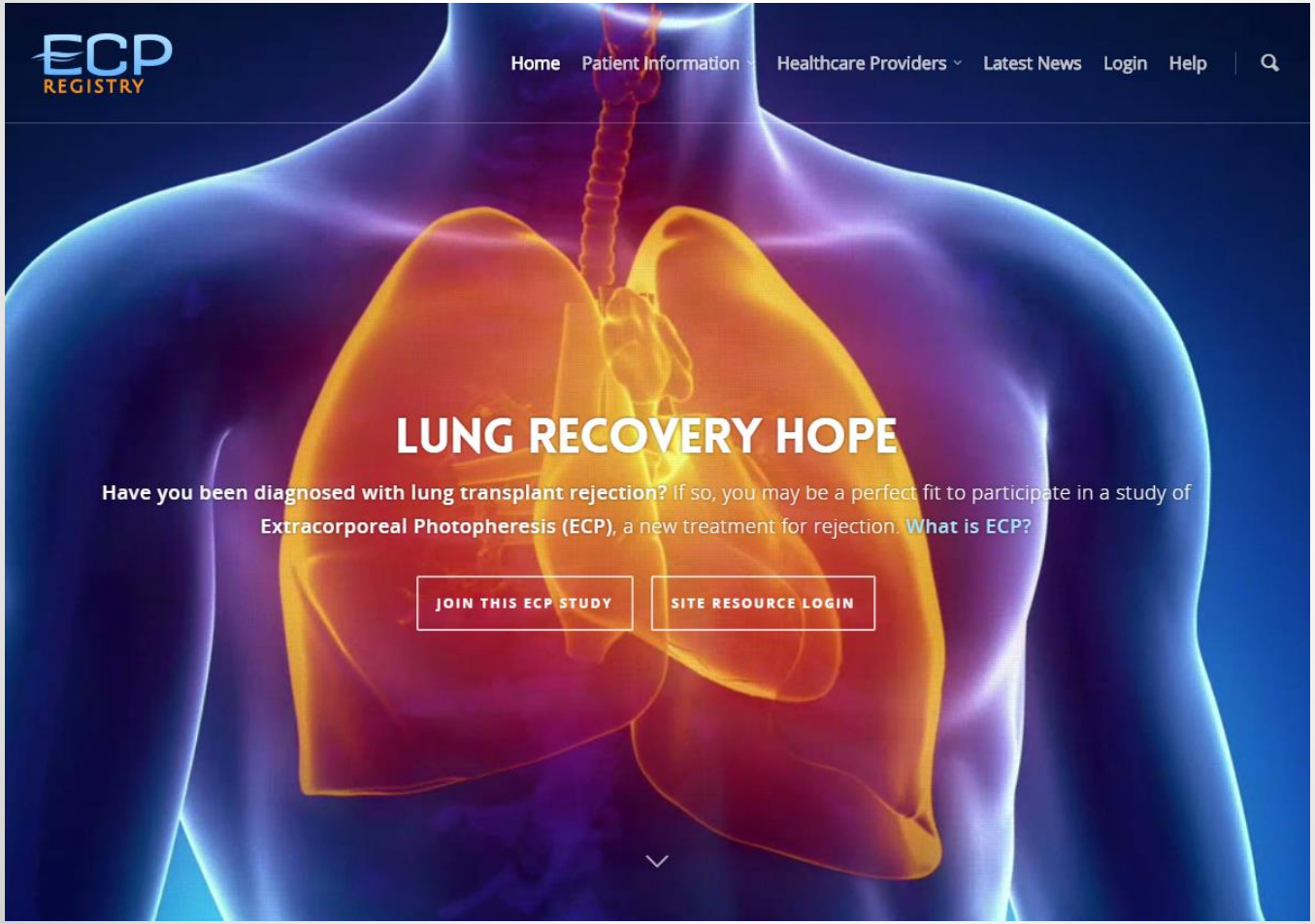
Welcome to the ECP REGISTRY Enrollment and COE CRF Training Presentation



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

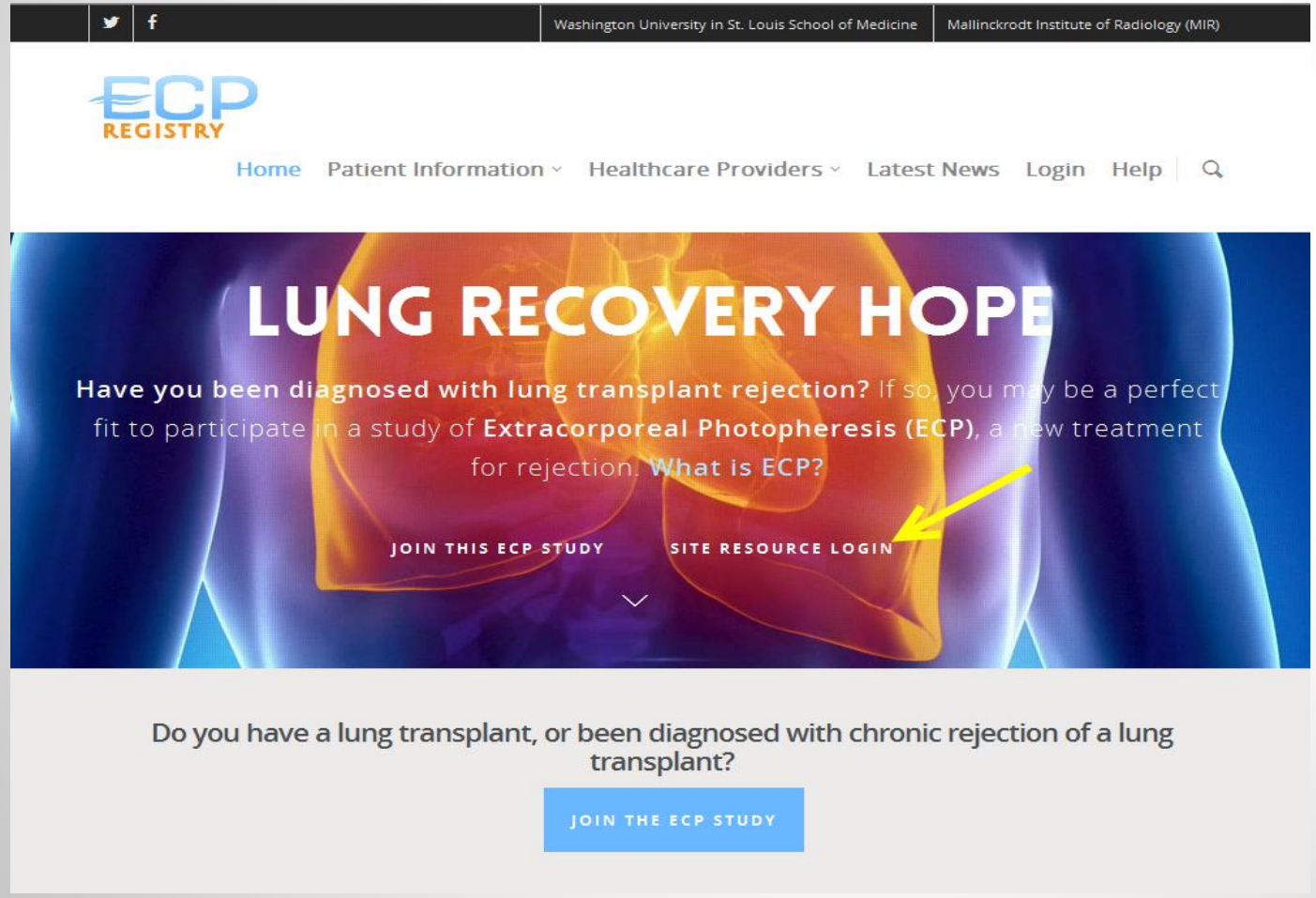
- Internet Explorer 8
- Internet Explorer 9
- Google Chrome

Please access the ECP REGISTRY 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.

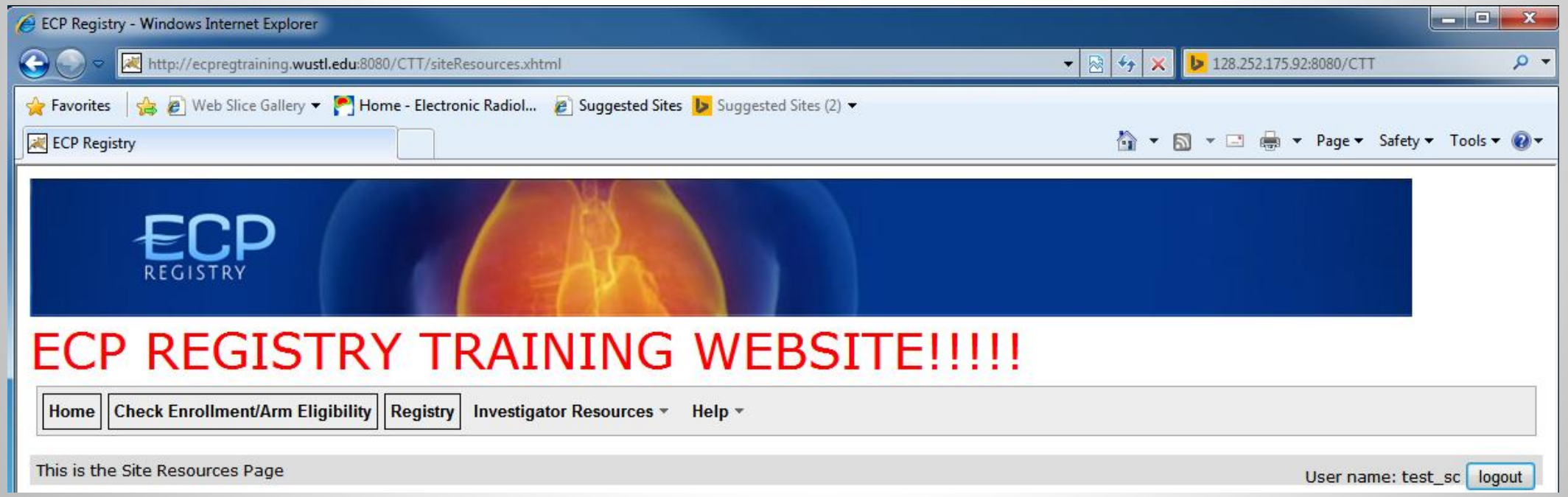


Logging into the ECP REGISTRY Secure Website

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

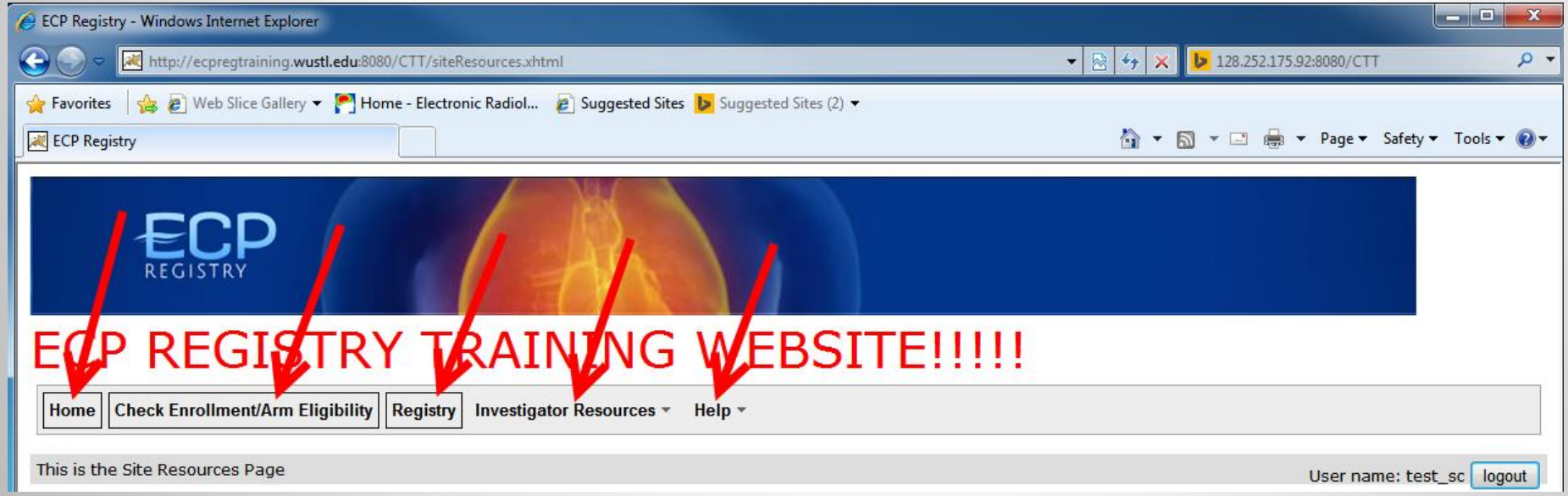
Site Resources Page

- 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

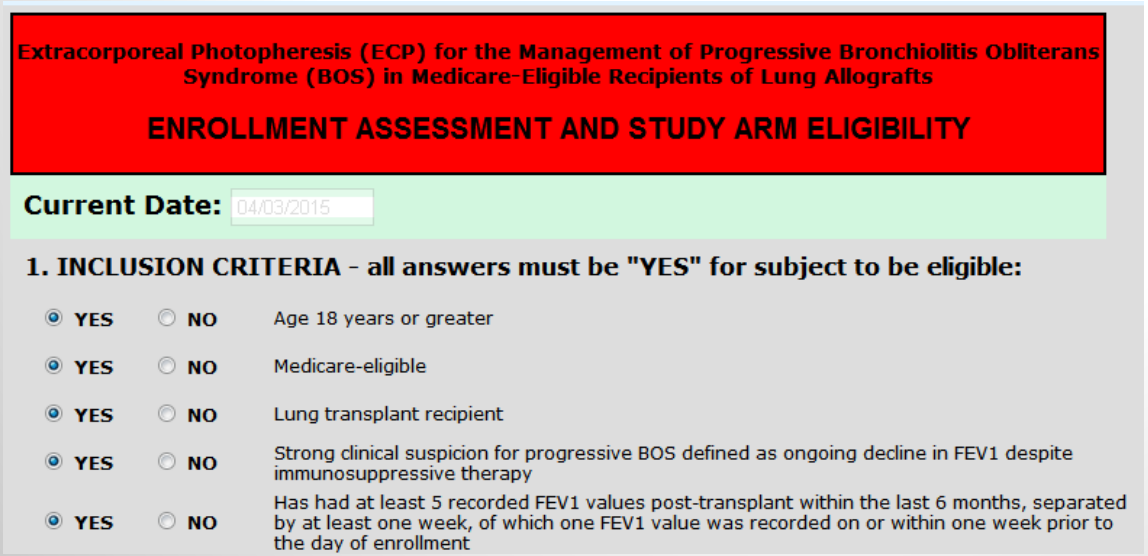
- Note there are three menu buttons and two menu items at the top of the ECP Site Resources page. (see red arrows in image below)
- The Home button directs you back to the ECP Registry home page.
- The Check Enrollment/Arm Eligibility button opens the **Enrollment Assessment and Study Arm Eligibility** 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

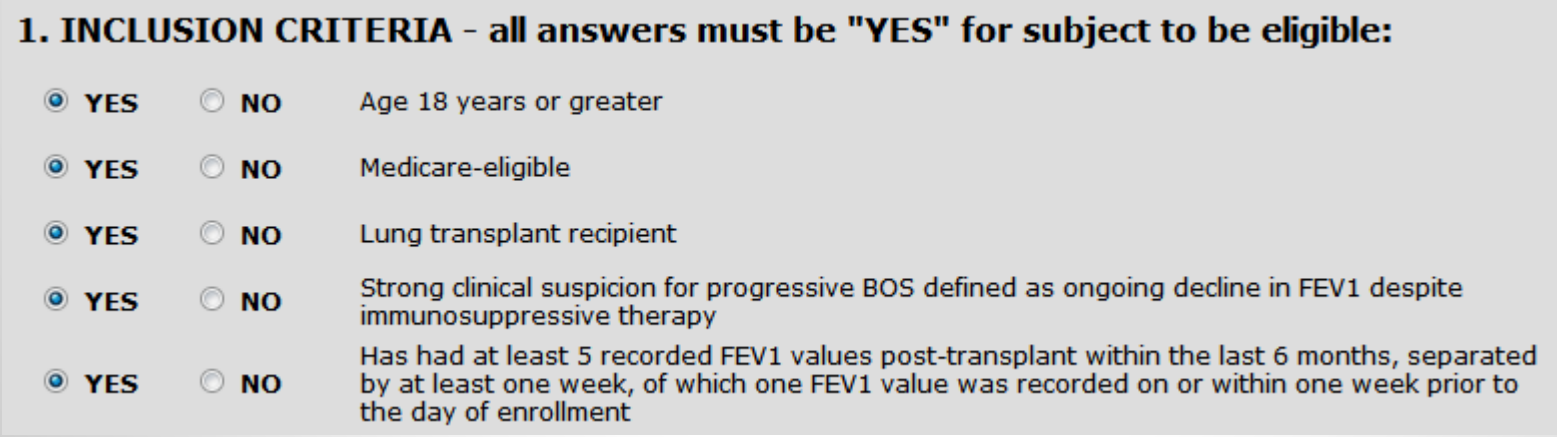
- Click the Check Enrollment/Arm Eligibility button, this will start the Enrollment process.

- 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.



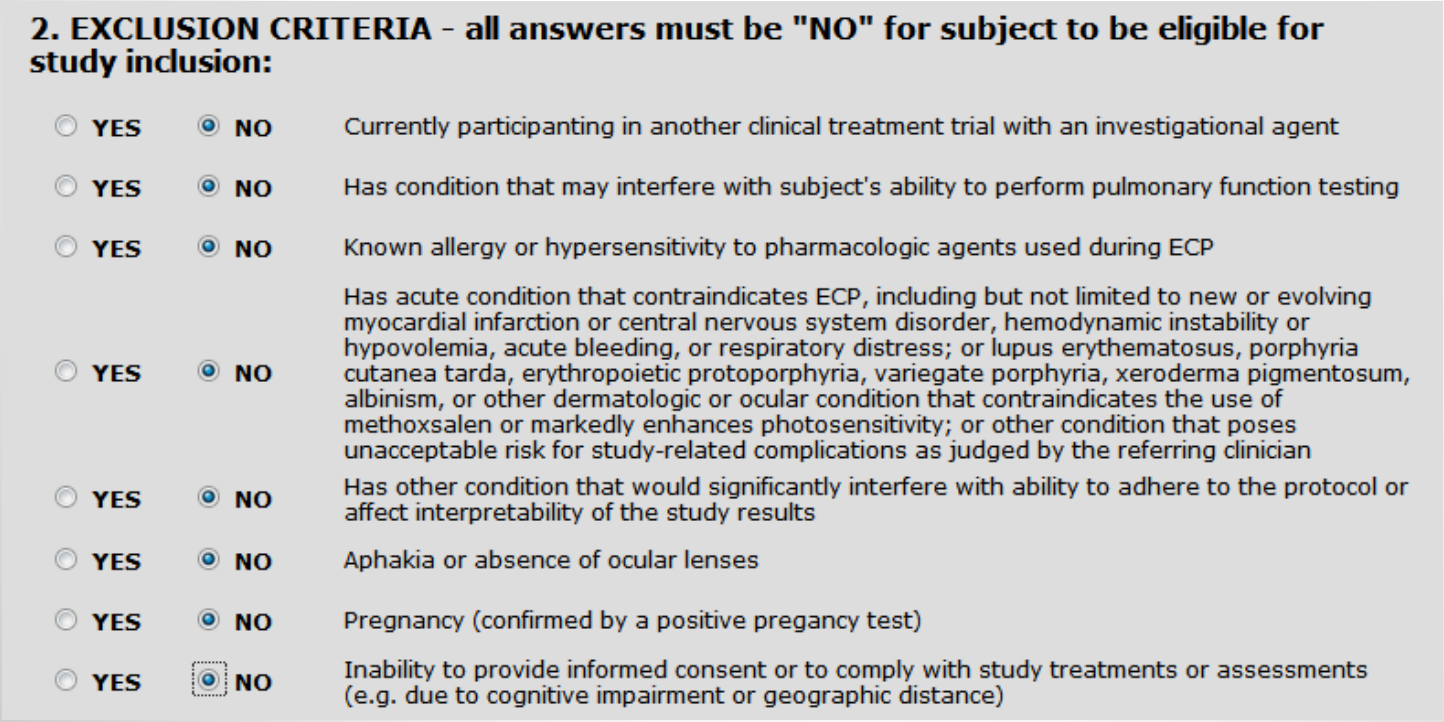
Enrollment Eligibility and Study Arm Determination

- 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.



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.

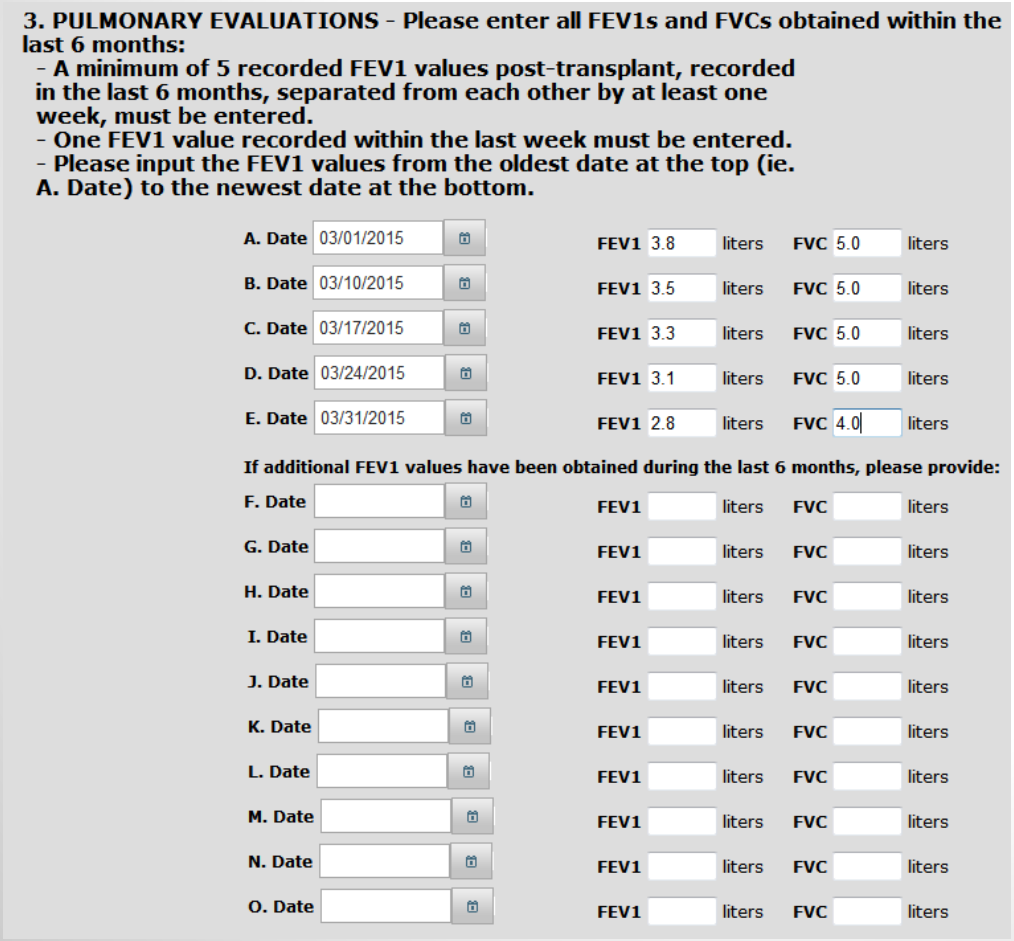


2. EXCLUSION CRITERIA - all answers must be "NO" for subject to be eligible for study inclusion:

YES	NO	Currently participanting in another clinical treatment trial with an investigational agent
YES	NO	Has condition that may interfere with subject's ability to perform pulmonary function testing
YES	NO	Known allergy or hypersensitivity to pharmacologic agents used during ECP
YES	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
YES	NO	Has other condition that would significantly interfere with ability to adhere to the protocol or affect interpretability of the study results
YES	NO	Aphakia or absence of ocular lenses
YES	NO	Pregnancy (confirmed by a positive pregancy test)
YES	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	03/01/2015	**FEV1**	3.8 liters	**FVC**	5.0 liters
B. Date	03/10/2015	**FEV1**	3.5 liters	**FVC**	5.0 liters
C. Date	03/17/2015	**FEV1**	3.3 liters	**FVC**	5.0 liters
D. Date	03/24/2015	**FEV1**	3.1 liters	**FVC**	5.0 liters
E. Date	03/31/2015	**FEV1**	2.8 liters	**FVC**	4.0 liters

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

F. Date		**FEV1**	liters	**FVC**	liters
G. Date		**FEV1**	liters	**FVC**	liters
H. Date		**FEV1**	liters	**FVC**	liters
I. Date		**FEV1**	liters	**FVC**	liters
J. Date		**FEV1**	liters	**FVC**	liters
K. Date		**FEV1**	liters	**FVC**	liters
L. Date		**FEV1**	liters	**FVC**	liters
M. Date		**FEV1**	liters	**FVC**	liters
N. Date		**FEV1**	liters	**FVC**	liters
O. Date		**FEV1**	liters	**FVC**	liters

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.

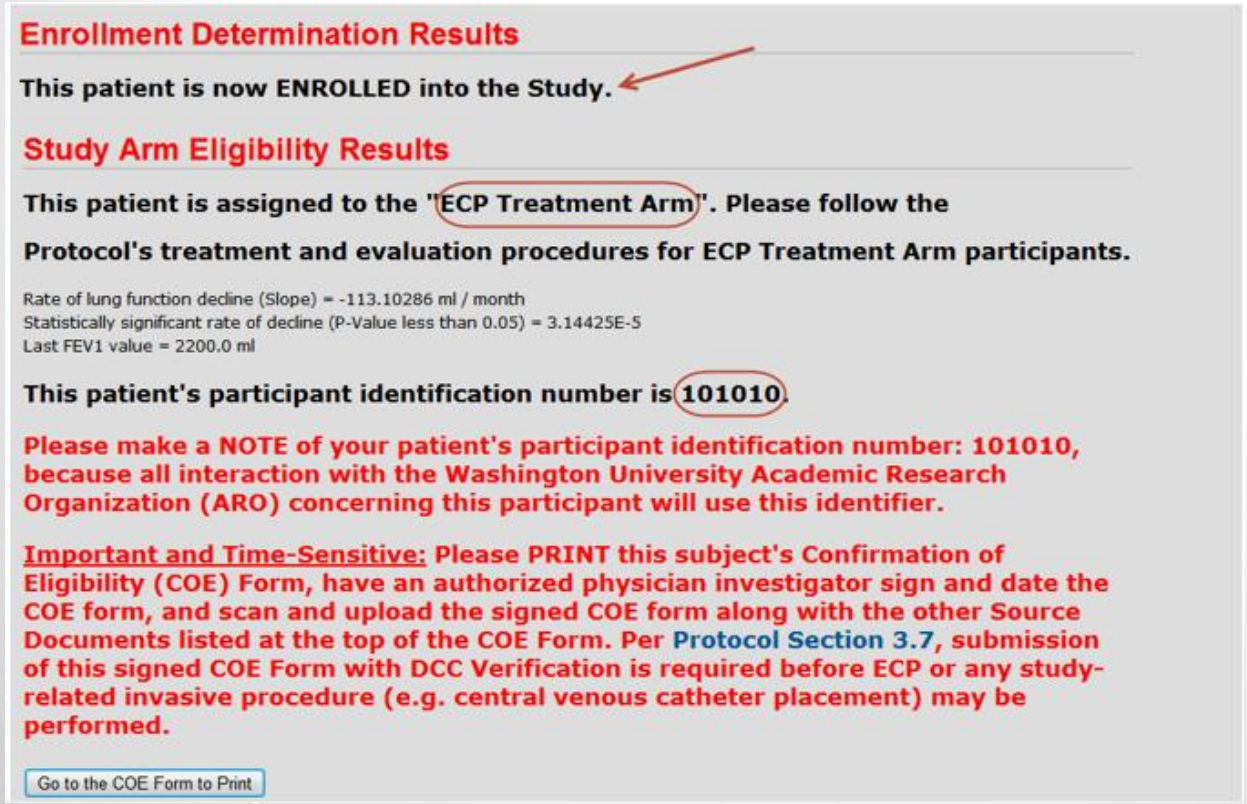
Enrollment Eligibility and Study Arm Determination

- 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.

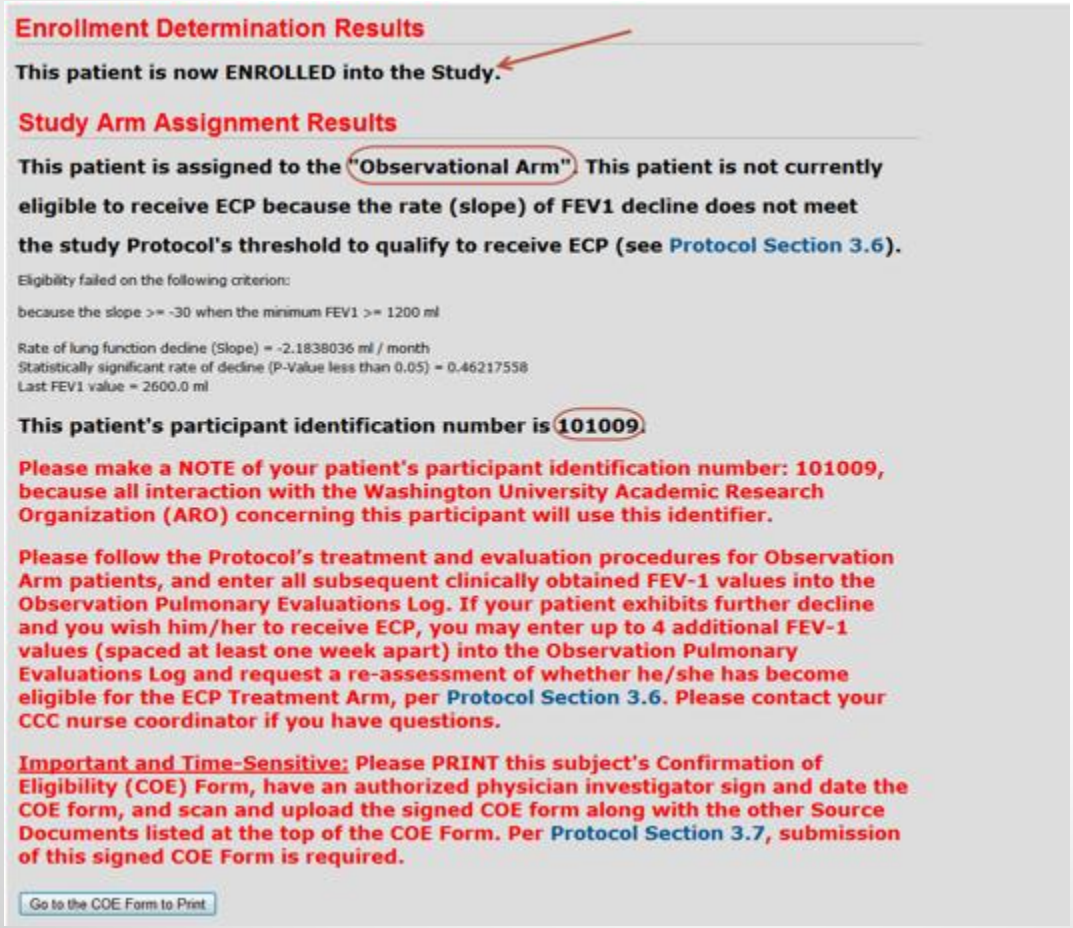
Enrollment Eligibility and Study Arm Determination

- 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 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.

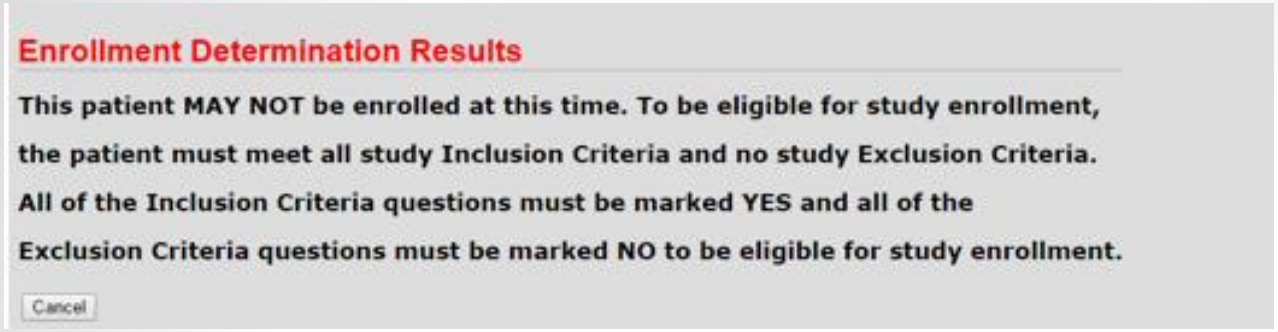
Please follow the Protocol's treatment and evaluation procedures for Observation Arm patients, and enter all subsequent clinically obtained FEV-1 values into the Observation Pulmonary Evaluations Log. If your patient exhibits further decline and you wish him/her to receive ECP, you may enter up to 4 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

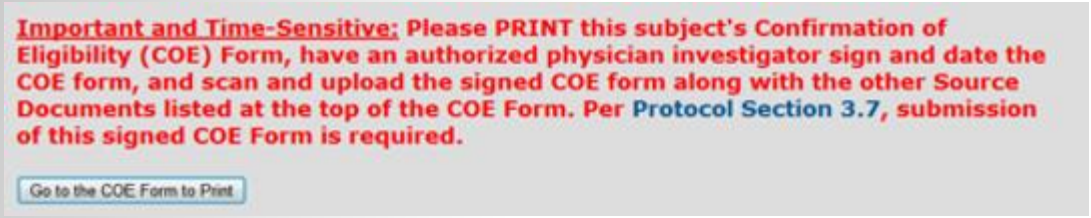
- In the example below, the participant MAY NOT be enrolled at this time, but may be re-evaluated at another time.



- 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

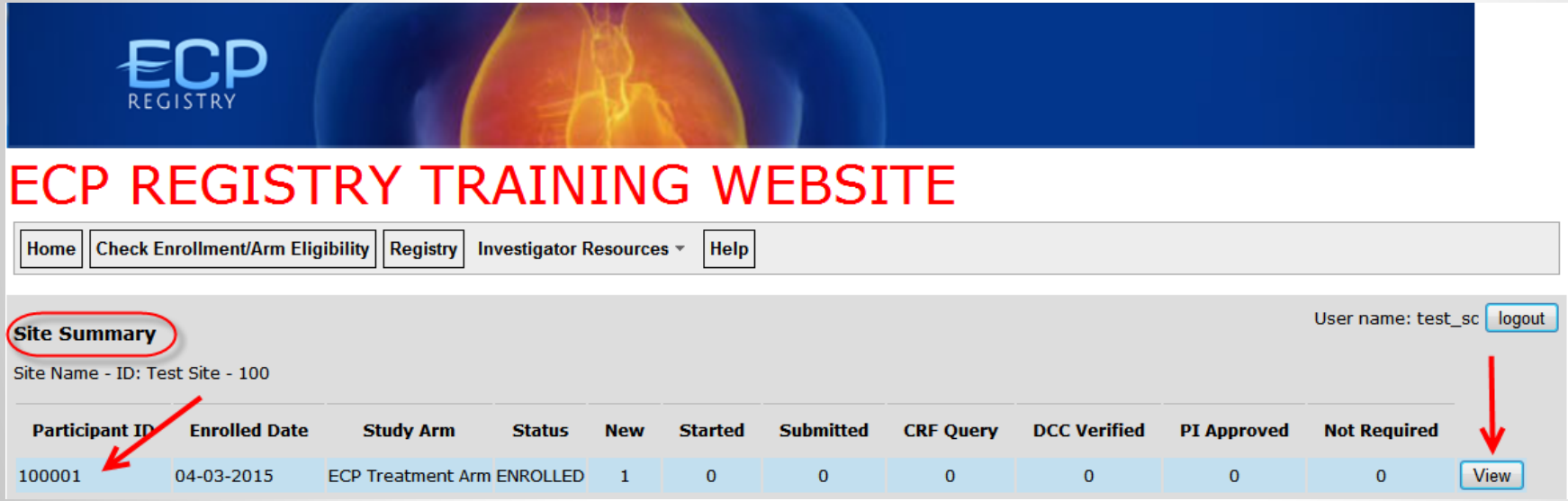
- Click the Go to the COE Form to Print button at the bottom of the **Enrollment Determination Results** page to be directed to the COE CRF and print.



- Clicking this button:
  - Populates he **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.

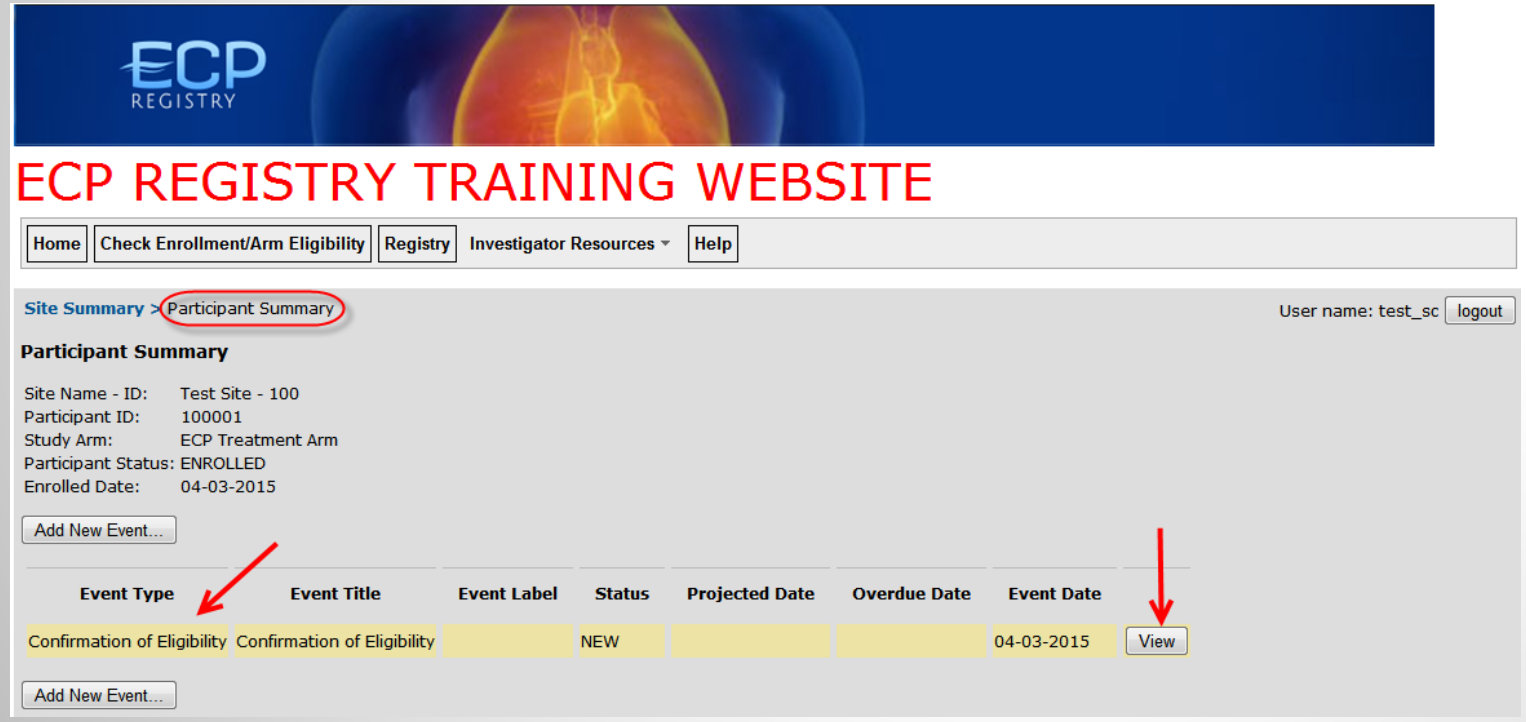
Printing the Confirmation of Eligibility CRF

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



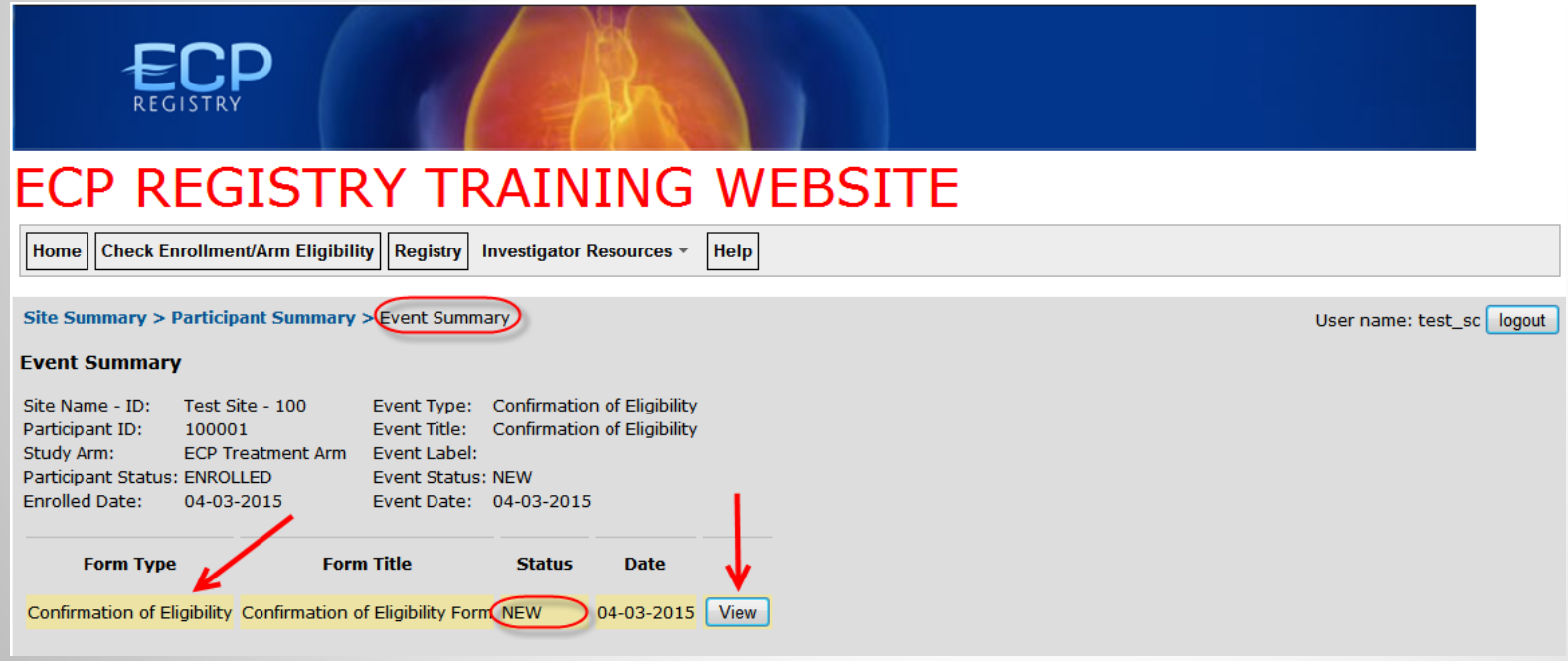
Printing the Confirmation of Eligibility CRF

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



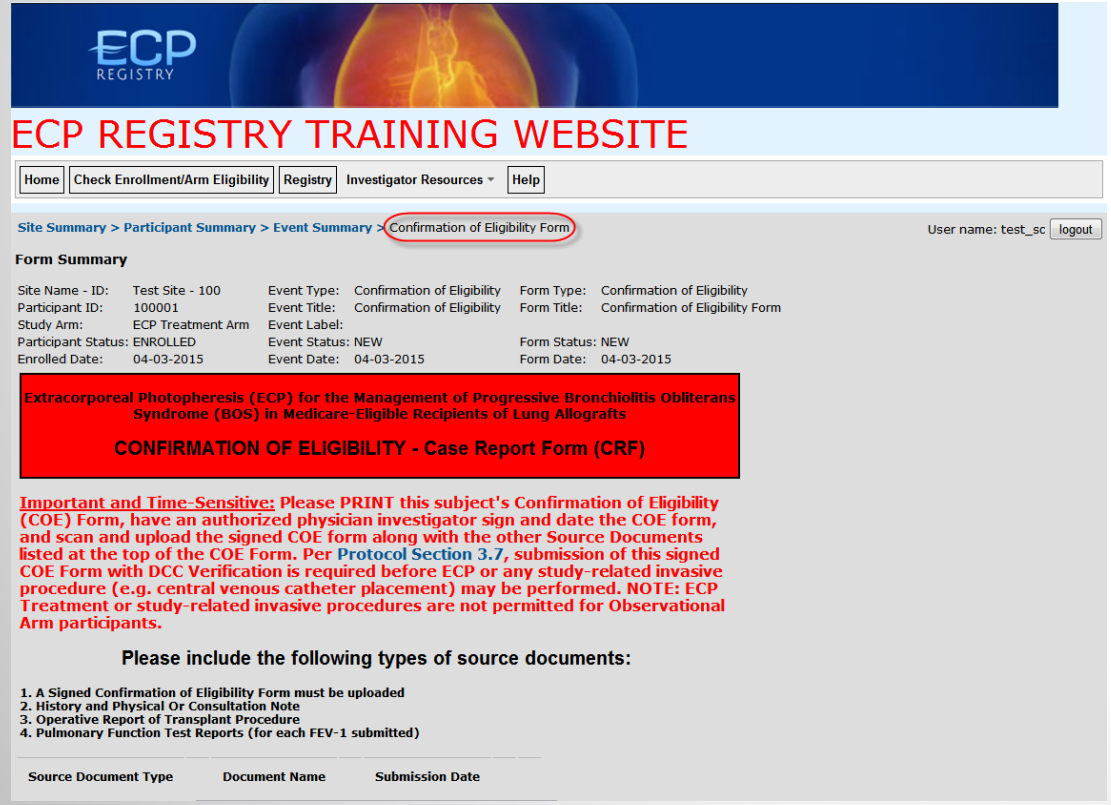
Printing the Confirmation of Eligibility CRF

- 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 View button to be directed to the **Confirmation of Eligibility** (COE) CRF.



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.



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.

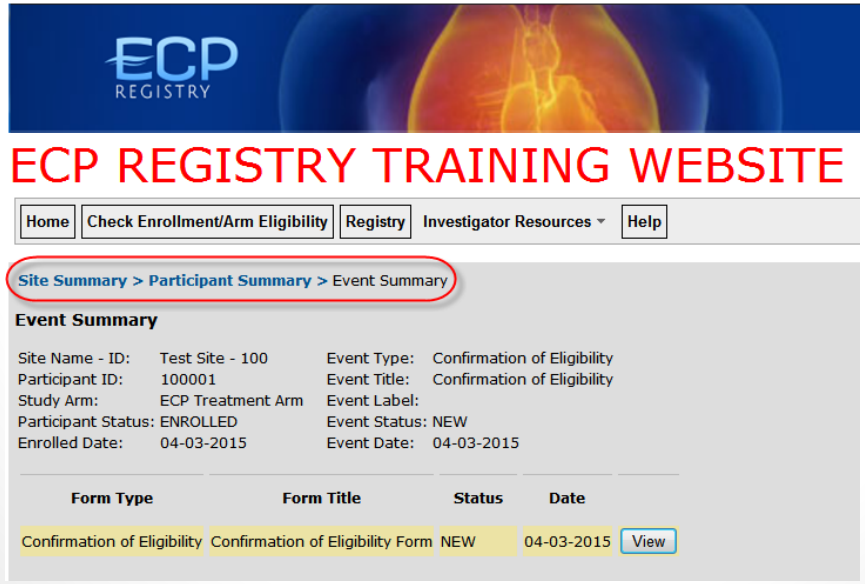
- Note blank copies of the ECP Registry CRF's are available on the ECP website at http://ecpregistry.wustl.edu located under Investigator Resources and may be used to hand write data to enter into the ECP website later.

ECP Navigation

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

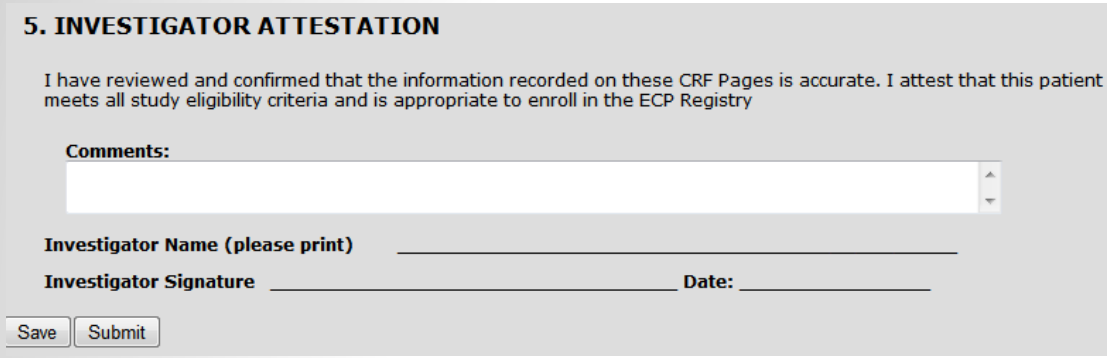
ECP Navigation

- 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.



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.



  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

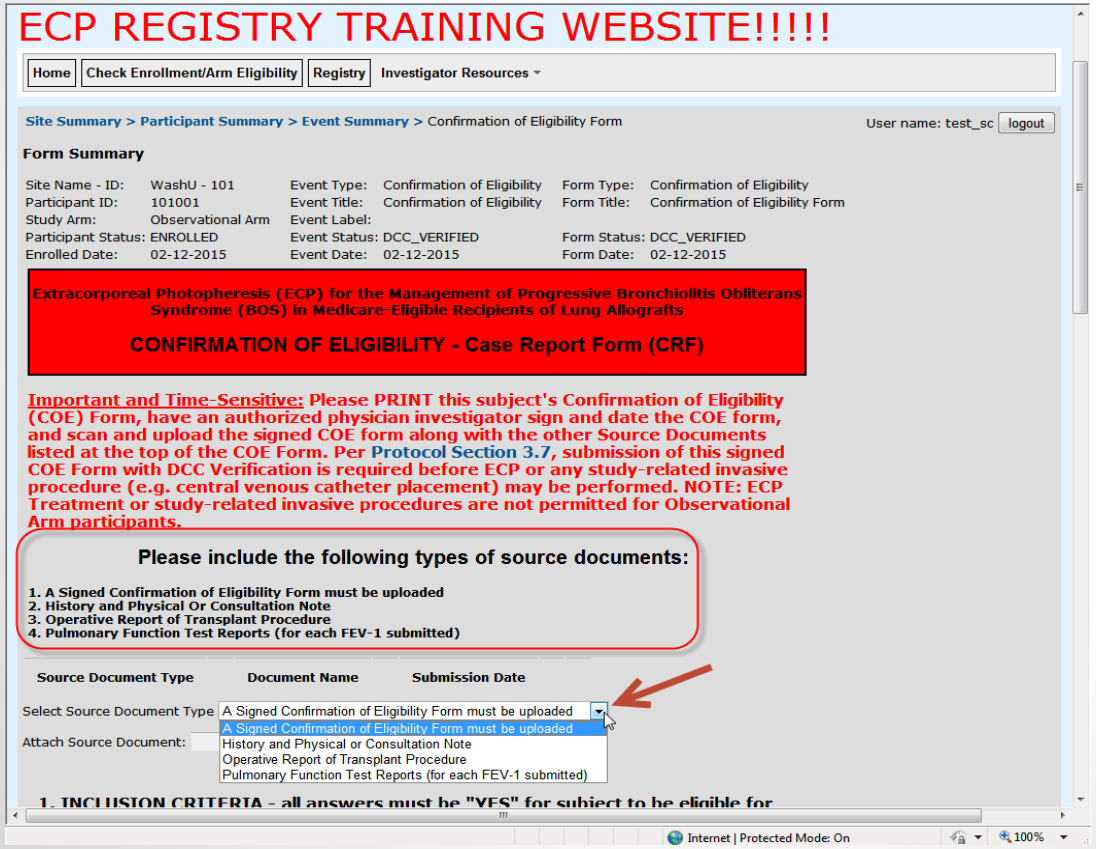
- Source documents are required to support and verify subject data. The specific source documentation required is identified at the top of each CRF.
- To scan source documents into pdf format:
  - Copy the source document(s).
  - **Remove all personal identifiers on the source documents including name, 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

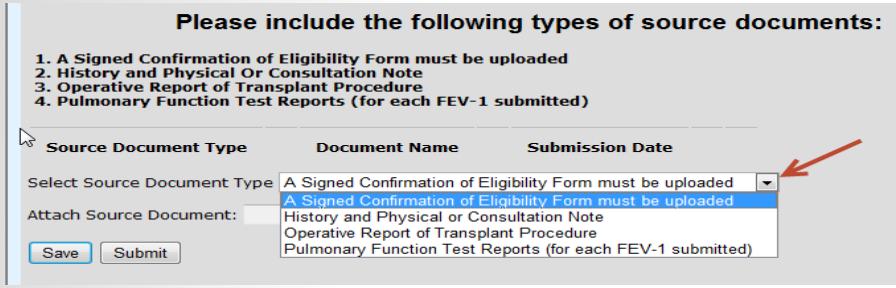
Upload pdf Files of Scanned Source Documents

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

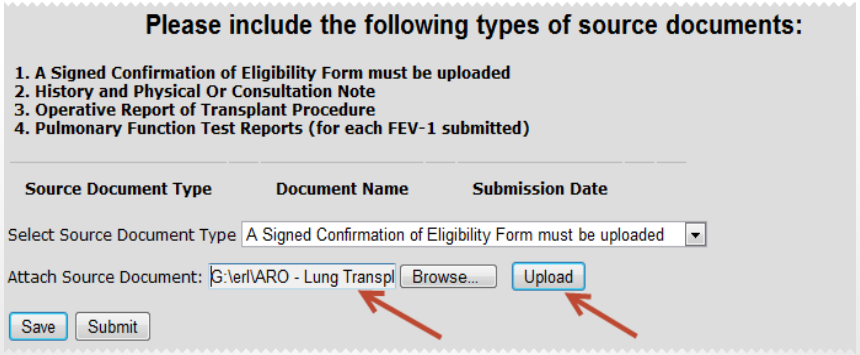


Upload pdf Files of Scanned Source Documents

- 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.



- 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.

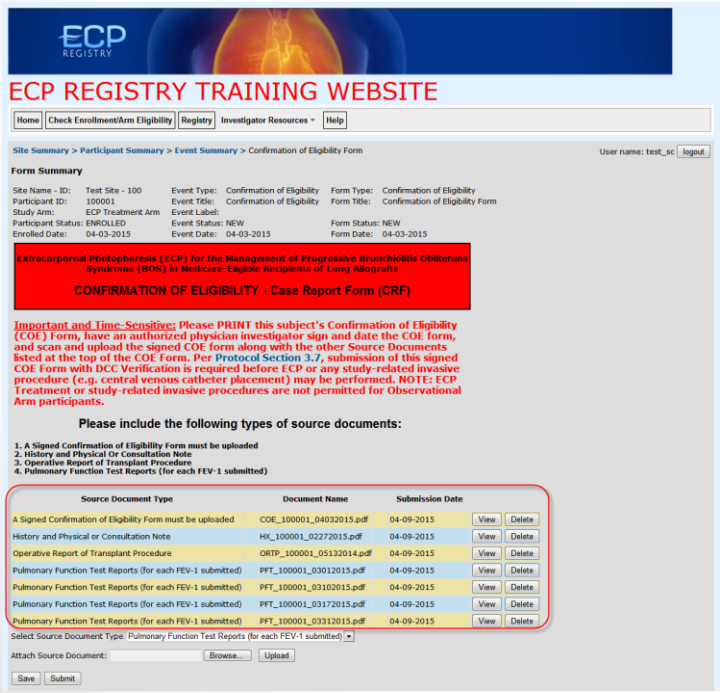


Upload pdf Files of Scanned Source Documents

- 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.

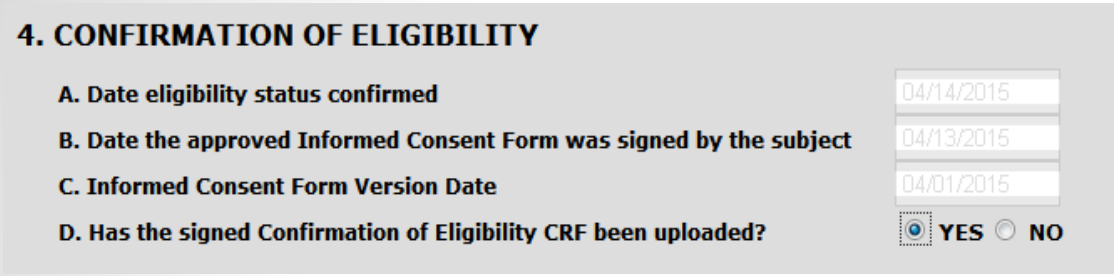
Completing the COE CRF Continued

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.

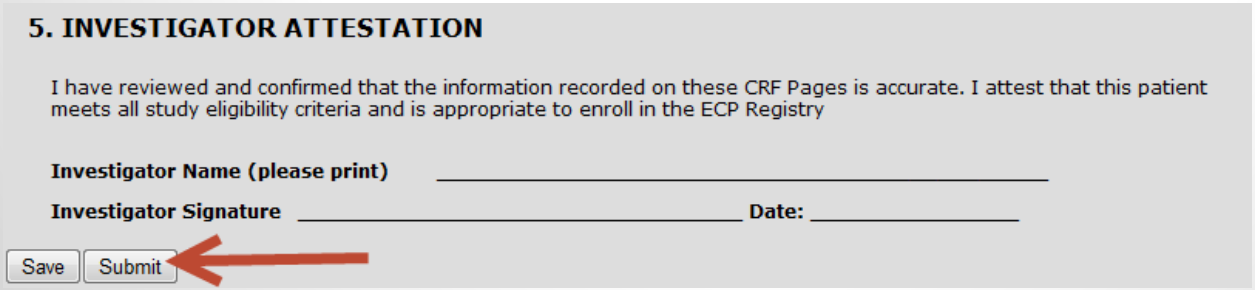


Completing the COE CRF Continued

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

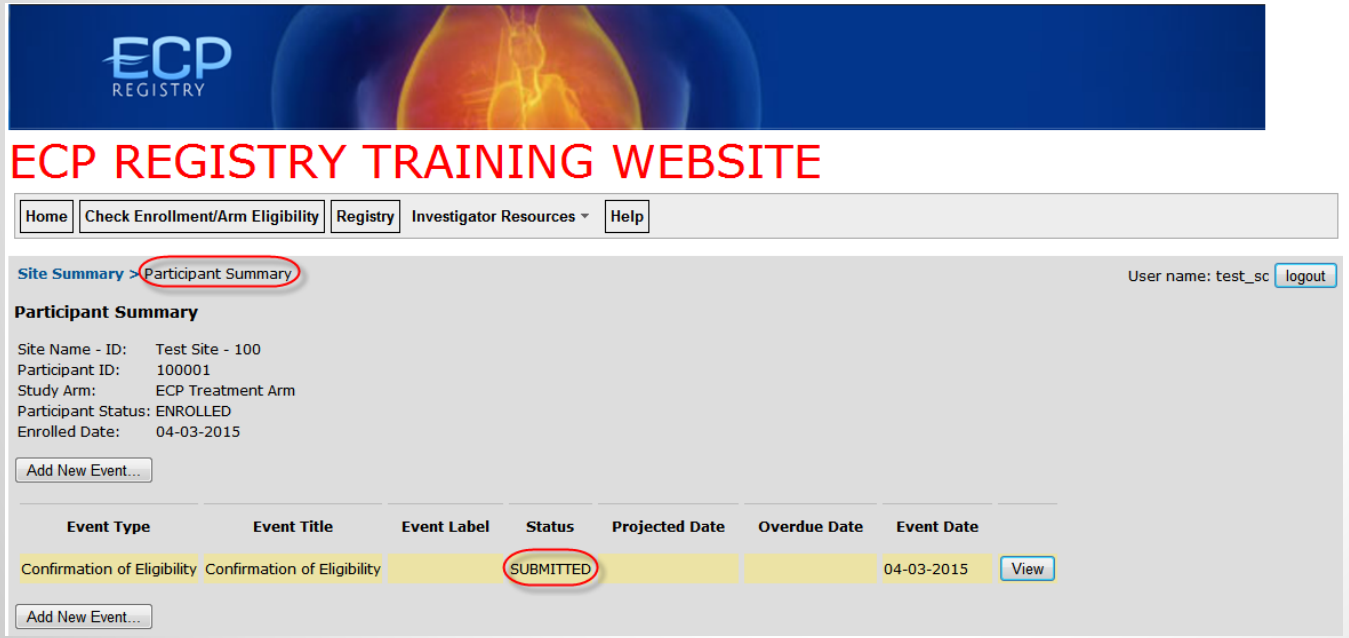


6. Click the **Submit** button.
7. Note, NO changes can be made to the COE CRF by clinical staff after clicking **Submit**. If a mistake is made, contact the DCC immediately!



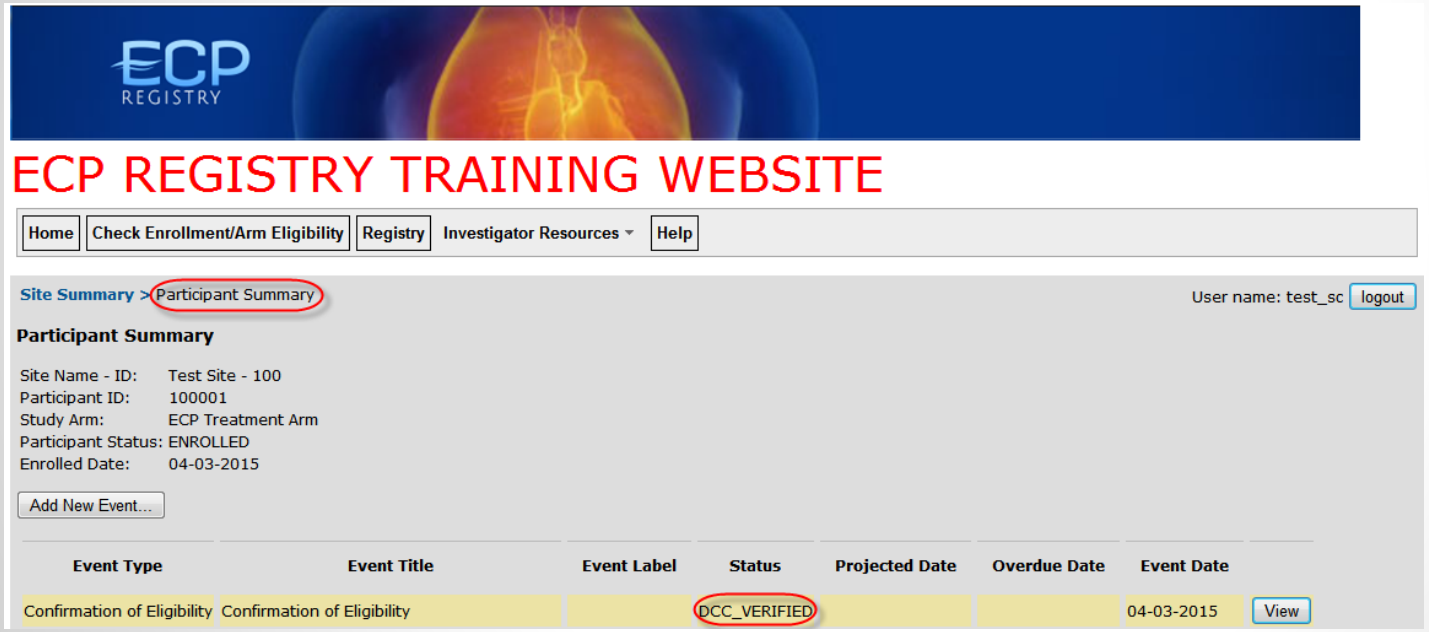
Completing the COE CRF Continued

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.



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.



Data Verification – DCC Staff

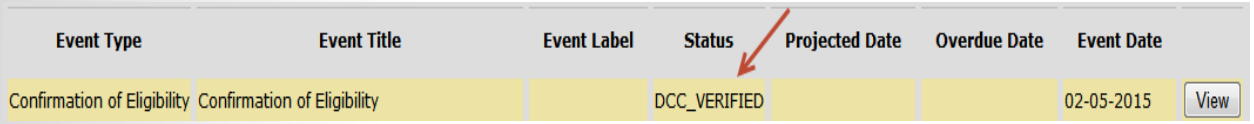
- The Data Coordinating Center (DCC) is responsible for validating CRF data after it has been submitted.
- When the status of a CRF becomes **SUBMITTED**, a technical coordinator from the DCC will examine the CRF's data and compare to the uploaded de-identified source documents.
- For each data field 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

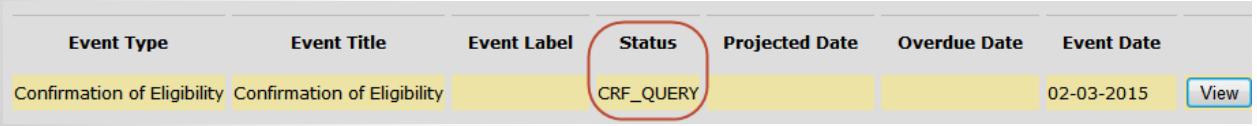
- Example of an Event Status marked DCC Verified by the DCC staff.



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.

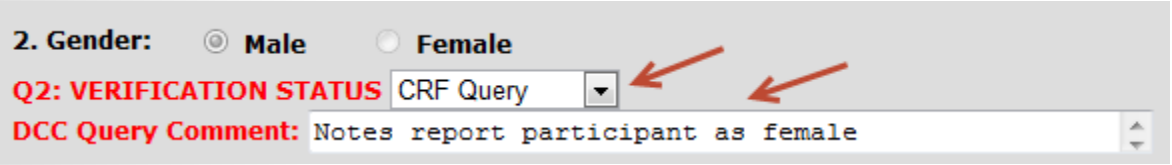
  Note: if several data fields are marked either CRF Query and Source Missing, the Status will only display CRF Query.



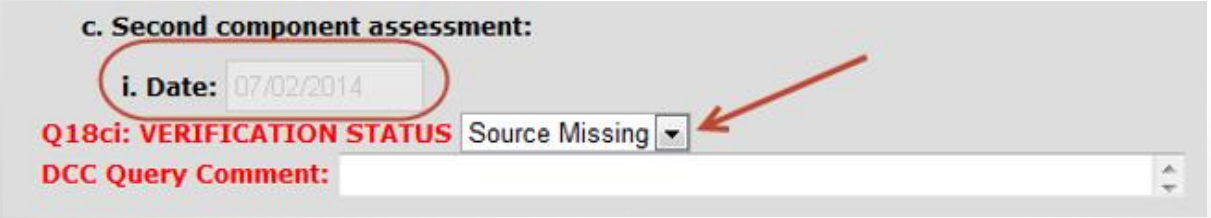
Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Confirmation of Eligibility	Confirmation of Eligibility		CRF_QUERY			02-03-2015	View

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.

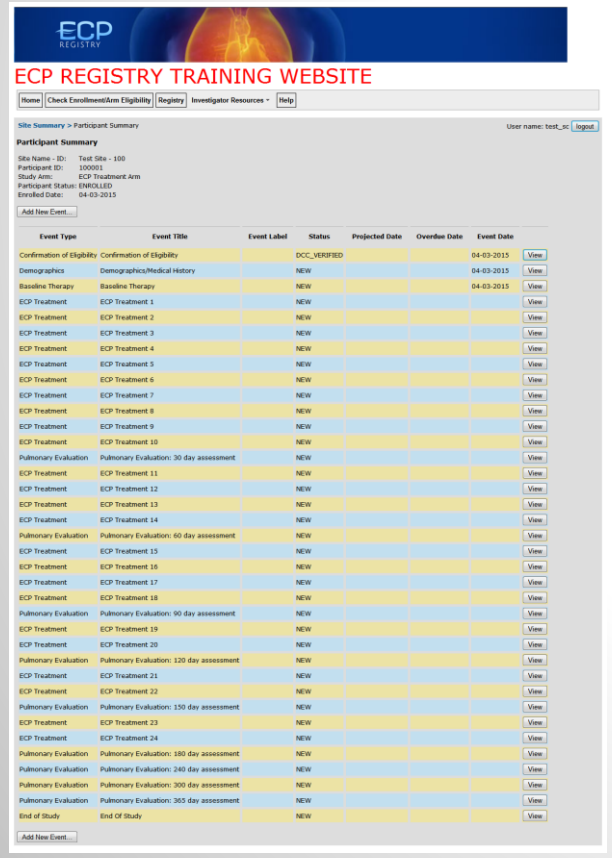


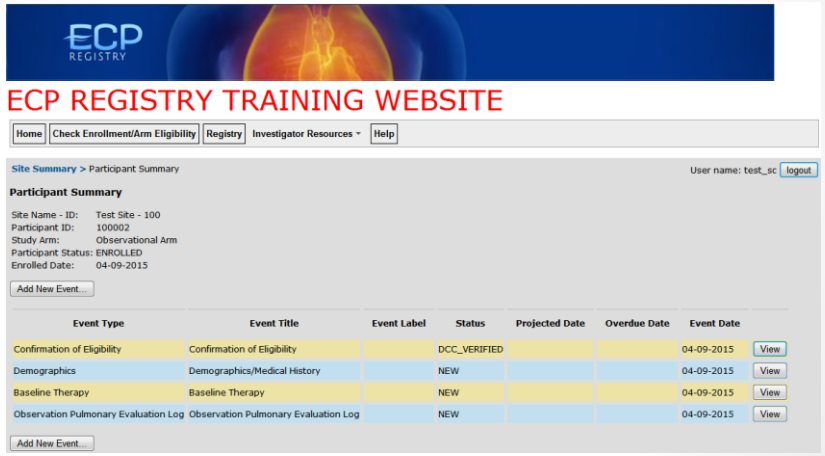
- If a data field is marked Source Missing, the CRF does not have an uploaded source document to confirm the value in that field.



Completed COE CRF

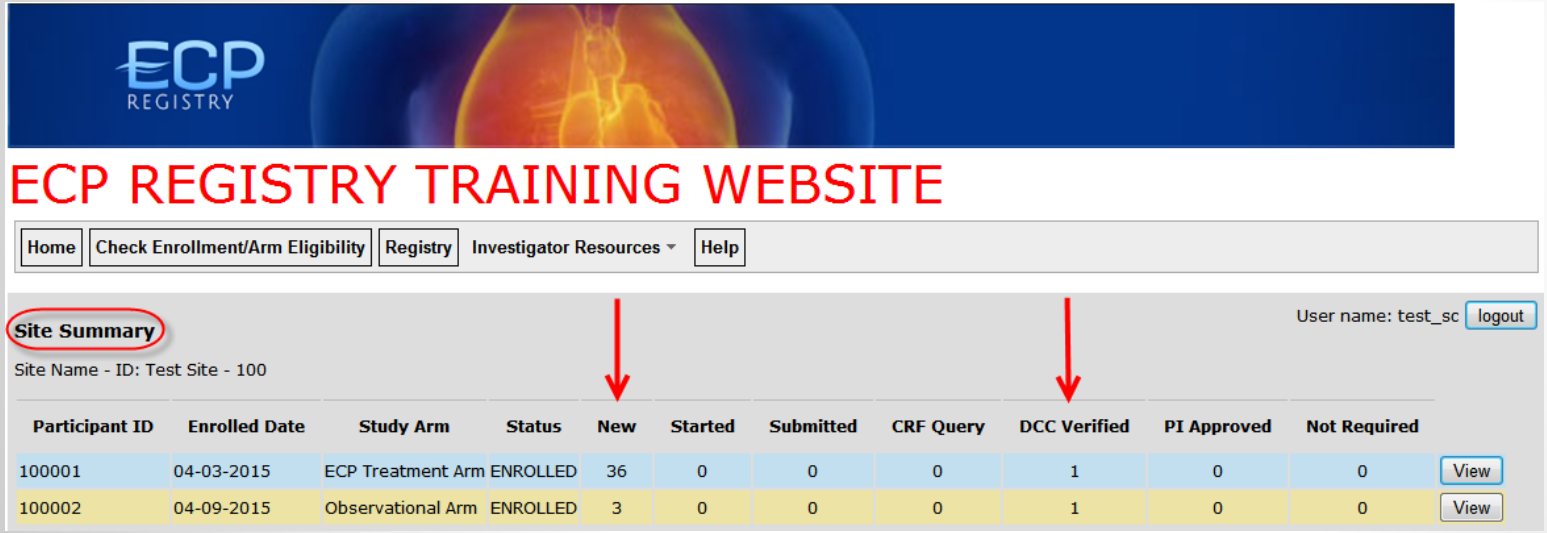
- When the **Status** of the **COE** Event changes to **DCC Verified**, the **Participant Summary** page will be populated with New Events.
- 36 new Events for the ECP Treatment Arm.
- 3 new Events for the Observational Arm.





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 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

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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 taylork@mir.wustl.edu