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

# CROSSOVER SAFETY CHECK - Case Report Form (CRF)

## Crossover Safety Check Form

**Important and Time-Sensitive: Please answer the question below and then PRINT this participant's Crossover Safety Check (CSC) Form, have an authorized physician investigator sign and date the CSC form, and scan and upload the signed CSC. Per Protocol Section 3.7, submission of this signed CSC Form is required before ECP or any study-related invasive procedure (e.g. central venous catheter placement) may be performed.**

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

**1. A Signed Crossover Safety Check Form must be uploaded**

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

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

Attach Source Document: Choose File | No file chosen | Upload

Save | Submit

## Safety Check

**1. Has the patient developed a new contraindication to the use of ECP Treatment therapy? (Please review the Protocol Section 3.3 for conditions that may apply.)** ○ YES ○ NO

**2. Has the signed Crossover Safety Check CRF been uploaded?** ○ YES ○ NO

**3. The following FEV1 values were used to calculate the Crossover Confirmation of Eligibility for this participant to be transferred from the Observational Arm to the ECP Treatment Arm.**

| | | | | | |
|---|---|---|---|---|---|
| **A. Date** | | **FEV1** | liters | **FVC** | liters |
| **B. Date** | | **FEV1** | liters | **FVC** | liters |
| **C. Date** | | **FEV1** | liters | **FVC** | liters |
| **D. Date** | | **FEV1** | liters | **FVC** | liters |
| **E. Date** | | **FEV1** | liters | **FVC** | liters |
| **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

## INVESTIGATOR ATTESTATION

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

**Investigator Name (please print)** _____

**Investigator Signature** _____ **Date:** _____

Save Submit