Meeting Minutes

Institution:	Maine Eye Center
Meeting Date:	October 20, 2025
Meeting Time	1:30 PM Eastern Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Bavaret, Tammy	Yes	Chair: Biosafety Expert/HGT Expert
Helm, Allen	Yes	Core Member: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Forrette, Lindsay	Yes	Local Unaffiliated Member
Pennoyer, Kelly	Yes	Local Unaffiliated Member
Manter, Heather	No	Site Contact

Invited Members Not in Attendance:	None
Guests:	Parenteau, Alec
Staff:	Payne, Kaylie

Call to Order: The IBC Chair called the meeting to order at 1:31 PM. 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: Previous meeting minutes from 4-25-25 were reviewed and approved with no changes requested.

New Business:

PI:	Moore, Jeffrey 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 (IVT) injection.

Biosafety Containment Level (BSL): The study agent 4D-150 is a replication-defective rAAV vector that does not encode a toxin molecule or potentially tumorigenic gene product and is produced in the absence of a helper virus. Therefore, 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. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030).

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.
  - In response to a question from the Committee, the Site confirmed the red non-sharps biohazardous waste container on the floor is brought in for excess biohazardous material and then stored in the Used Vial Storage room. The Committee had no concerns.

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 2:01 PM

Post-Meeting Pre-Approval Note: None