INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, May 11, 2026**
Time:	4:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Ophthalmic Consultants of Boston and Boston Eye Surgery and Laser Center, Boston, MA
Principal Investigator:	**Jeffrey S Heier, MD**
Protocol:	AbbVie, Inc., **RGX-314-2102**
NCT Number:	NCT04514653
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 2, Randomized, Dose-escalation, Ranibizumab-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of RGX-314 Gene Therapy Delivered via One or Two Suprachoroidal Space (SCS) Injections in Participants with Neovascular Age-Related Macular Degeneration (nAMD) (AAVIATE)

1. Call to order:

The Meeting was called to order at 4:01 pm Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present was one Institutional Representative and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

The Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for ABBV-RGX-314, since it consists of an AAV vector administered in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of ABBV-RGX-314 locally**, provided that all other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Committee noted that the study agent is provided in two formulations, refrigerated or frozen, and there are different storage requirements for each as noted in the Biological Risk Assessment and Summary.
2. The Institutional Representative stated that the study agent for this protocol is provided as the frozen formulation.
3. The Committee discussed a note on the sharps container in the OR at the surgery center which indicates that medication should be “wasted” prior to disposal of the syringe. The Institutional Representative stated that this OR is not used for this protocol but will follow up with IBC Services on what is meant by the note on the sharps container.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 4:12 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 11.0, dated 07-17-2025
Investigator's Brochure, Version 15, dated 03-24-2026
Pharmacy Manual, Version 11.0, dated 07-21-2025
Dual Suprachoroidal Administration Manual, Version 3.0, dated 11-05-2020
Suprachoroidal Admin Manual, Refrigerated IP Dilution (5.0x10 11 GC), Version 1.0, dated 10-25-2021
Single Suprachoroidal Administration Manual, (1.5 x 1012 GC), Version 4.0, dated 11-10-2025
Single Suprachoroidal Admin with IP Dilution (5.0x10 11 GC), Version 3.0, dated 05-25-2021
Single Suprachoroidal Admin with IP Dilution (1.0 x10 12 GC), Version 1.0. dated 07-19-2021
Single Suprachoroidal Admin Manual, Version 3.0, dated 11-05-2020
Single SC Admin with Dilution (1E12 GC) and Subtenon Steroid Manual, Version 1.0, dated 07-26-2022
Research Modification Evaluation, Protocol, Version 11.0
Research Modification Evaluation, Investigator's Brochure, Version 15
Research Modification Evaluation, Pharmacy Manual, Version 11.0
Research Modification Evaluation, Single SCS Admin Manual (1.5x1012 GC), Version 4.0
Biological Risk Assessment and Summary, updated 04-14-2026
Research Modification Evaluation, Additional Storage Location, dated 08-28-2025
Site Map, OCB, updated 07-31-2025
Site Inspection Checklist, expires 04-16-2028, updated 04-23-2026
Photos, dated 11-24-2025
Biohazard Sign, Ophthalmic AAV Study Agents, dated 04-20-2026
Biosafety SOP, Ophthalmic AAV Study Agents, dated 04-20-2026
Biosafety SOP, Addendum for ABBV-RGX-314, dated 04-20-2026
Training, Shipping Certification, expires 02-27-2027
CRRF, dated 02-06-2026
Prior Meeting Minutes, Continuing, dated 05-29-2025