Meeting Minutes

Institution:	Thompson and Sjaarda, PA dba Retina Specialists
Meeting Date:	June 08, 2026
Meeting Time	2:30 PM Eastern Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Noriea, Nicholas	Yes	Chair: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Reed, Craig	Yes	Core Member: Biosafety Expert/HGT Expert
Hawley, Bob	Yes	Local Unaffiliated Member
Morland, Melissa	Yes	Local Unaffiliated Member
Khan, Malika	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
None		

Guests:	None
Staff:	Sreedharan, Aswathy

Call to Order: The IBC Chair called the meeting to order at 2:31PM 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 6-30-25 were approved by the IBC with no changes. There were no votes against and no abstentions.
New Business:

PI:	Barañano, David MD, PhD
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:	Annual 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. The administration of this agent
in a clinical setting further requires compliance with 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 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 Annual Review Report 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.
    - In response to a question from the Committee, the Site confirmed that the

biohazard sign is posted on the Storage Room. The Site photos will be administratively updated to indicate this.
- In response to a question from the Committee, the Site confirmed that the IP storage room has vinyl flooring and is easily cleanable.
- The Committee noted that the used vial storage container labeling was on the inside of the container. The Site confirmed they will move the labeling to the outside of the container to minimize potential for contamination.
- The Site confirmed a spill kit is available at the clinic. The Site also confirmed the dosing location has the elements for a spill kit but was unsure if these materials were consolidated as a kit. The Committee stipulated the Site confirm the dosing facility has a biological spill kit available consisting minimally of a virucidal disinfectant, absorbent material (e.g., paper towels), a set of PPE, and a red biohazardous waste bag by 6/8/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP
- The Site confirmed that eyewashes are tested at frequent intervals for operation.
- The Committee discussed the photo of the sealed biohazardous bags appearing to contain waste containers. The Site noted this photo does not represent waste practices but was rather provided as a follow up to previous committee request. The Chair noted this was likely a miscommunicated request to ensure waste containers are covered when not in use. The Committee agreed the Site's described current waste practices of keeping the waste containers closed when not in use and having the waste hauler pick up the waste directly from the location is sufficient and had no further concerns.

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: None
  - The Committee stipulated the Site confirm the dosing facility has a biological spill kit available consisting minimally of a virucidal disinfectant, absorbent material (e.g., paper towels), a set of PPE, and a red biohazardous waste by 8/8/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

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IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 3:18 PM Eastern Time

Post-Meeting Pre-Approval Note: None