



Institutional Biosafety Committee
Meeting Minutes

Date: 09/02/2025 **Start time:** 3:00pm (ET) **End time:** 5:00pm (ET)

Advarra IBC meetings are closed to the public to protect confidential and proprietary information as outlined in the Advarra IBC standard operating procedures.

Chair: Paul Gulig

Voting Members Present: Nichole Tower (Committee Member), Alain Houmeidan (Committee Member), Scott Swindle (Committee Member), Begoña Comin-Anduix (Committee Member), Warren Rummage (Committee Member), Marisa Merkt (Community Member)

Other Persons Present: [REDACTED]

Conflict of Interest: The IBC Chair queried the IBC to identify any potential conflicts of interest and requested that any potential conflicts of interest be disclosed to the IBC. The IBC Chair then reminded the IBC that if any potential conflicts of interest were identified as the meeting progressed, disclosure would need to occur at that time. Identified potential conflict of interest: ☐ Yes ☒ No

Study Summary Information for Minutes			
Protocol #	[REDACTED]	IBC Study Submission ID #	PROTO202500051
Study Title	A Phase 3, Randomized, Double-Masked, Active-Controlled Trial of a Single Intravitreal Injection of [REDACTED] in Adults with Macular Neovascularization Secondary to Age-Related Macular Degeneration [REDACTED]		
Agent	Adeno-Associated Virus (AAV)		
Agent Characteristics	Replication deficient vector; Risk Group 1		
rDNA Category	III-C-1		
Description of Recombinant Nucleic Acid Sources	[REDACTED] [REDACTED]		

Description of Genetically Modified Microbes or Vectors	Replication-deficient Adeno-associated virus (AAV)				
Description of Transgene Expression	[REDACTED] [REDACTED]				
Risk Assessment of Procedures	- Preparation of Dose - Sharps Safety - Standard Precautions - Administered Injection into the Eye - Sharps Safety - Standard Precautions - Dispose of all materials as biohazardous waste				
Site Information					
Site Name	Cincinnati Eye Institute – Cincinnati, OH			IBC Site Submission ID #	SAF202500394
PI Name	Robert Sisk				
Site Biosafety Level	BSL2				
Staff Training Verified by PI Signed SOP	☒ Yes ☐ No				
Motions, Votes, and Committee's Decision					
Motion: Approve					
Conditions: N/A					
Motion	First: [REDACTED]		Second: [REDACTED]		
Votes	For: 7	Against: 0	Recused: 0	Absent: 0	Abstained: 0

Chair Signature
Approved by Chair: Name: Paul A. Gulig, Ph.D. Date: 2025/09/12