Meeting Minutes

Institution:	Black Hills Regional Eye Institute
Meeting Date:	January 27, 2026
Meeting Time	1:30 PM Mountain 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
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Ellis, Robert	Yes	Core Member: Biosafety Expert/HGT Expert
Mowell, Ronalda (joined at 1:56 PM MT)	Yes	Local Unaffiliated Member
Ambrosino, Helena	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Funk, Jason	Yes	Local Unaffiliated Member

Guests:	Devi, Krishna; Roubideaux, Shannon
Staff:	Smith, Jennifer; Hemmelgarn, Marian

Call to Order: The IBC Chair called the meeting to order at 1:35 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: None

New Business:

PI:	Abraham, Prema
Sponsor:	Perceive Biotherapeutics, Inc.
Protocol:	PBI-AMD-002 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 unilateral 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 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 noted that preparation will occur on the benchtop in the photo with the -80 freezer. Additional photos were provided of the incorrect room and those will be administratively removed from the slideshow.
    - The Site indicated that some administration areas are carpeted. The Committee stipulated that the Site cover the carpet with plastic in administration areas where the study agent is going to manipulated and send updated photos to Sabai by 2/27/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP. The Site Checklist will be administratively updated to reflect this.
    - The Committee stipulated that the Site post a colored eyewash placard above the plumbed eyewash station and send an updated photo to Sabai by 2/27/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Site confirmed that the emergency number on the Biohazard Sign does connect to personnel who are knowledgeable about the study agent.
    - The Site confirmed that there is hand sanitizer in the preparation room.
    - The Site confirmed that the preparation room door is closed during study agent activities.
    - The Committee recommended that the Site carry eyewash bottles with the study agent to administration locations.

Motion: A motion of Approval with Stipulations 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:
    - The Committee stipulated that the Site cover the carpet with plastic in administration areas where the study agent is going to manipulated and send updated photos to Sabai by 2/27/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Committee stipulated that the Site post a colored eyewash placard above the plumbed eyewash station and send an updated photo to Sabai by 2/27/26. The

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Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 2:20 PM

Post-Meeting Pre-Approval Note: None