

Extracorporeal Photopheresis for the Management of Progressive Bronchiolitis Obliterans Syndrome in Medicare-Eligible

Recipients of Lung Allografts

ECP Site Delegation of Authority Log Site Name _____ Site # _____

STUDY PERSONNEL (Please Print)	SIGNATURE of Study Personnel	Initials of Study Personnel	ROLE(s)	RESPONSIBILITY CODE(s) (Use codes below)	START Date	PI Initials & Date <i>Start date verification</i>	END Date	PI Initials & Date <i>End date verification</i>

Role: **A** = PI **B** = Co-Investigator **C** = Research Coordinator **D** = Regulatory **E** = Data Entry **F** = Other (Please specify in table above)

Delegated Study Responsibilities

- 1 = Screening
- 2 = Obtain Informed Consent
- 3 = Subject Enrollment / Subject Randomization online
- 4 = Sign Confirmation of Eligibility (Must be a PI or Co-I)
- 5 = IRB Submission
- 6 = Regulatory Files Maintenance
- 7 = Obtain Medical History and Baseline Physical Exam

- 8 = Electronic Data Entry
- 9 = Schedule PFT's and ECP Visits per ECP Protocol
- 10 = Administer QOL questionnaire
- 11 = Data Query Resolutions
- 12 = AE / SAE Reporting and Entry
- 13 = SAE Sign off (Must be a PI or Co-I)
- 14 = Other (Specify in table above)

Start of Study – PI Printed Name: _____ PI Signature: _____ Date: _____

End of Study – PI Printed Name: _____ PI Signature: _____ Date: _____