

# 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-314-2202  
**NCT Number:** NCT04567550  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase 2, Randomized, Controlled, Dose-escalation Study to Evaluate the Efficacy, Safety, and Tolerability of RGX-314 Gene Therapy Delivered via a Single Suprachoroidal Space (SCS) Injection in Participants With Diabetic Retinopathy (DR) With and Without Center Involved-Diabetic Macular Edema (CI-DME) (ALTITUDE)

### 1. Call to order:

The Meeting was called to order at 4:12 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

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### **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 4:15 pm Eastern Time.

### **15. Post-meeting notes:** None.

#### **Documents reviewed:**

Agenda

Protocol, Version 10.0, dated 07-02-2024

Investigator's Brochure, Version 15, dated 03-24-2026

Pharmacy Manual, Version 11.0, dated 03-26-2025

Suprachoroidal Administration Manual, Refrigerated IP Dilution (5.0x10<sup>11</sup> GC), Version 1.0, dated 10-25-2021

Suprachoroidal Admin Manual, Refrigerated IP Dilution (1.0x10<sup>12</sup> GC), Version 1.0, dated 07-17-2023

Single Suprachoroidal Administration with IP Dilution (5.0x10<sup>11</sup> GC), Version 3.0, dated 05-25-2021

Single Suprachoroidal Administration with IP Dilution (1.0 x10<sup>12</sup> GC), Version 1.0. dated 07-19-2021

Single Suprachoroidal Administration Manual, Version 3.0, dated 11-05-2020

Single Suprachoroidal Administration Manual, (1.5 x 10<sup>12</sup> GC), Version 4.0, dated 11-10-2025

Research Modification Evaluation, Investigator's Brochure, Version 15

Research Modification Evaluation, Single SCS Admin Manual (1.5x10<sup>12</sup> GC), Version 4.0

Research Modification Evaluation, Additional Storage Location, dated 08-28-2025

Biological Risk Assessment and Summary, updated 04-14-2026

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