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

ADVERSE EVENT WORKSHEET AND SERIOUS ADVERSE EVENT

Participant ID:

Title of Adverse Event (AE)(Diagnosis):

Current Date:

Onset Date: **Time:**

SECTION I. BASIC INFORMATION FOR ADVERSE EVENT

1. Was the event fatal? ○ YES ○ NO (if yes, notify IRB, CCC, and submit completed AE/SAE form within 24 hours)

2. Was the event life-threatening? ○ YES ○ NO (if yes, notify IRB, CCC, and submit completed AE/SAE form within 24 hours)

3. Which of the following criteria apply to this event?

○ YES	○ NO	Resulted in persistent or significant disability/incapacity (serious injury)
○ YES	○ NO	Resulted in hospital admission or prolongation of hospitalization
○ YES	○ NO	Resulted in pregnancy abortion
○ YES	○ NO	Resulted in congenital anomaly or birth defect in baby born to subject
○ YES	○ NO	Cancer in a neonate/infant born to female subject
○ YES	○ NO	Required aggressive medical/surgical intervention to prevent serious injury
○ YES	○ NO	Seriously jeopardized subject's health
○ YES	○ NO	Resulted in emergency department visit or activation of acute response team

4. Do ALL THREE of the following criteria apply to this event? ○ YES ○ NO

a. This event is unexpected (see Protocol Section 6.4); and

b. This event is related or possibly related to study participation (see Protocol Section 6.4); and

c. This event suggests that the research places subjects or others at a greater risk of harm (physical, psychological, economic, or social harm) than was previously known or recognized.

SECTION II. BASIC INFORMATION FOR SERIOUS ADVERSE EVENT OR UNANTICIPATED PROBLEM

Report Type: ○ Initial ○ Follow-up ○ Final

Date of participant enrollment in study:

Date event became serious (for SAE only): _____ **Time:** _____

Date event became known to investigator or study team member: _____ **Time:** _____

Date of completion of last ECP procedure: _____ **Time:** _____ **Not Applicable:** ☐

Date event resolved: _____ **Time:** _____ **Or ongoing:** ☐

1. Was this event fatal?

If YES:

a. Date of death: _____ **Time:** _____ **Or unknown:** ☐

b. Cause of death: _____

c. Is a copy of autopsy report attached, if performed? ○ YES ○ NO

2. Was the event life-threatening?

3. Was this event related or possibly related to the use of ECP? ○ YES ○ NO

4. Did this event occur or begin during or within 6 hours after ECP? ○ YES ○ NO

5. Was this event related or possibly related to a central venous catheter that was placed for the purpose of performing ECP? ○ YES ○ NO

6. Was this event possibly, probably, or definitely related to the use of methoxsalen: ○ YES ○ NO

○ Possibly ○ Probably ○ Definitely

This Serious Adverse Event (SAE) must be reported to the CCC. Immediately complete Section III of this form, submit the signed completed Case Report Form, upload the relevant de-identified source documents, notify your CCC coordinator, and follow your local IRB's guidelines for SAE/UP reporting.

SECTION III. DETAILED INFORMATION FOR SERIOUS ADVERSE EVENT OR UNANTICIPATED PROBLEM

A. Full chronological description - include body site/system, setting (e.g. hospital, home), specific signs and symptoms:

B. Expectedness (see Protocol Section 6.4)? ○ Unexpected ○ Expected

C. Date of last administration of methoxsalen before event: Not Applicable: ☐

Date: **Time:**

Dose:

D. Treatment given:

○ YES	○ NO	1. None
○ YES	○ NO	2. Non-invasive treatment (e.g. medical therapy)
○ YES	○ NO	3. Minimally-Invasive Treatment (e.g. cather-based or endoscopic procedure)
○ YES	○ NO	4. Open Surgery

Please specify, if the answers to question D2, D3, and/or D4 are YES:

E. Relevant medical history:

F. Relevant lab/imaging findings:

G. Outcome at time of report:

○ Death ○ Not Yet Recovered ○ Recovered With Sequalae ○ Recovered Without Sequalae

H. Comments:

After submitting this worksheet, please open the Serious Adverse Event (SAE) Form then print the SAE form, sign and date it. Then upload the signed SAE form and other relevant source document into the SAE form, and notify your CCC coordinator.

Investigator Signature _____ **Date** _____

Name of Investigator _____

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