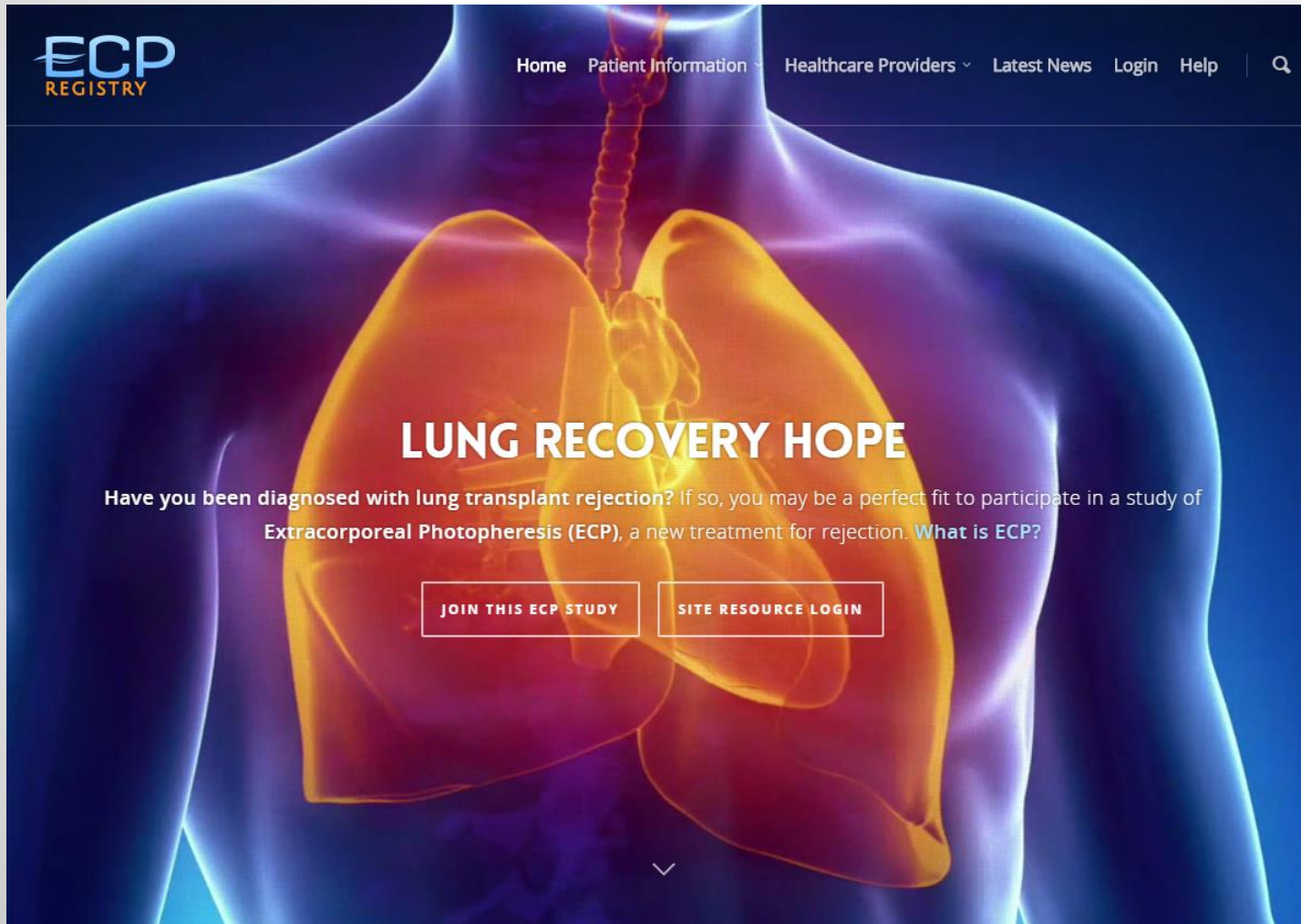


# Welcome to the Summary of the Website Training Presentation



# 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 a Summary of Procedures for using the ECP Registry.
- All site training will be done on an ECP 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

## Operating Systems

- Windows 8
- Windows 7
- Windows XP
- MAC


## Browsers

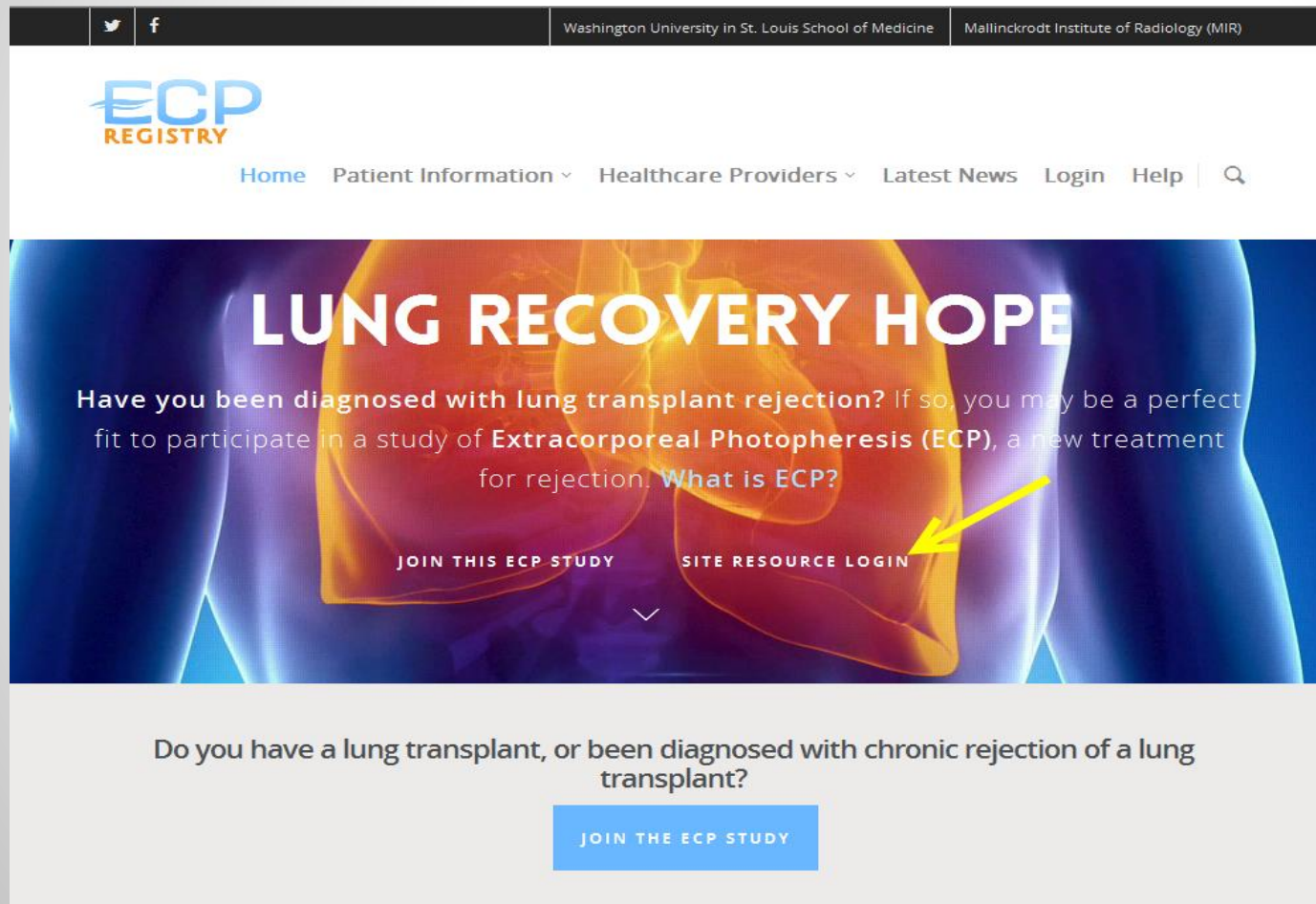
- Internet Explorer 8
- Internet Explorer 9
- Google Chrome

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





# Logging into the Secure Website

- The ECP Registry Site Resources Login page displays.
- Login using your assigned username and password.

**ECP Registry Site Resources Login**

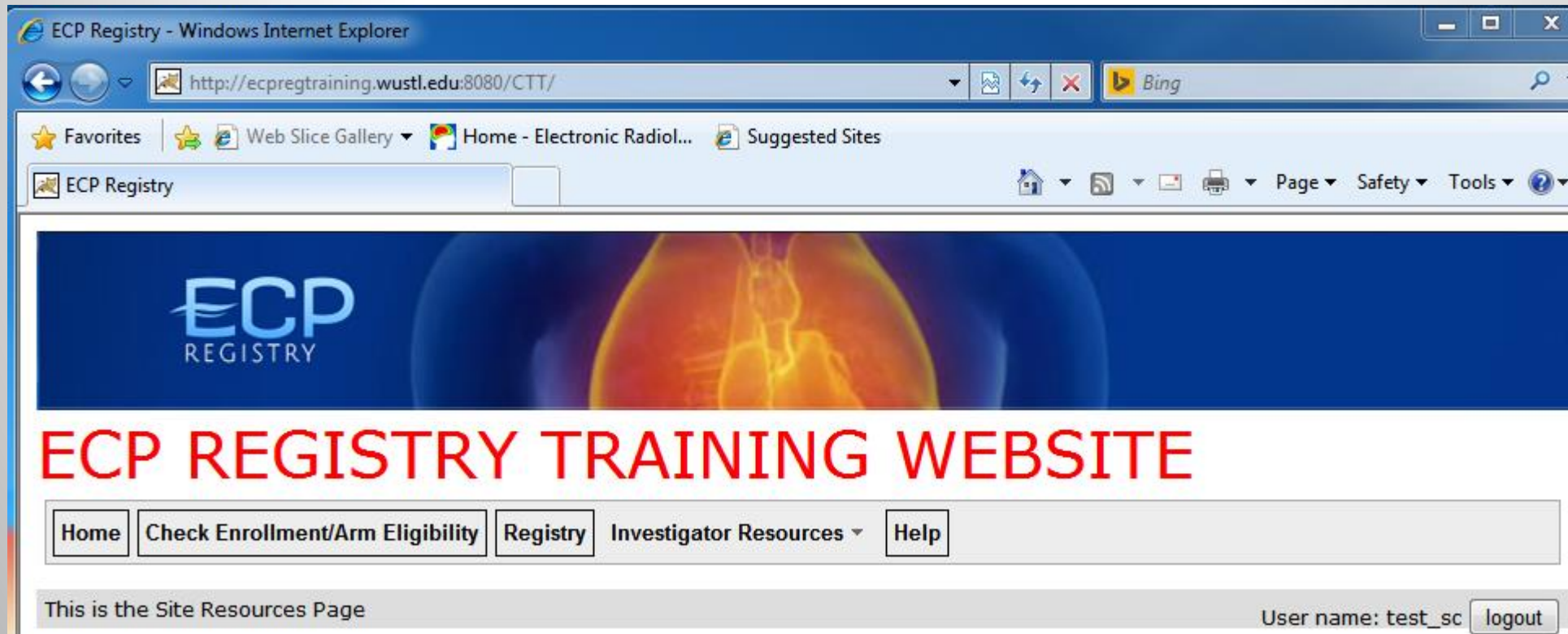
Username:

Password

Remember Me ☐

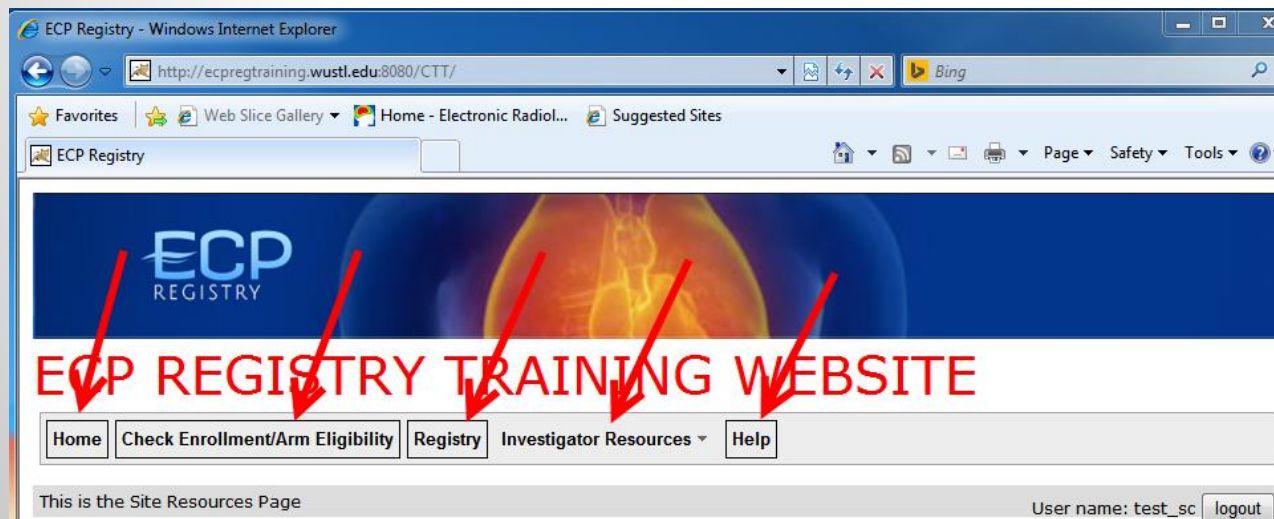
# Site Resources Page

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





- Note there are Four menu buttons and one menu item 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

- Enrollment process begins when the **Check Enrollment/Arm Eligibility** button is clicked.
- The **Enrollment Assessment and Study Arm Eligibility** form will display.
- Enter the participant's information to enroll them into the ECP study.
- Click the **Determine Enrollment and Study Arm Eligibility...** button, after entering the required information.

**NOTE:** All forms on the training website have bright red banners to distinguish the training website from the live website.

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

**ENROLLMENT ASSESSMENT AND STUDY ARM ELIGIBILITY**

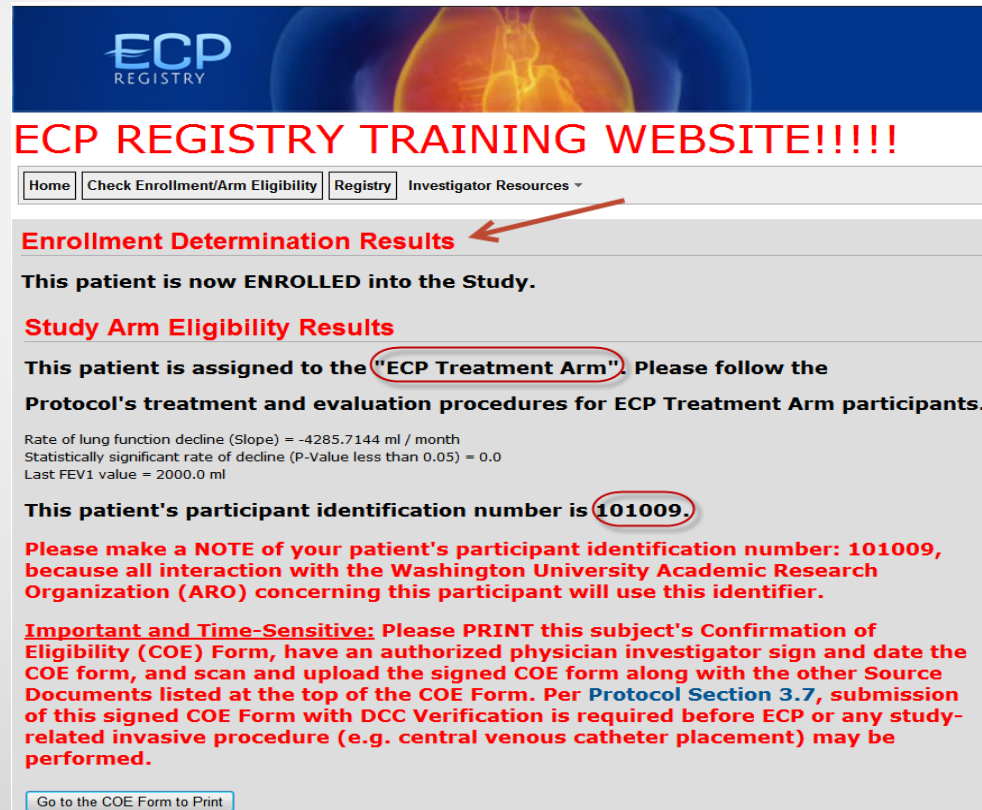
**Current Date:** 02/17/2015

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

<input type="radio"/> YES	<input type="radio"/> NO	Age 18 years or greater
<input type="radio"/> YES	<input type="radio"/> NO	Medicare-eligible
<input type="radio"/> YES	<input type="radio"/> NO	Lung transplant recipient
<input type="radio"/> YES	<input type="radio"/> NO	Strong clinical suspicion for progressive BOS defined as ongoing decline in FEV1 despite immunosuppressive therapy
<input 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

- After clicking the [Determine Enrollment and Study Arm Eligibility...](#) button, a page will display depicting whether the participant was enrolled to the observation arm or the treatment arm. The assigned participant ID number.
- In the example below, the participant was enrolled in the **ECP Treatment Arm** of the study. Note the rate of lung function decline (slope) and statistically significant rate of decline.
- This Participant was assigned **ID number 101009**.



The screenshot displays the ECP Registry Training Website. At the top, there is a blue header with the ECP Registry logo and a background image of a human torso with a glowing heart. Below the header, a navigation bar contains links: Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. The main content area is titled "Enrollment Determination Results" in red, with a red arrow pointing to it. Below this, a message states: "This patient is now ENROLLED into the Study." The next section, "Study Arm Eligibility Results", indicates: "This patient is assigned to the 'ECP Treatment Arm'. Please follow the Protocol's treatment and evaluation procedures for ECP Treatment Arm participants." Below this, specific data is provided: "Rate of lung function decline (Slope) = -4285.7144 ml / month", "Statistically significant rate of decline (P-Value less than 0.05) = 0.0", and "Last FEV1 value = 2000.0 ml". The participant's identification number, 101009, is circled in red. A red note instructs the user to make a note of this number for all interactions with the Washington University Academic Research Organization (ARO). An "Important and Time-Sensitive" section follows, detailing the requirements for the Confirmation of Eligibility (COE) Form, including signing, dating, and uploading it. At the bottom, a button labeled "Go to the COE Form to Print" is visible.

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

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

**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) = -4285.7144 ml / month  
Statistically significant rate of decline (P-Value less than 0.05) = 0.0  
Last FEV1 value = 2000.0 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.

**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](#)

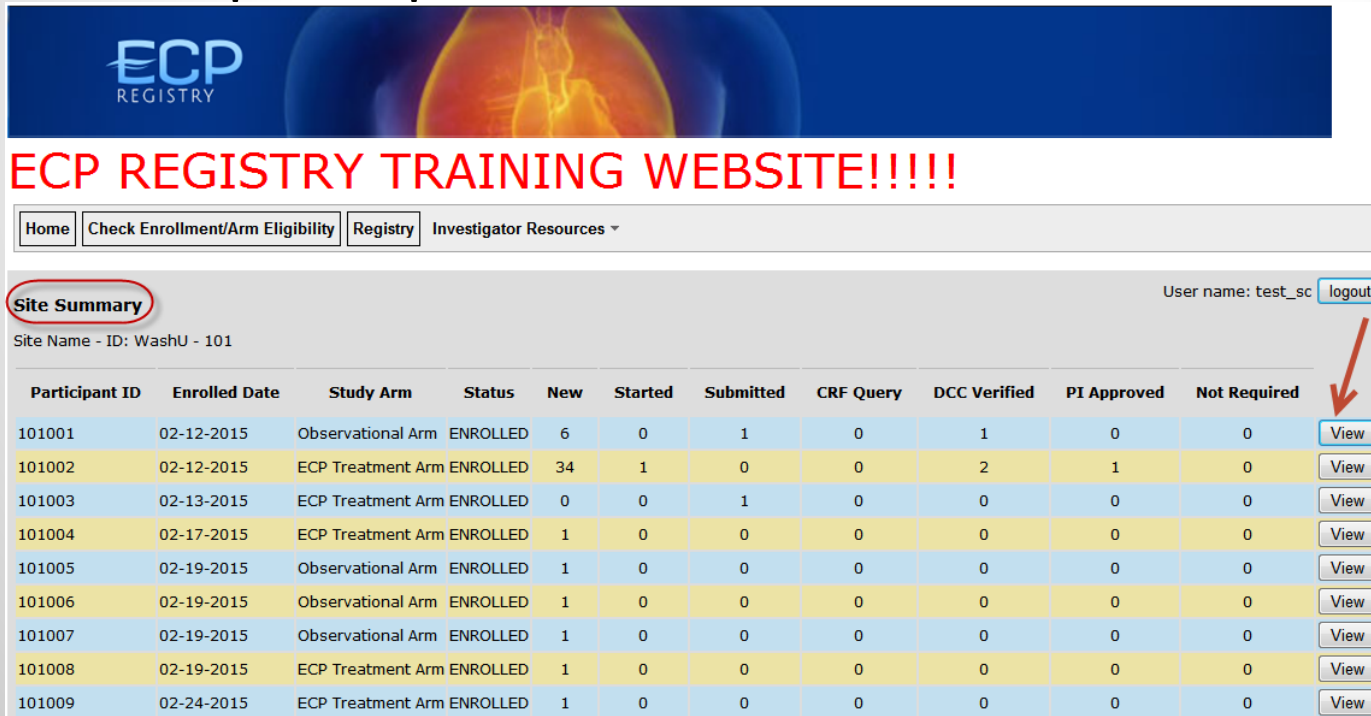
# Enrollment Eligibility and Study Arm Determination

- Following Enrollment.
  1. Click  button.
  2. You will be directed to the **Site Summary** page.
  3. Click the  button for the assigned Participant ID.
  4. You will be directed to the **Participant Summary** page.
  5. Click the  button for the **Confirmation of Eligibility** Event.
  6. You will be directed to the **Event Summary** page.
  7. Click the  button for the **Confirmation of Eligibility** Form.
  8. You will be directed to the **Confirmation of Eligibility** CRF.
  9. Right Click on the **Confirmation of Eligibility** CRF.
  10. Select Print in the pop up window.
  11. Print the **Confirmation of Eligibility** CRF.
  12. Have the form signed by the PI or Co-I.
  13. Upload the signed **Confirmation of Eligibility** Form and required source documents within 24 hours of enrollment.

**NOTE:** Please see  Enrollment Process Training Presentation for detailed instructions of this process.

# Site Summary Page

- The **Site Summary** page displays all enrolled participants for your site.
- Use this page to:
  1. Track all your site's participants.
  2. Navigate to the **Participant Summary** page by clicking the  button for the assigned Participant ID.
- The example below is for Site Name - ID: WashU - 101 and the site currently has nine participants enrolled.



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

Home Check Enrollment/Arm Eligibility Registry Investigator Resources ▾

Site Summary User name: test\_sc [logout](#)

Site Name - ID: WashU - 101

Participant ID	Enrolled Date	Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	
101001	02-12-2015	Observational Arm	ENROLLED	6	0	1	0	1	0	0	<a href="#">View</a>
101002	02-12-2015	ECP Treatment Arm	ENROLLED	34	1	0	0	2	1	0	<a href="#">View</a>
101003	02-13-2015	ECP Treatment Arm	ENROLLED	0	0	1	0	0	0	0	<a href="#">View</a>
101004	02-17-2015	ECP Treatment Arm	ENROLLED	1	0	0	0	0	0	0	<a href="#">View</a>
101005	02-19-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	<a href="#">View</a>
101006	02-19-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	<a href="#">View</a>
101007	02-19-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	<a href="#">View</a>
101008	02-19-2015	ECP Treatment Arm	ENROLLED	1	0	0	0	0	0	0	<a href="#">View</a>
101009	02-24-2015	ECP Treatment Arm	ENROLLED	1	0	0	0	0	0	0	<a href="#">View</a>

# Participant tracking information displayed on the Site Summary Page:

- **Participant ID**
- **Enrollment date**
- **Study Arm** – Either ECP Treatment Arm or Observational Arm.
- **Status** – of participant
  - Enrolled – Currently active participant
  - Completed – End of Study reached after one year of participation
  - Withdrawn – By PI, by participant, or by death of participant
- **New** – The number of newly created CRFs.



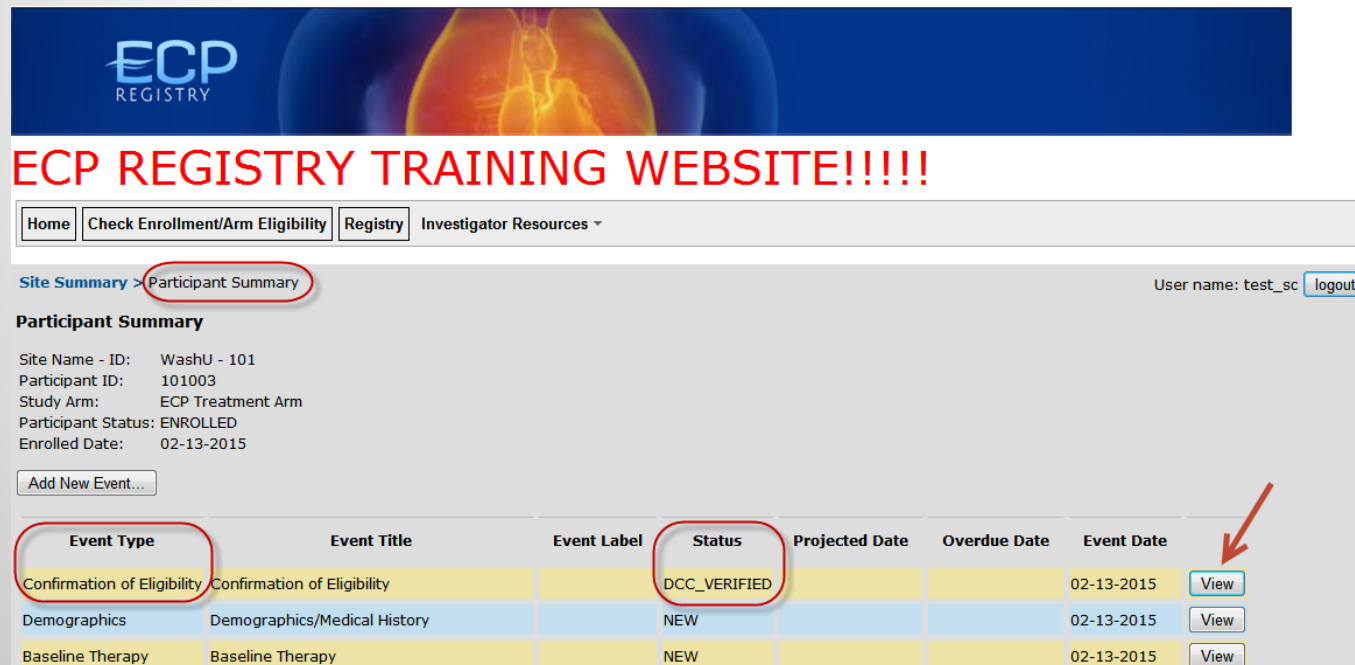
# Participant tracking information displayed on the Site Summary Page:

- **Started** – The number of CRFs for which data entry was started, but the CRFs are not yet submitted.
- **Submitted** – The number of CRFs submitted and ready for data verification.
- **CRF Query** – The number of CRFs that have gone through data verification by DCC staff and currently require correction or additional source documents by the site staff.
- **DCC Verified** – The number of CRFs verified by the DCC staff as complete and accurate.
- **PI Approved** – The number of CRFs with site PI approval after DCC verification.
- **Not Required** – The number of CRFs which will not be completed because of participant withdrawal.

# Participant Summary Page

- The **Participant Summary** page displays the **Events** for a specific participant.
- Use this page to:
  1. Track a participant's events.
  2. Navigate to the **Participant Event** page by clicking the **View** button of the event.
- In this example, this participant is in the ECP Treatment Arm and has 3 events listed.

**NOTE:** The **Confirmation of Eligibility Event** must have a **Status** of **DCC VERIFIED** before a participant may receive treatment.



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

Home Check Enrollment/Arm Eligibility Registry Investigator Resources ▾

Site Summary > **Participant Summary** User name: test\_sc [logout](#)

**Participant Summary**

Site Name - ID: WashU - 101  
Participant ID: 101003  
Study Arm: ECP Treatment Arm  
Participant Status: ENROLLED  
Enrolled Date: 02-13-2015

[Add New Event...](#)

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			02-13-2015	<a href="#">View</a>
Demographics	Demographics/Medical History		NEW			02-13-2015	<a href="#">View</a>
Baseline Therapy	Baseline Therapy		NEW			02-13-2015	<a href="#">View</a>

# Event tracking information displayed on the Participant Summary Page:

- **Event Type** – The type of event created.
- **Event Title** – The Title of the event created.
- **Event Label** – Only used for Serious Adverse Events.
- **Status** – of event
  - New – Newly created event
  - Started – Event has been started but not saved
  - Saved – Event or CRF has been started and saved but not submitted
  - Submitted – Event or CRF has been submitted
  - CRF Query – Event has been reviewed by DCC and needs data correction
  - DCC Verified – Verified by the DCC staff as complete and accurate
  - PI Approved – Event approved by the site PI

# Event tracking information displayed on the Participant Summary Page:

- **Projected Date** – Used for tracking ECP Treatment, PFTs and End of Study events
- **Overdue Date** – Used for tracking PFT and End of Study events
- **Event Date** – The date the event was created by the site

# Participant Events (CRFs)

- The list of **Events** differs depending if the participant is in the ECP Treatment arm or the Observational arm.
- **Events** are created in two ways:
  1. After the **Confirmation of Eligibility** (COE) CRF status becomes **DCC Verified** the software will automatically create 36 new events for the ECP Treatment Arm and 3 new events for the Observational Arm.
  2. Using the **Add New Event** button on the **Participant Summary** page.

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			02-12-2015	<a href="#">View</a>


[Site Summary](#) > Participant Summary

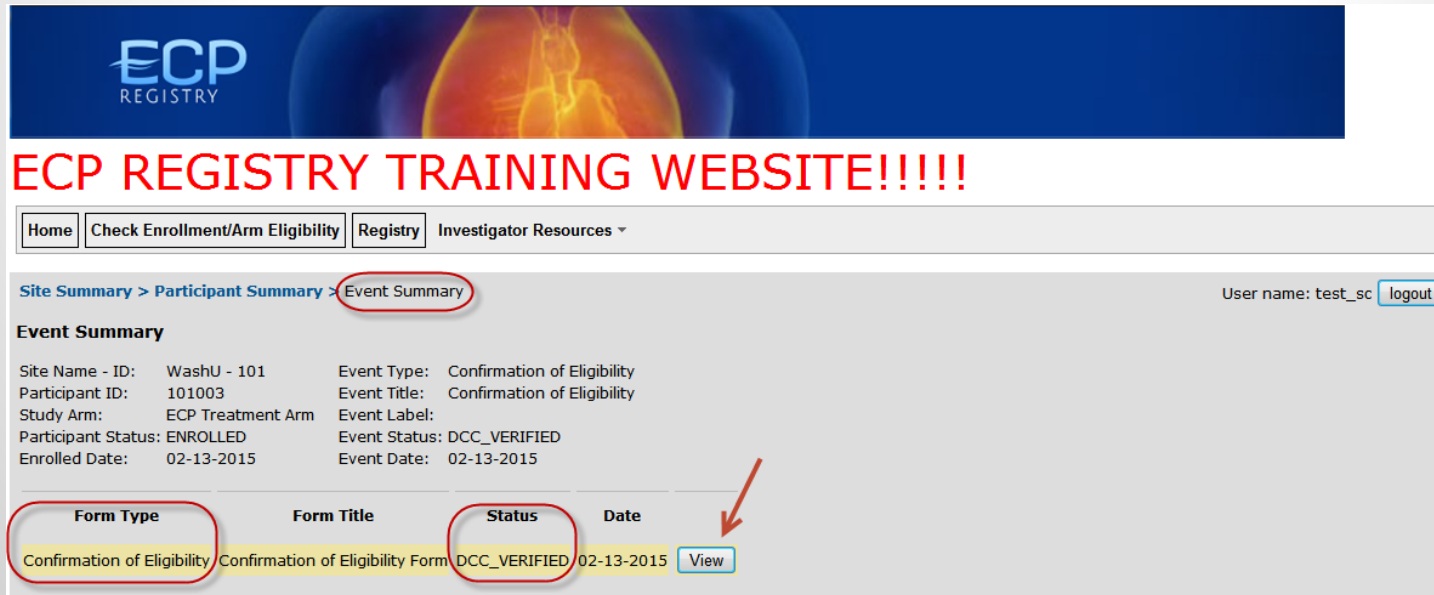
## Participant Summary

Site Name - ID: WashU - 101  
Participant ID: 101001  
Study Arm: Observational Arm  
Participant Status: ENROLLED  
Enrolled Date: 02-12-2015

[Add New Event...](#)

# Event Summary Page

- The **Event Summary** page displays information about a particular **Case Report Form** for a specific participant.
- Use this page to track a specific participant's particular Case Report Form.
- In this example, this is the participant's COE Form and it has been DCC VERIFIED.
- On the Event Summary page, click the  button, this will direct you to that particular **Case Report Form**.



**ECP**  
REGISTRY

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

Home Check Enrollment/Arm Eligibility Registry Investigator Resources ▾

Site Summary > Participant Summary > **Event Summary** User name: test\_sc [logout](#)

**Event Summary**

Site Name - ID:	WashU - 101	Event Type:	Confirmation of Eligibility
Participant ID:	101003	Event Title:	Confirmation of Eligibility
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	DCC_VERIFIED
Enrolled Date:	02-13-2015	Event Date:	02-13-2015

Form Type	Form Title	Status	Date	
Confirmation of Eligibility	Confirmation of Eligibility Form	DCC_VERIFIED	02-13-2015	<a href="#">View</a>



# CRF tracking information displayed on the Event Summary Page:

- **Form Type** – The type of event created
- **Form Title** – The Title of the event created
- **Status** – of form
  - New – Newly created event
  - Started – Event has been started but no data saved
  - Saved – Event has been started and saved but not submitted
  - Submitted – Event has been submitted
  - CRF Query – Event has been reviewed by DCC and needs data correction
  - DCC Verified – Verified by the DCC staff as complete and accurate
  - PI Approved – Event approved by the site PI
- **Date** – the form was created

# **ECP Treatment Arm – CRFs**

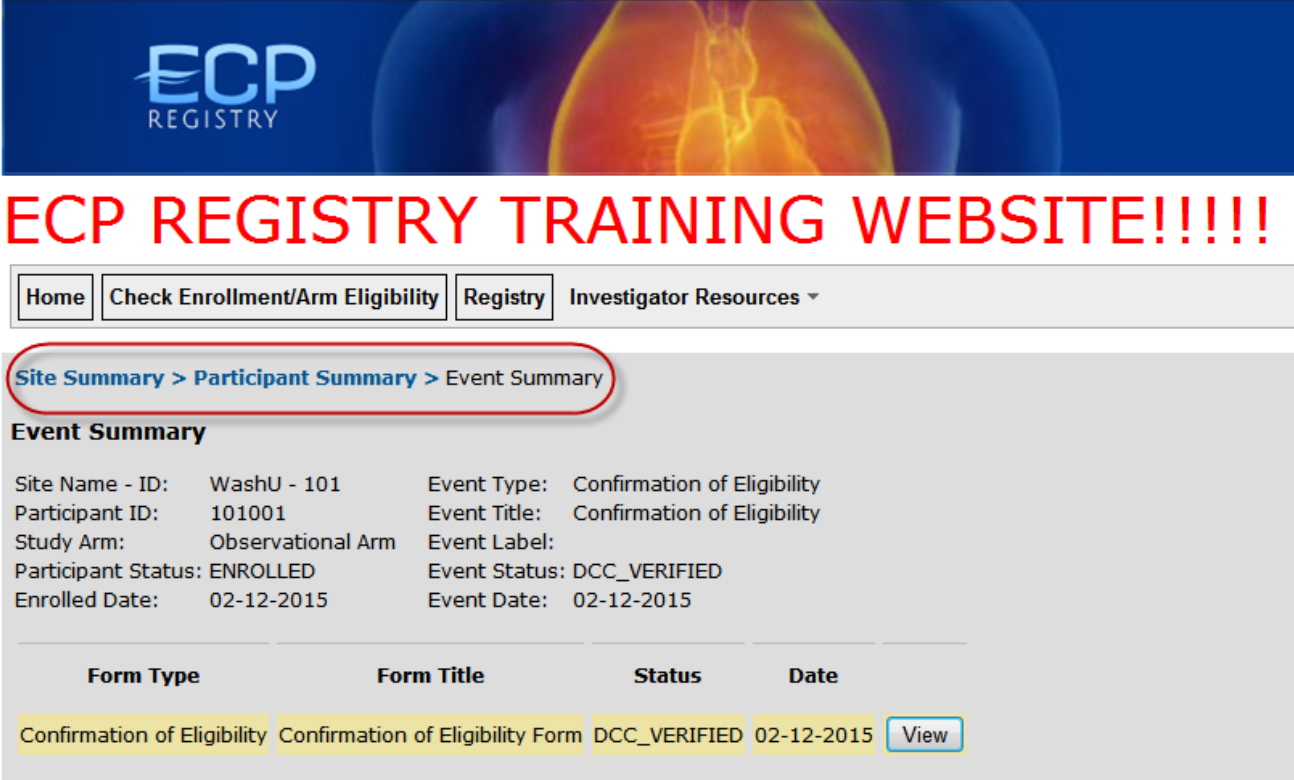
- Confirmation of Eligibility (COE)
- Demographics/Medical History
- Baseline Therapy
- ECP Treatment
- Pulmonary Function Test (PFT)
- Change in Therapy
- Serious Adverse Event (SAE)
- End of Study

# Observational Arm – CRFs

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

# Data Entry and 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.) **NOTE:** **Site Summary** and the **Participant Summary** 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. At the top is a blue header with the ECP Registry logo and a heart graphic. Below the header is a red banner with the text "ECP REGISTRY TRAINING WEBSITE!!!!". Underneath is a navigation bar with links: Home, Check Enrollment/Arm Eligibility, Registry, and Investigator Resources. Below the navigation bar is a breadcrumb trail: Site Summary > Participant Summary > Event Summary. The "Site Summary" and "Participant Summary" links are circled in red. Below the breadcrumb trail is the "Event Summary" section, which displays details for a specific event. At the bottom is a table with columns: Form Type, Form Title, Status, Date, and a View button.

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

Home Check Enrollment/Arm Eligibility Registry Investigator Resources ▾


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

**Event Summary**

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

Form Type	Form Title	Status	Date	
Confirmation of Eligibility	Confirmation of Eligibility Form	DCC_VERIFIED	02-12-2015	<a href="#">View</a>

# Data Entry and Navigation

- The ECP Registry will log a user out two hours after the user has not had interaction with the website server, such as saving or submitting a form or changing to a different page.
- If the ECP Registry logs a user out, any unsaved data will not be saved.
- When adding data to a CRF, always **Save** before leaving a page. A good practice is to **Save** every 10 – 15 minutes.
- To enter a date, click either the calendar icon  next to the date field and select the date, or manually enter the date in the format MM/DD/YYYY.
- To navigate from one data field to the next, use Tab key or the mouse to select a field.

# Data Entry and Navigation

- To navigate to a field that requires a selection with a radio button, the user must manually click the selection with the mouse. A user cannot tab to a radio button selection.
- If you submit a CRF and the screen does not return to the **Participant Summary** page, scroll through the CRF screen looking for error messages in red. Usually a data field has been left blank or an amount is outside the allowable range.
- Do not use the **Backspace** key or click a **back arrow** on a screen to try to return to a previous page. Instead, select **Site Summary** or **Participant Summary** breadcrumb links to navigate back.



# 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	<a href="#">View</a>

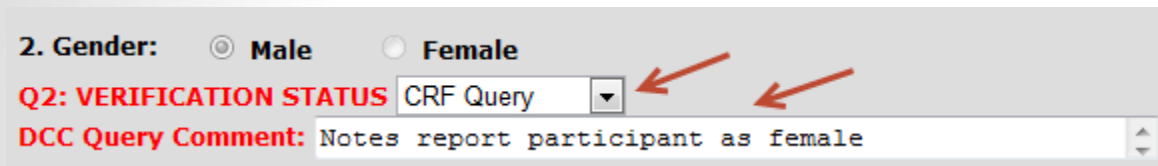
- Example of an Event Status marked CRF Query by the DCC staff.

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	
Confirmation of Eligibility	Confirmation of Eligibility		CRF_QUERY			02-03-2015	<a href="#">View</a>

# 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.



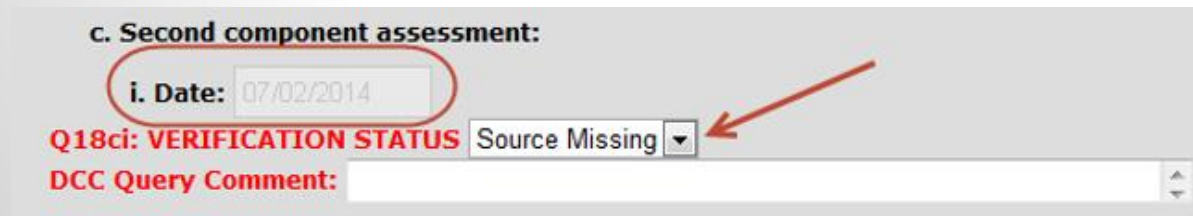
2. Gender: ☒ Male ☐ Female

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 it, 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.

# Scan and Upload Source Documents

- Source documents are required to support and verify participant data.
- The specific source documents required are identified at the top of each CRF.
- De-identify and scan source documents into pdf format.
- Uploaded pdf files into the specific CRF.
- In the example below, a Signed Confirmation of Eligibility Form has been scanned and uploaded.

**NOTE:** Please see  Enrollment CRFs Training Presentation for detailed instructions of this process.

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](#)

# 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 training.
- Please sign the Attestation Form located on the ECP website <http://ecpregistry.wustl.edu> under the Investigator Resources drop down menu.
- Keep the original in your ECP Registry Binder.
- Forward a copy to [taylork@mir.wustl.edu](mailto:taylork@mir.wustl.edu)