Meeting Minutes

Institution:	Southeastern Retina Associates, PC
Meeting Date:	March 24, 2026
Meeting Time	4:00 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
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert

Invited Members Not in Attendance:

Member	Voting	Member Type
Welch, Jim	Yes	Local Unaffiliated Member
Pritchett, Christopher	Yes	Local Unaffiliated Member
Fung, Valerie	No	Site Contact

Guests:	Youngblood, Tyler (Site Representative)
Staff:	Sreedharan, Aswathy

Call to Order: The IBC Chair called the meeting to order at 4:04 PM Eastern Time. A quorum was present as defined in the Sabai IBC Charter. The Chair noted that there were no local unaffiliated members present at the meeting, but there was quorum with the current attendance. The Committee had no concerns holding the review without local members present.

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.

Meeting Minutes

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 12-12-2025 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Kleinman, Mark MD
Sponsor:	AbbVie Inc.
Protocol:	RGX-314-3101 A Randomized, Partially Masked, Controlled, Phase 3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ASCENT)
Review Type:	Change in Research Review
NIH Guidelines Section:	III-C-1

Trial Summary: RGX-314-3101 (also known as M23-409) is a Phase 3, multicenter, partially masked, randomized, active-controlled, parallel-arm study sponsored by AbbVie Inc and designed to investigate the efficacy and safety of the study agent ABBV-RGX-314 administered as a single subretinal injection in participants with neovascular age-related macular degeneration (nAMD). ABBV-RGX-314 (also known as RGX-314 and surabgene lomparvovec [sura-vec]) is a recombinant adeno-associated viral vector (rAAV) serotype 8, containing a transgene that encodes for soluble anti-vascular endothelial growth factor (VEGF) antigenbinding fragment (Fab) protein. The investigational product (IP) is administered by subretinal injection.

Biosafety Containment Level (BSL): The study agent ABBV-RGX-314 is based on a Risk Group 1 (RG1) AAV vector that does not contain hazardous transgenes and is not handled or manufactured in the presence of a helper virus, thus biosafety level-1 (BSL-1) is the minimum recommended containment level for handling the 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, and other applicable information provided by the Site for the purposes of the IBC review.
  - The Chair noted that this is a change in Research review to change the surgical center location. The Committee had no concerns with the changes.
  - The Site verified that the information provided by the Chair was accurate.
  - In response to a question from the Committee, the Site confirmed that the eyewash bottles are placed in the Surgery Room.

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 4:19 PM Eastern Time

Post-Meeting Pre-Approval Note: None