



Institutional Biosafety Committee
Meeting Minutes

Date: 08/28/2025 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: Dan Eisenman (Committee Member), Darlene Ward (Committee Member), Nichole Tower (Committee Member), Warren Rummage (Committee Member), Alain Houmeidan (Committee Member), Scott Swindle (Committee Member), Shane Gillooly (Committee Member), Nicoletta Tieken (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 #	PROTO202500082
Study Title	An Open-label, Multicenter, Two Part, Ascending Dose Followed by a Controlled Trial to Assess the Safety and Efficacy of a Subretinal Administration of [REDACTED] in Participants with Stargardt Disease [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	<ul style="list-style-type: none"> • Recombinant protein that functionally replaces [REDACTED] that is mutated in the disease 		

Description of Genetically Modified Microbes or Vectors	<ul style="list-style-type: none"> • Replication-deficient Adeno-associated virus (AAV) 				
Description of Transgene Expression	<ul style="list-style-type: none"> • [REDACTED] gene replacement 				
Risk Assessment of Procedures	<ul style="list-style-type: none"> • Preparation of Dose <ul style="list-style-type: none"> ○ Sharps Safety ○ Standard Precautions • Administered Injection into the Eye <ul style="list-style-type: none"> ○ Sharps Safety ○ Standard Precautions • Dispose of all materials as biohazardous waste 				
Site Information					
Site Name	Retina Foundation of the Southwest - Dallas, TX	IBC Site Submission ID #	SAF202500294		
PI Name	Karl Csaky, M.D., Ph.D.				
Site Biosafety Level	BSL2				
Staff Training Verified by PI Signed SOP	<input checked="" type="checkbox"/>	Yes	<input type="checkbox"/>	No	
Motions, Votes, and Committee's Decision					
Motion: Approve					
Conditions: N/A					
Motion	First: [REDACTED]		Second: [REDACTED]		
Votes	For: 9	Against: 0	Recused: 0	Absent: 0	Abstained: 0

Chair Signature

Approved by Chair:

Name: Paul A. Gulig, Ph.D.

Date: 2025/11/21