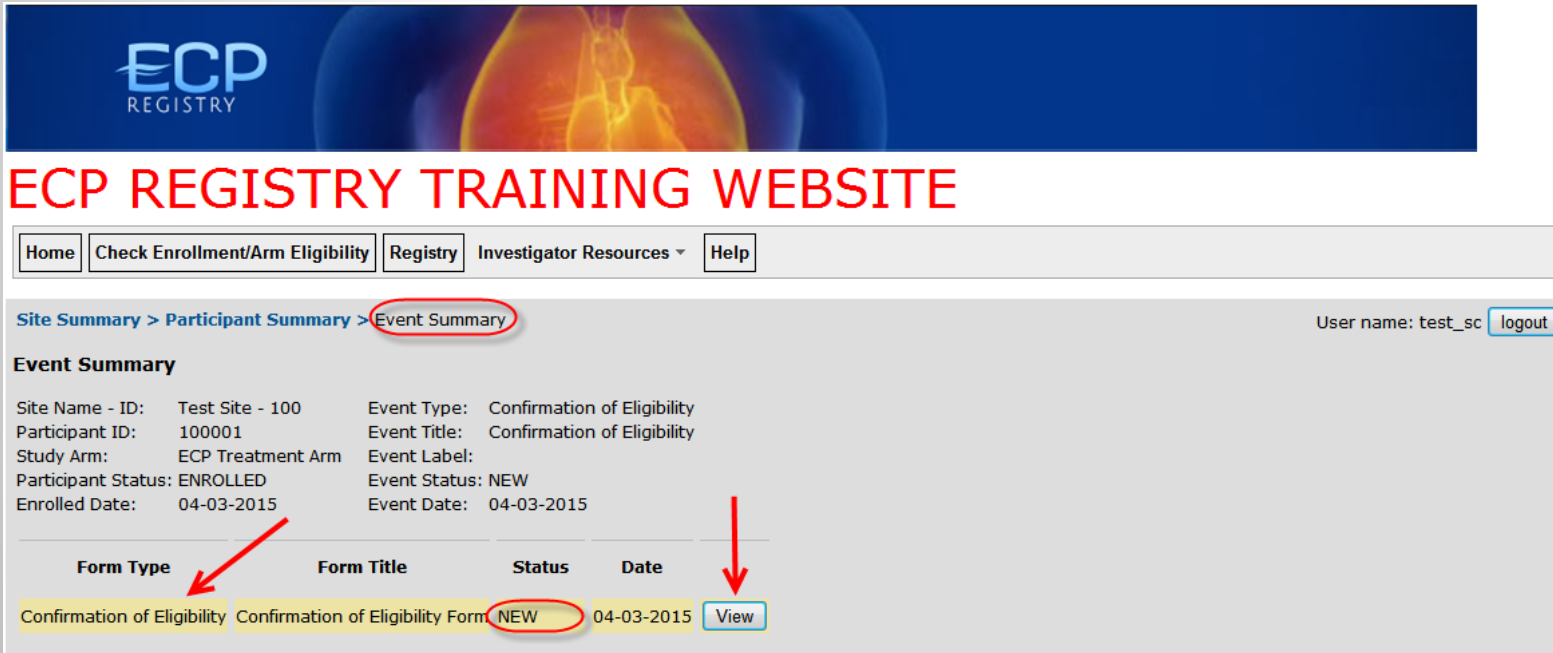


The screenshot displays the ECP Registry Training Website interface. At the top, there is a blue banner with the ECP Registry logo and a medical illustration. Below the banner, the text "ECP REGISTRY TRAINING WEBSITE" is written in red. A navigation bar contains links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. The "Participant Summary" tab is selected and circled in red. The page title is "Participant Summary". On the right, it shows "User name: test_sc" and a "logout" button. The main content area displays participant information: Site Name - ID: Test Site - 100, Participant ID: 100001, Study Arm: ECP Treatment Arm, Participant Status: ENROLLED, and Enrolled Date: 04-03-2015. Below this is an "Add New Event..." button. A table lists events with columns: Event Type, Event Title, Event Label, Status, Projected Date, Overdue Date, and Event Date. The first row shows "Confirmation of Eligibility" for the Event Type and Title, with a status of "NEW" and an event date of "04-03-2015". A red arrow points to the "View" button next to this row. Another "Add New Event..." button is at the bottom left.

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Confirmation of Eligibility	Confirmation of Eligibility		NEW			04-03-2015	View

Printing the Confirmation of Eligibility CRF

- The **Event Summary** page is now displayed.
- In the example below, the **Confirmation of Eligibility** form is listed and the status column reads **NEW**.
- Click the  button to be directed to the **Confirmation of Eligibility (COE) CRF**.



ECP REGISTRY TRAINING WEBSITE

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary > Participant Summary > **Event Summary** User name: test_sc [logout](#)

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	View

Printing the Confirmation of Eligibility CRF

- The **Confirmation of Eligibility** (COE) CRF is now displayed and can be printed.
- Review and confirm all data entered is accurate.
- The **COE** CRF is ready to be printed, signed and uploaded.

The screenshot displays the ECP Registry Training Website interface. At the top, there is a blue header with the ECP Registry logo and a navigation bar with links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. Below the navigation bar, a breadcrumb trail shows the path: Site Summary > Participant Summary > Event Summary > Confirmation of Eligibility Form, with the last item highlighted. A user login area on the right shows 'User name: test_sc' and a 'logout' button. The main content area is titled 'Form Summary' and contains a table of form details:

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

Below the table, a red box contains the text: 'Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts' and 'CONFIRMATION OF ELIGIBILITY - Case Report Form (CRF)'. A red text block follows, stating: 'Important and Time-Sensitive: Please PRINT this subject's Confirmation of Eligibility (COE) Form, have an authorized physician investigator sign and date the COE form, and scan and upload the signed COE form along with the other Source Documents listed at the top of the COE Form. Per Protocol Section 3.7, submission of this signed COE Form with DCC Verification is required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed. NOTE: ECP Treatment or study-related invasive procedures are not permitted for Observational Arm participants.'

Below this, a section titled 'Please include the following types of source documents:' lists four items:

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)





At the bottom, there is a table header for source documents:

Source Document Type	Document Name	Submission Date
----------------------	---------------	-----------------

Printing CRFs

- All CRF's may be printed.
 - Right click using your mouse on an open CRF.
 - A pop up box will display.
 - Select Print.
-
- Note blank copies of the ECP Registry CRF's are available on the ECP website at <http://ecpregistry.wustl.edu> located under Investigator Resources and may be used to hand write data to enter into the ECP website later.

ECP Navigation

- If need to come back and print 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.



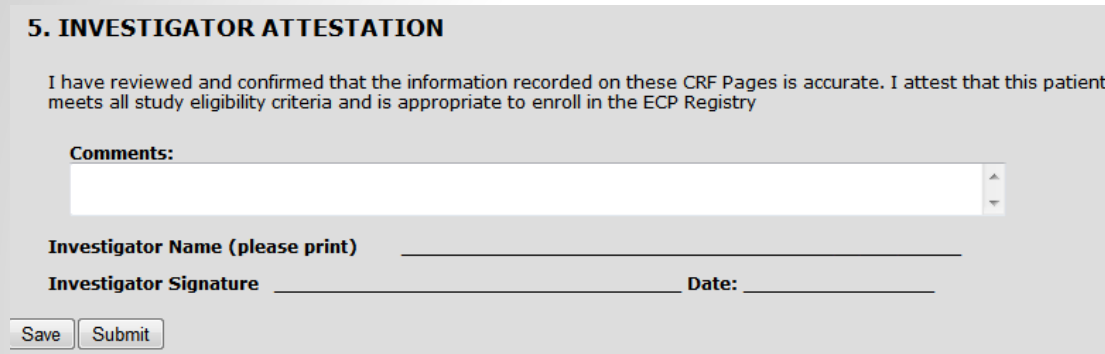
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Site Name - ID:	Test Site - 100	Event Type:	Confirmation of Eligibility
Participant ID:	100001	Event Title:	Confirmation of Eligibility
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	04-03-2015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

Form Type	Form Title	Status	Date	
Confirmation of Eligibility	Confirmation of Eligibility Form	NEW	04-03-2015	View

Completing the COE CRF

- To complete the COE CRF:
 1. Have the bottom of the printed **COE** CRF signed by the PI or Co-I.



5. INVESTIGATOR ATTESTATION

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

Comments:

Investigator Name (please print) _____

Investigator Signature _____ **Date:** _____

2. Scan and upload the required supporting source documents listed here and on the COE CRF.
 - The printed and signed COE CRF
 - A History and Physical or Consultation Notes
 - An Operative Report of Transplant Procedure
 - Pulmonary Function Test Report for each FEV-1 submitted

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 naming convention provided.

File Naming Guide for pdfs

Source Document Types	PDF file name
A Signed Confirmation of Eligibility Form	COE_participantid#.pdf
History and Physical or Consultation Note	HX_participantid#.pdf
Operative Report of Transplant Procedure	OPRTP_participantid#.pdf
Pulmonary Function Test Reports	PFT_participantid#_mmddyyyy.pdf
Clinical Note or Medication Record Form	MEDS_participantid#_mmddyyyy.pdf
Photopheresis Procedure Note/Report	ECP_participantid#_mmddyyyy.pdf
CBC - Lab Report	CBC_participantid#_mmddyyyy.pdf
Progress Note or Clinical Note describing complication	PROGRESS_participantid#_mmddyyyy.pdf
Autopsy Report	AUTRPT_participantid#.pdf
Crossover Safety Check Form	CSC_participantid#_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 TRAINING WEBSITE!!!!

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

Site Summary > Participant Summary > Event Summary > Confirmation of Eligibility Form User name: test_sc [logout](#)

Form Summary

Site Name - ID:	WashU - 101	Event Type:	Confirmation of Eligibility	Form Type:	Confirmation of Eligibility
Participant ID:	101001	Event Title:	Confirmation of Eligibility	Form Title:	Confirmation of Eligibility Form
Study Arm:	Observational Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	DCC_VERIFIED	Form Status:	DCC_VERIFIED
Enrolled Date:	02-12-2015	Event Date:	02-12-2015	Form Date:	02-12-2015

Extracorporeal Photophoresis (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 other Source Documents listed at the top of the COE Form. Per [Protocol Section 3.7](#), submission of this signed COE Form with DCC Verification is required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed. NOTE: ECP Treatment or study-related invasive procedures are not permitted for Observational Arm participants.

Please include the following types of source documents:

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

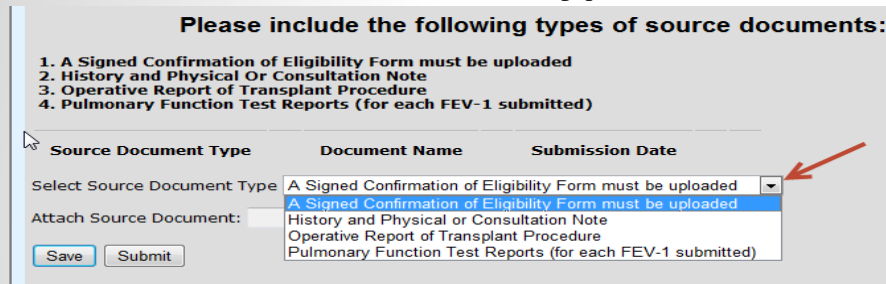
Source Document Type	Document Name	Submission Date
Select Source Document Type	A Signed Confirmation of Eligibility Form must be uploaded	
Attach Source Document:	A Signed Confirmation of Eligibility Form must be uploaded	
	History and Physical or Consultation Note	
	Operative Report of Transplant Procedure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

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

Internet | Protected Mode: On

Upload pdf Files of Scanned Source Documents

- 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.



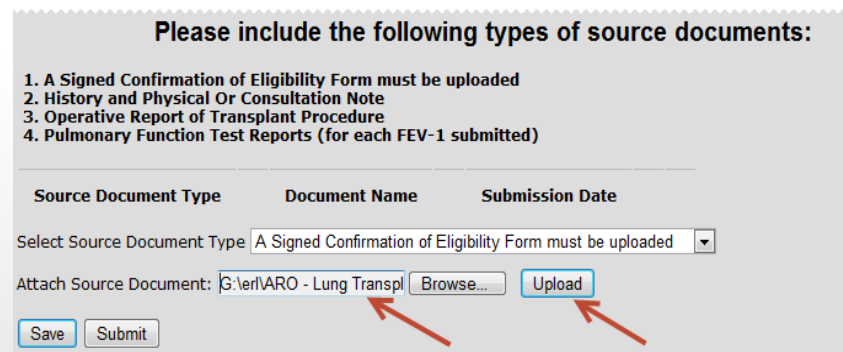
Please include the following types of source documents:

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

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

Save Submit

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

Source Document Type	Document Name	Submission Date
Select Source Document Type	A Signed Confirmation of Eligibility Form must be uploaded	
Attach Source Document:	G:\erl\ARO - Lung Transpl	

Save Submit

Upload pdf Files of Scanned Source Documents

- 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	View	Delete

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

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

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

Completing the COE CRF Continued

3. Confirm all required source document pdfs are uploaded and the correct **Source Document Type** was selected from the drop down menu.
4. After all required source document pdfs are uploaded, the top of the COE CRF will appear as example below.

ECP REGISTRY TRAINING WEBSITE

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

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

User name: test_sc login

Form Summary

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

Extracorporeal Photophoresis (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 other Source Documents listed at the top of the COE Form. Per Protocol Section 3.7, submission of this signed COE Form with DCC Verification is required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed. NOTE: ECP Treatment or study-related invasive procedures are not permitted for Observational Arm participants.

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_100001_04032015.pdf	04-09-2015	View Delete
History and Physical or Consultation Note	HK_100001_02272015.pdf	04-09-2015	View Delete
Operative Report of Transplant Procedure	ORIP_100001_05132014.pdf	04-09-2015	View Delete
Pulmonary Function Test Reports (for each FEV-1 submitted)	PFT_100001_03012015.pdf	04-09-2015	View Delete
Pulmonary Function Test Reports (for each FEV-1 submitted)	PFT_100001_03102015.pdf	04-09-2015	View Delete
Pulmonary Function Test Reports (for each FEV-1 submitted)	PFT_100001_03172015.pdf	04-09-2015	View Delete
Pulmonary Function Test Reports (for each FEV-1 submitted)	PFT_100001_03312015.pdf	04-09-2015	View Delete

Select Source Document Type Pulmonary Function Test Reports (for each FEV-1 submitted) x

Attach Source Document: Browse Upload

Save Submit

Completing the COE CRF Continued

5. Answer question 4D, “Has the signed COE CRF been uploaded?”

4. CONFIRMATION OF ELIGIBILITY

A. Date eligibility status confirmed	04/14/2015
B. Date the approved Informed Consent Form was signed by the subject	04/13/2015
C. Informed Consent Form Version Date	04/01/2015
D. Has the signed Confirmation of Eligibility CRF been uploaded?	<input checked="" type="radio"/> YES <input type="radio"/> NO

6. Click the **Submit** button.
7. Note, NO changes can be made to the COE CRF by clinical staff after clicking **Submit**. If a mistake is made, contact the DCC immediately!

5. INVESTIGATOR ATTESTATION

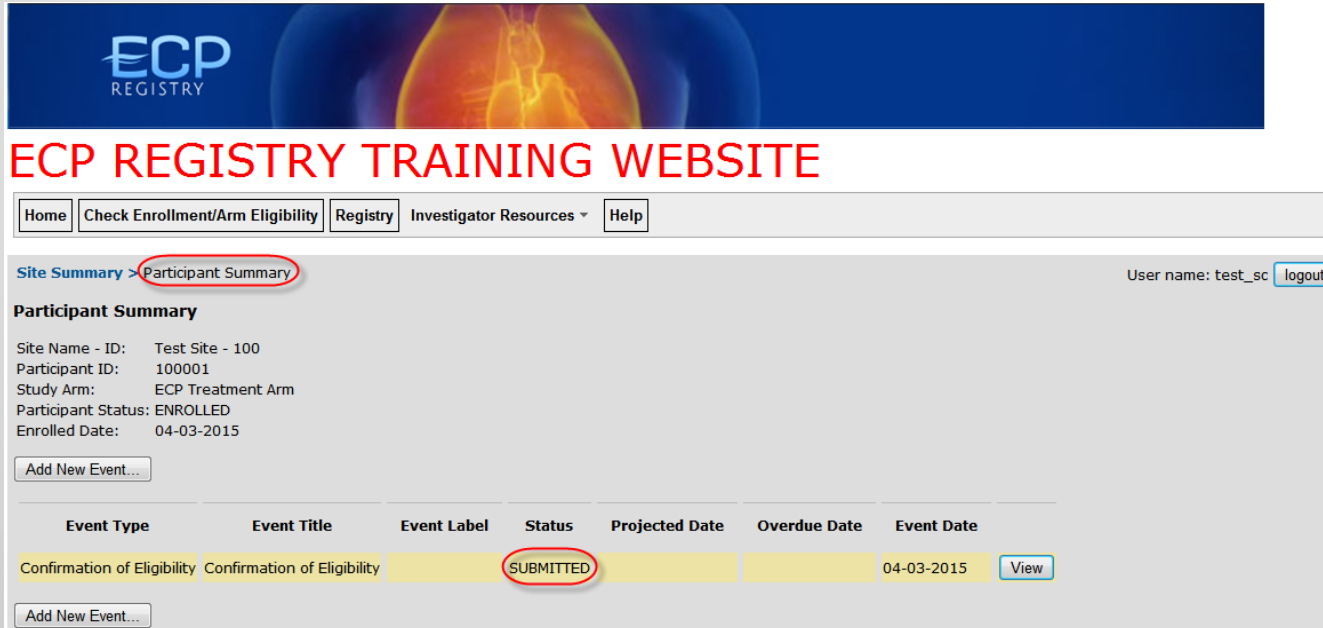
I have reviewed and confirmed that the information recorded on these CRF Pages is accurate. I attest that this patient meets all study eligibility criteria and is appropriate to enroll in the ECP Registry

Investigator Name (please print) _____

Investigator Signature _____ Date: _____

Completing the COE CRF Continued

7. After clicking the **Submit** button, the **Participant Summary** page will display.
8. The **Status** of the **COE** Event has changed to **SUBMITTED**.
9. Note, Per Protocol Section 3.7, submission of the signed COE CRF and DCC Verification are required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed.



The screenshot displays the ECP Registry Training Website interface. At the top, there is a blue banner with the ECP Registry logo and a heart graphic. 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. The "Participant Summary" link is highlighted with a red circle. The user name "test_sc" and a "logout" button are visible in the top right corner. The "Participant Summary" section shows the following details:

- Site Name - ID: Test Site - 100
- Participant ID: 100001
- Study Arm: ECP Treatment Arm
- Participant Status: ENROLLED
- Enrolled Date: 04-03-2015

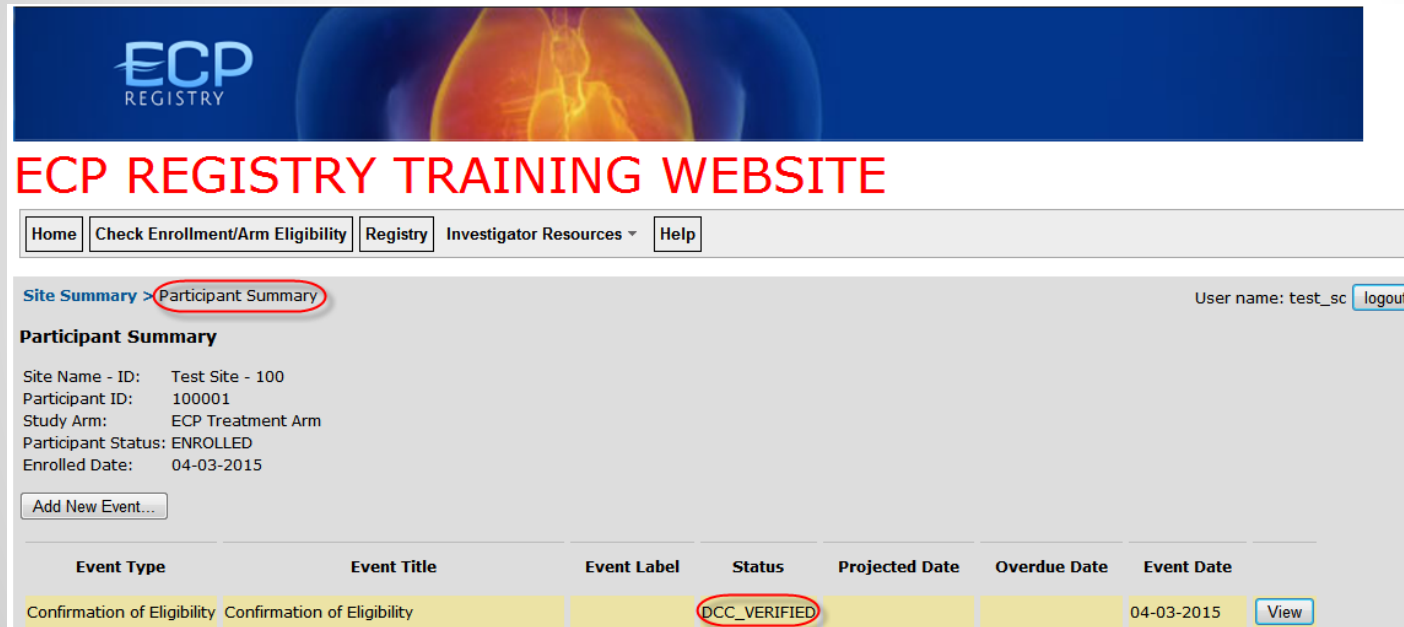
Below the details, there is an "Add New Event..." button. A table lists the events:

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		SUBMITTED			04-03-2015

The "SUBMITTED" status is highlighted with a red circle. A "View" button is next to the event date. At the bottom, there is another "Add New Event..." button.

Completing the COE CRF Continued

10. Follow the Data Verification process in the next to two slides until the **Status** of the **COE** Event has changed to **DCC VERIFIED**.
11. That completes the **COE** CRF.



The screenshot displays the ECP Registry Training Website interface. At the top, there is a blue banner with the ECP Registry logo and a heart image. Below the banner, the text "ECP REGISTRY TRAINING WEBSITE" is written in red. A navigation bar contains links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. The main content area shows the "Participant Summary" page, with "Participant Summary" highlighted in a red circle. The page displays participant details: Site Name - ID: Test Site - 100, Participant ID: 100001, Study Arm: ECP Treatment Arm, Participant Status: ENROLLED, and Enrolled Date: 04-03-2015. A "logout" button is visible next to the user name "test_sc". Below the details, there is a table with columns: Event Type, Event Title, Event Label, Status, Projected Date, Overdue Date, and Event Date. The table contains one row with the following data: Event Type: Confirmation of Eligibility, Event Title: Confirmation of Eligibility, Event Label: (empty), Status: DCC_VERIFIED (circled in red), Projected Date: (empty), Overdue Date: (empty), and Event Date: 04-03-2015. A "View" button is located next to the Event Date.

ECP REGISTRY TRAINING WEBSITE

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary > **Participant Summary** User name: test_sc logout

Participant Summary

Site Name - ID: Test Site - 100
Participant ID: 100001
Study Arm: ECP Treatment Arm
Participant Status: ENROLLED
Enrolled Date: 04-03-2015

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			04-03-2015 View

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 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	
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			02-05-2015	View

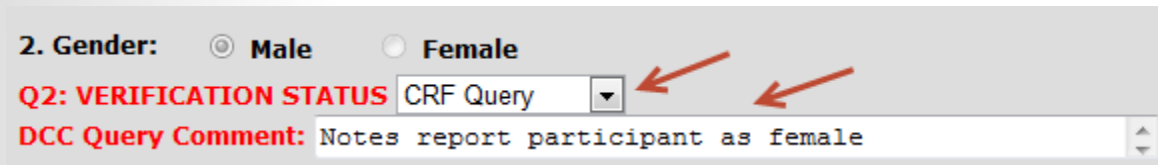
- Example of an Event Status marked CRF Query by the DCC staff.

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	
Confirmation of Eligibility	Confirmation of Eligibility		CRF_QUERY			02-03-2015	View

Data Verification – examples from the COE CRF

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



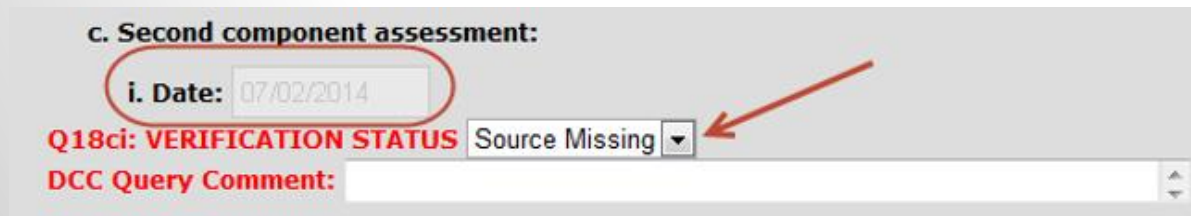
2. Gender: ☒ Male ☐ Female

Q2: VERIFICATION STATUS CRF Query

DCC Query Comment: Notes report participant as female

This screenshot shows a form section for gender. Below the radio buttons, the 'Q2: VERIFICATION STATUS' is set to 'CRF Query'. Two red arrows point to this dropdown menu. Below that, the 'DCC Query Comment' field contains the text 'Notes report participant as female'.

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



c. Second component assessment:

i. Date: 07/02/2014

Q18ci: VERIFICATION STATUS Source Missing

DCC Query Comment:

This screenshot shows a form section for a second component assessment. The date '07/02/2014' is circled in red. Below it, the 'Q18ci: VERIFICATION STATUS' is set to 'Source Missing', with a red arrow pointing to the dropdown menu. The 'DCC Query Comment' field is empty.

Completed COE CRF

- When the **Status** of the **COE Event** changes to **DCC Verified**, the **Participant Summary** page will be populated with New Events.
- 36 new Events for the ECP Treatment Arm.
- 3 new Events for the Observational Arm.

The screenshot shows the 'Participant Summary' page for the ECP Registry Training Website. The page header includes the ECP Registry logo and navigation links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. The user is logged in as 'test_sc'. The page displays the following information:

- Site Name - ID: Test Site - 100
- Participant ID: 100001
- Study Arm: ECP Treatment Arm
- Participant Status: ENROLLED
- Enrolled Date: 04-09-2015

Below this information is a table of events. The table has columns for Event Type, Event Title, Event Label, Status, Projected Date, Overdue Date, and Event Date. The events are listed in a table with 7 columns. The first row is 'Confirmation of Eligibility' with status 'DCC_VERIFIED' and event date '04-03-2015'. The subsequent rows are 'Demographics', 'Baseline Therapy', and 'ECP Treatment' (1 through 10), all with status 'NEW' and event date '04-03-2015'. The table continues with 'Pulmonary Evaluation' events (30 day assessment, 60 day assessment, 90 day assessment, 120 day assessment, 150 day assessment, 180 day assessment, 240 day assessment, 300 day assessment, 365 day assessment) and 'End of Study'.

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			04-03-2015
Demographics	Demographics/Medical History		NEW			04-03-2015
Baseline Therapy	Baseline Therapy		NEW			04-03-2015
ECP Treatment	ECP Treatment 1		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			
ECP Treatment	ECP Treatment 11		NEW			
ECP Treatment	ECP Treatment 12		NEW			
ECP Treatment	ECP Treatment 13		NEW			
ECP Treatment	ECP Treatment 14		NEW			
Pulmonary Evaluation	Pulmonary Evaluation: 60 day assessment		NEW			
ECP Treatment	ECP Treatment 15		NEW			
ECP Treatment	ECP Treatment 16		NEW			
ECP Treatment	ECP Treatment 17		NEW			
ECP Treatment	ECP Treatment 18		NEW			
Pulmonary Evaluation	Pulmonary Evaluation: 90 day assessment		NEW			
ECP Treatment	ECP Treatment 19		NEW			
ECP Treatment	ECP Treatment 20		NEW			
Pulmonary Evaluation	Pulmonary Evaluation: 120 day assessment		NEW			
ECP Treatment	ECP Treatment 21		NEW			
ECP Treatment	ECP Treatment 22		NEW			
Pulmonary Evaluation	Pulmonary Evaluation: 150 day assessment		NEW			
ECP Treatment	ECP Treatment 23		NEW			
ECP Treatment	ECP Treatment 24		NEW			
Pulmonary Evaluation	Pulmonary Evaluation: 180 day assessment		NEW			
Pulmonary Evaluation	Pulmonary Evaluation: 240 day assessment		NEW			
Pulmonary Evaluation	Pulmonary Evaluation: 300 day assessment		NEW			
Pulmonary Evaluation	Pulmonary Evaluation: 365 day assessment		NEW			
End of Study	End Of Study		NEW			

The screenshot shows the 'Participant Summary' page for the ECP Registry Training Website. The page header includes the ECP Registry logo and navigation links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. The user is logged in as 'test_sc'. The page displays the following information:

- Site Name - ID: Test Site - 100
- Participant ID: 100002
- Study Arm: Observational Arm
- Participant Status: ENROLLED
- Enrolled Date: 04-09-2015

Below this information is a table of events. The table has columns for Event Type, Event Title, Event Label, Status, Projected Date, Overdue Date, and Event Date. The events are listed in a table with 7 columns. The first row is 'Confirmation of Eligibility' with status 'DCC_VERIFIED' and event date '04-09-2015'. The subsequent rows are 'Demographics', 'Baseline Therapy', and 'Observation Pulmonary Evaluation Log', all with status 'NEW' and event date '04-09-2015'.

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			04-09-2015
Demographics	Demographics/Medical History		NEW			04-09-2015
Baseline Therapy	Baseline Therapy		NEW			04-09-2015
Observation Pulmonary Evaluation Log	Observation Pulmonary Evaluation Log		NEW			04-09-2015

Site Summary page

- The example below is of the **Site Summary** page and shows the total **New** Events created after completing the **COE** CRF for two participants; one in the ECP Treatment Arm and one in the Observational Treatment Arm.

ECP REGISTRY TRAINING WEBSITE

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary User name: test_sc logout

Site Name - ID: Test Site - 100

Participant ID	Enrolled Date	Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	
100001	04-03-2015	ECP Treatment Arm	ENROLLED	36	0	0	0	1	0	0	View
100002	04-09-2015	Observational Arm	ENROLLED	3	0	0	0	1	0	0	View

ECP Treatment Arm – CRFs

- Confirmation of Eligibility (COE)
- Demographics/Medical History
- Baseline Therapy
- ECP Treatment
- Pulmonary Evaluation (Pulmonary Function Test)
- Change in Therapy
- Serious Adverse Event
- End of Study

Observational Arm – CRFs

- Confirmation of Eligibility (COE)
- Demographics/Medical History
- Baseline Therapy
- Observational Pulmonary Evaluation Log
- Pulmonary Evaluation (Pulmonary Function Test)
- Change in Therapy
- Serious Adverse Event
- End of Study
- Crossover Safety Check

For Questions - DCC Contacts

Name	Role	Email	Phone
Joan Moulton	Technical Coordinator and Help Desk Manager	moultonj@mir.wustl.edu	314-362-7185
Mary Wolfsberger	Technical Coordinator and Help Desk Manager	wolfsbergerm@mir.wustl.edu	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