Meeting Minutes

Institution:	Cincinnati Eye Institute
Meeting Date:	March 18, 2026
Meeting Time	12:00 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
Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
Espinola, Marcia	Yes	Local Unaffiliated Member
Nordling, Diana	Yes	Local Unaffiliated Member
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Conrad, Kelye	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type

Guests:	Chachare, Deepali
Staff:	McFarland, Christine

Call to Order: The IBC Chair called the meeting to order at 12:01 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 8/25/25 were approved by the IBC with no changes. There were 0 votes against and 0 abstentions.

New Business:

PI:	Sisk, Robert MD, FACS
Sponsor:	Opus Genetics
Protocol:	OPGx-BEST1 DUO-1001: A Phase 1b/2a, Open-Label, Dose-Exploration Basket Study to Investigate the Safety and Tolerability of Subretinally Injected OPGx-BEST1 Administered in Patients with Either Autosomal-Dominant BEST1 Disease (Best Vitelliform Macular Dystrophy [BVMD]) or Autosomal-Recessive Bestrophinopathy (ARB)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: OPGx-BEST1 DUO-1001 is a first-in-human, open-label, dose-exploration Phase 1b/2a clinical trial sponsored by Opus Genetics and designed to evaluate the safety, tolerability, and preliminary efficacy of OPGx-BEST1, an investigational gene therapy, in adult participants with genetically confirmed Best Vitelliform Macular Dystrophy (BVMD) or Autosomal-Recessive Bestrophinopathy (ARB). The investigational medicinal product, OPGx-BEST1, is a recombinant adeno-associated virus serotype 2 (AAV2) vector encoding a codon-optimized human BEST1 gene under the control of the retinal pigment epithelium-specific VMD2 promoter. The investigational product (IP) is administered by a single subretinal injection of OPGx-BEST1 in one eye.

Biosafety Containment Level (BSL): OPGx-BEST1 is a recombinant, replication-defective adeno-associated virus serotype 2 (AAV2) vector designed to deliver a codon-optimized human BEST1 gene to retinal pigment epithelium cells. OPGx-BEST1 is considered a Risk Group 1 (RG1) agent under the *NIH Guidelines*, as it is not associated with disease in healthy adult humans and does not contain hazardous transgenes. Therefore, the use of Biosafety Level 1 (BSL-1) containment is considered the default containment level for handling this RG1 study agent under the *NIH Guidelines II-A-3*. Administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens 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 aerosols, 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), use of a Biological Safety Cabinet for IP preparation, 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 overview of the Site's arrangements and activities with the study agent provided by the Chair was accurate.
    - In response to a question from the Committee, the Site clarified that the sharps shown in the photo of the Operating room on the staging area are capped and unused and confirmed that used sharps are disposed of inside biohazardous sharps containers. The Site noted that the sharps container is placed in the staging area and close to the surgeon performing the vitrectomy to facilitate safe disposal. The Site further clarified that if surgical items are dropped on the floor during the operation, they are not retrieved until completion of the procedure to maintain the sterile field and the entire area including the floor is disinfected afterwards. The Committee had no additional concerns but asked that the slide be annotated to note that used sharps are disposed of in a biohazard sharps container.
    - The Committee discussed the biohazard door sign shown posted on the biosafety cabinet (BSC) in the Pharmacy and stipulated that the Site replace the door sign with a biohazard sticker and send an updated photo to Sabai. The Site confirmed that the biohazard door sign is also posted on the door when study agent is in use. The Committee had no further concerns.
    - The Committee discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. At the specific request of the Site, the Committee agreed to approve the study at BSL-2 to allow for this study to be conducted in a manner that was consistent with other clinical studies approved at the Site.

Motion: A motion of Full Approval for the study at BSL-2 was passed by unanimous vote. There were 0 votes against and 0 abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
    - The Committee stipulated that the Site replace the door sign posted on the BSC with just the biohazard symbol (e.g. sticker, magnet, etc.) and send an updated photo to Sabai by 4/17/2025. The Committee agreed that resolution of this stipulation can be approved following review by the Associate Partner.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 12:42 PM Eastern Time.

Post-Meeting Pre-Approval Note: None