Meeting Minutes

Institution:	Retina Northwest, P.C. - Sylvan
Meeting Date:	September 25, 2025
Meeting Time	11:30 AM Pacific Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
Helm, Allen	Yes	Core Member: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Brickey, Debra	Yes	Local Unaffiliated Member
Johnson, Amanda	Yes	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Newton, Paul	Yes	Local Unaffiliated Member

Guests:	Larsen, Cynthia
Staff:	Hemmelgarn, Marian

Call to Order: The IBC Chair called the meeting to order at 11:32 AM. 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: None

New Business:

PI:	Patel, Apurva MD
Sponsor:	Perceive Biotherapeutics, Inc.
Protocol:	PBI-AMD-002 A Phase 1/2a Study of VOY-101 in Subjects with Advanced Non-Neovascular Age-Related Macular Degeneration (JOURNEY)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: PBI-AMD-002 is an open-label, multi-center Phase I/IIa clinical trial sponsored by Perceive Biotherapeutics, Inc. and designed to assess the safety, tolerability, and efficacy of a single, unilateral intravitreal (IVT) injection of escalating dose levels of VOY-101 therapy in subjects with geographic atrophy (GA) secondary to advanced non-neovascular age-related macular degeneration (AMD). VOY-101 is a recombinant adeno-associated viral vector, AAV serotype 2, containing a transgene that encodes the truncated isoform of human Complement Factor H (hCFHT). The investigational product (IP) is administered by intravitreal (IVT) injection.

Biosafety Containment Level (BSL): The study agent VOY-101 is based on a replication-defective, recombinant Risk Group 1 AAV with no known oncogene or toxin and manufactured in the absence of helper virus, thus BSL-1 is considered the recommended containment level under the NIH Guidelines. The administration of this agent in a clinical setting further 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, splashes, and needlestick exposures of the IP during preparation and/or administration procedures. 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 Committee discussed the carpeting in rooms where the study agent is being handled. The Site confirmed they are in the process of obtaining plastic mats to cover the carpeting in these areas. The Committee agreed to contingently approve the study at the Site pending placement of plastic mats over the carpeting in front of the storage unit, by the preparation area (including under the new bench area once installed), and around the administration area. The Committee further requested updated photos of these areas once the mats are installed as part of the contingent approval. The Site Checklist will be administratively updated to note the presence of carpeting and use of plastic coverings. The Committee suggested removing carpeting altogether in the future if possible. Additionally, the Site indicated that carpet tiles could be removed if they become contaminated; this information will be administratively added to the Site Checklist.
  - In response to a question from the Committee, the Site confirmed that the participant will not be present in the exam room during agent preparation. Further, the Site confirmed that a glove exchange is performed between agent preparation and administration. The Facility Details form will be administratively updated to reflect these practices.
  - The Committee requested the Biohazard Sign be revised to define AAV.
  - The Site confirmed that the biohazard waste is stored in the Staff Restroom, which is a controlled access room that is currently used as a restroom in addition to storage. Access to the room is limited to staff, including custodial staff. The Committee discussed this arrangement at length and suggested the Site consider a different location for biohazardous waste storage. With limited alternatives, the Site indicated that this restroom is the best option given that it is uncarpeted and access-controlled. The Committee recommended that custodial staff be given study agent-specific biohazard training.
  - The Site indicated they are awaiting arrival of cardboard biohazard waste boxes to be used in the preparation/administration room. The Committee contingently approved the use of the biohazard waste boxes pending plastic mat/tray placement under the box and that the box has a lid, or the Site use a lidded plastic waste bin (preferably foot-operated) marked with a biohazard symbol. The Committee further requested an updated photo of the biohazard waste container once installed in the preparation/administration room as part of the contingent approval.

Motion: A motion of Contingent 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:
  - The Committee agreed to contingently approve the study at the Site pending placement of plastic mats over the carpeting in front of the storage unit, by the preparation area (including under the new bench area once installed), and around the administration area. The Committee further requested updated photos of these areas once the mats are installed as part of the contingent approval. These contingent items must be submitted to Sabai by 10/24/25. The Committee agreed that Full Approval for this study will only be issued after resolution of this contingency has been approved following review by the Chair.
  - The Committee contingently approved the use of the biohazard waste boxes pending plastic mat/tray placement under the box and that the box has a lid, or the Site use a lidded plastic waste bin (preferably foot-operated) marked with a biohazard symbol. The Committee further requested an updated photo of the biohazard waste container once installed in the preparation/administration room. These contingent items must be submitted to Sabai by 10/24/25. The Committee agreed that Full Approval for this study will only be issued after resolution of this contingency has been approved following review by the Chair.

- 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 12:26 PM

Post-Meeting Pre-Approval Note: None