Meeting Minutes

Institution:	Retina Foundation of the Southwest
Meeting Date:	Monday, August 25, 2025
Meeting Time	8:00 AM Central 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 Campbell, Mark / Yes / Core Member: Biosafety Expert/HGT Expert Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Berg, Rance / Yes / Local Unaffiliated Member Naik, Veena / Yes / Local Unaffiliated Member Jones, Kaylie / No / Site Contact
Invited Members Not in Attendance:	None
Guests:	None
Staff:	Stark, Casey Hemmelgarn, Marian

Call to Order: The IBC Chair called the meeting to order at 8:01 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:	Pennesi, Mark
Sponsor:	Opus Genetics
Protocol:	OPGx-LCA5-1001 A Phase 1b/2a, Open Label, Dose Exploration Study to Investigate the Safety and Tolerability of Subretinally Injected OPGx-001 Administered in Patients with LCA5-Associated Inherited Retinal Degeneration (LCA5-IRD) with Concurrent Non-Interventional Follow-Up of Untreated Participants.
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: OPGx-LCA5-1001 is an open-label Phase Ib/IIa trial sponsored by Opus Genetics and designed to assess the safety, tolerability, and preliminary efficacy of OPGx-001 in participants ≥ 13 years of age with LCA5-Associated Inherited Retinal Degeneration (LCA5- IRD). OPGx-001 is a recombinant, replication-defective adeno-associated virus (AAV) vector expressing unmodified human lebercilin (LCA5) protein to restore functional lebercilin in photoreceptors. The investigational product (IP) is administered by subretinal injection.

Biosafety Containment Level (BSL): The study agent OPGx-001 is a recombinant Risk Group 1 AAV vector that does not encode hazardous transgenes and is used in the absence of a helper virus, therefore BSL-1 is the minimal recommended containment level under the *NIH Guidelines.* The Sponsor calls for Biosafety Level 2 as the recommended containment level for handling this 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 that the biosafety cabinet has been recently recertified. The Site provided the updated certification report during the meeting. The Committee had no concerns.
  - The Site confirmed that they have recently renewed their bloodborne pathogens training and provided an updated certificate during the meeting. The Committee had no concerns.
  - The Site confirmed that the off-site SurgiCare Center is approximately two miles from the Site's clinical location. The Committee had no concerns.
  - The Site confirmed that a plumbed eyewash is located down the hallway near the operating room suites. The Site Map will be administratively updated to indicate the location of the plumbed eyewash.
  - The Site confirmed that study agent is primed into a luer-to-luer lock syringe connection. The Facility Details report will be administratively updated to note this preparation practice.
  - The Committee noted that the sink in the lab does not have paddle handles or another hands-free mechanism to operate the sink and recommended the Site consider adding hands-free mechanisms to comply with good biosafety practices.
  - The Committee recommended the Site consider posting the eyewash placard above the eyewash station in the lab. The Site informed the Committee that the eyewash station is situated on an island counter and has no walls surrounding the counter. The Committee recommended the Site consider hanging the placard from the ceiling or consider alternative methods for posting signage in the absence of a wall-mounted placard. The Site had no concerns.
  - The Site confirmed that the white storage unit as seen in the representative photos is a refrigerator and would not be used for study agent storage. The Committee had no concerns.

- The Committee noted that the magnetic biohazard sign placed on the Room 93A door frame could easily fall off when the door is opened and/or closed. The Committee stipulated that the Site place the sign directly on the door and send an updated photo to Sabai IBC Services.
- The Committee noted that the representative Site photos indicate the transport container as an "Internal Transport Container". Since the study agent will be transported off-site, the representative Site photos will be administratively updated to "Transport Container".
- The Site confirmed that biohazard waste is picked up by a licensed waste vendor at each location and is not transported between locations. The Committee had no concerns.
- The Site confirmed that the operating rooms have separate sharps and non-sharps waste containers. The Committee stipulated that the Site provide an updated photo of the sharps and non-sharps waste containers in the operating room. If these photos cannot be obtained, the photo slide will be administratively updated to indicate the Site confirmed waste is segregated appropriately.
- The Site confirmed that a staff member will be transporting the study agent to the SurgiCare center and not via a courier service. The Site additionally confirmed that study agent will be transported per IATA standards. The Facility Details report will be administratively updated to note this practice.
- 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 Sponsor requirements.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
  - Place the biohazard sign directly on the door in 93A and send an updated photo by 9/25/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - Provide an updated photo of sharps and non-sharps waste containers in the operating room by 9/25/2025. If these photos cannot be obtained, the photo slide will be administratively updated to indicate the Site confirmed waste is segregated appropriately. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Pennesi, Mark
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 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 subretinal injection.

Biosafety Containment Level (BSL): 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. 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*. The Sponsor calls for Biosafety Level 2 as the recommended containment level for handling this 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).
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    - 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.
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Motion: A motion of Approval with Stipulations for the study at BSL-2 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
  - Place the biohazard sign directly on the door in 93A and send an updated photo by 9/25/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - Provide an updated photo of sharps and non-sharps waste containers in the operating room by 9/25/2025. If these photos cannot be obtained, the photo slide will be administratively updated to indicate the Site confirmed waste is segregated appropriately. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 8:39 AM

Post-Meeting Pre-Approval Note: None