Meeting Minutes

Institution:	Southeastern Retina Associates, PC		
Meeting Date:	December 12, 2025 at 2:30 PM		
Meeting Time	2:30 PM Eastern Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	**Member**	**Voting**	**Member Type**
	Noriea, Nicholas	Yes	Chair: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Welch, Jim	Yes	Local Unaffiliated Member
	Youngblood, Tyler	No	Site Contact
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Pritchett, Christopher	Yes	Local Unaffiliated Member
Guests:	None		
Staff:	Sreedharan, Aswathy		

Call to Order: The IBC Chair called the meeting to order at 2:34 PM Eastern Time. A quorum was present as defined in the Sabai IBC Charter.

Conflicts of Interest: The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

Public Comments: No public comments were made prior to or at the meeting.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from August 6, 2025 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Kleinman, Mark MD
Sponsor:	4D Molecular Therapeutics, Inc.
Protocol:	4D-150-C003 A Phase 3, Randomized, Double-Masked, Active-Controlled Trial of a Single Intravitreal Injection of 4D-150 in Adults with Macular Neovascularization Secondary to Age-Related Macular Degeneration (4FRONT-1)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: 4D-150-C003 is a Phase 3 clinical trial sponsored by 4D Molecular Therapeutics, Inc., and designed to evaluate the safety and efficacy of 4D-150 in adult participants with macular neovascularization (MNV) secondary to age-related macular degeneration (nAMD). 4D-150 is a recombinant, replication-defective adeno-associated virus (rAAV) vector designed to express two anti-VEGF transgene components [miR-(VEGF-C) and coAFLB] that are designed to inhibit angiogenesis and vascular leakage in the eyes of individuals with nAMD. The investigational product (IP) is administered by intravitreal injection

Biosafety Containment Level (BSL): 4D-150 may be classified as a Risk Group 1 (RG1) agent under the NIH Guidelines and Biosafety Level 1 (BSL-1) may be considered as the minimum containment level for handling the study agent.

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).

- The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
- The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the PI's credentials and other applicable information provided by the Site for the purposes of the IBC review.
  - The Site verified that the information provided by the Chair was accurate.
  - The Site confirmed the biohazard waste area is access controlled. The Committee had no concerns.
  - The Committee agreed they are not familiar with the specifics of local building code, but encouraged the Site to confirm whether any biohazard storage containers should be rearranged to comply with clearance requirements. The Site had no concerns.
  - The Site described their plans to mitigate any potential exposure during preparation and priming including that the study agent will be prepared and primed without the participant present in the room. If the agent is prepared in the same room used for dosing, the participant will be entering after preparation is complete. The Committee recommended the Site provide any additional mitigation strategies approved by the institution to reduce the potential for needlestick when priming into the gauze pad.
  - The Chair polled the Committee for any concerns in the event Sabai granted administrative approval to move the storage location for a different IBC-approved agent to the storage room approved for this study. The Committee had no concerns or questions.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 3:13 PM Eastern Time

Post-Meeting Pre-Approval Note: None