



January 16, 2026

MEMORANDUM: Public Posting of IBC Meeting Minutes on an Institutional Website

Dear Colleagues,

Since June 1, 2025, the NIH Office of Science Policy (OSP) has required all IBC meeting minutes to be posted online for public access. In December 2025, NIH OSP also began requiring all IBC registrations maintained in the NIH's IBC Registration Management System (IBC-RMS) to include the website where IBC meeting minutes are publicly posted. To facilitate these processes for our institutional clients, WCG has been posting meeting minutes to a dedicated WCG website and updating IBC registrations in IBC-RMS to include a link to that page.

The NIH OSP has since provided further guidance to WCG that institutions are required to post IBC meeting minutes themselves on an *institutional* website; linking to or relying on external repositories like WCG's does not meet the NIH requirement. Minutes must be posted following each IBC review meeting, after allowable redactions have been made.

To satisfy this NIH directive, please provide WCG IBC Services with the website you will be using to publicly post IBC meeting minutes via email to IBCServices@wgcclinical.com. Upon receipt, we will update your IBC registration in the IBC-RMS to include the website URL.

We realize that this may be challenging and take time to implement for many of our institutional partners. If WCG can be of any assistance in this matter, please contact us at the email address noted above.

We thank you for your ongoing collaboration and efforts to ensure clinical research is conducted safely and in line with all relevant requirements.

A handwritten signature in black ink, appearing to read 'Christopher Doyle'.

Christopher Doyle
Sr. Director, WCG IBC Services

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, March 2, 2026
Time: 8:00 am Pacific Time
Location: Zoom Teleconference
Institution: Sierra Eye Associates, Reno, NV
Principal Investigator: Arshad Khanani, MD, BA, MA
Protocol: Sierra Eye Associates, SEA1979
NCT Number: NCT06942520
Meeting Type: Continuing Review of Protocol and Site
Title: A Randomized, Open Label, Controlled, Phase 2 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 AAV Gene Therapy Administered via Subretinal Delivery in Participants with Center Involved-Diabetic Macular Edema

1. Call to order:

The Meeting was called to order at 8:00 am Pacific Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five voting members were present, including two local members 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: 5 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.

Point of Discussion:

1. The Institutional Representative noted that the protocol is designed to evaluate the safety and efficacy of the study agent in subjects with diabetic macular edema. The Chair confirmed that the Biological Risk Assessment and Summary would be revised to reflect this.

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 RGX-314, since it consists of an AAV vector administered by injection 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 RGX-314 locally**, provided that other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 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 recommended that prefilled disposable eyewash bottles be checked monthly to ensure they are replaced prior to expiration.
2. The Institutional Representative confirmed that the study agent-specific Biohazard Sign is posted during study agent handling activities.
3. The Institutional Representative stated that the study agent is stored in the Basement at Sierra Eye Associates as noted on the Site Inspection Checklist.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:11 am Pacific Time.

15. Post-meeting notes: After the meeting, the IBC Chair noted that all site documents need to be revised to reflect the Basement study agent storage location.

Documents reviewed:

Agenda

Protocol, Version 1, Amendment 3, dated 01-23-2025

Investigator's Brochure, Version 14, dated 03-24-2025

Pharmacy Manual, dated 12-06-2024

Subretinal Administration Manual, Version 7.0, dated 10-30-2025

Research Modification Evaluation, Protocol, Version 1, Amendment 3

Research Modification Evaluation, Investigator's Brochure, Version 14

Research Modification Evaluation, Subretinal Administration Manual, Version 6.0

Research Modification Evaluation, Subretinal Administration Manual, Version 7.0

Biological Risk Assessment and Summary, updated 11-12-2025

Site Map, dated 06-18-2025

Site Map, Visionary Surgery Center of Nevada, dated 12-06-2024

Site Inspection Checklist, expires 02-17-2028

Photos, dated 06-18-2025

Biohazard Sign, ABBV-RGX-314, dated 02-13-2026

SOP, Biosafety for ABBV-RGX-314, dated 02-25-2026

Training, Shipping Certification, expires 05-30-2026

CRRF, dated 11-05-2025

Prior Meeting Minutes, Initial, dated 02-04-2025



March 2, 2026

Arshad Khanani, MD, BA, MA
Sierra Eye Associates

Dear Dr. Khanani,

SUBJECT: INSTITUTIONAL BIOSAFETY COMMITTEE DETERMINATION

Sponsor: Sierra Eye Associates
Protocol: SEA1979, Version 1, Amendment 3, dated 01-23-2025
Title: A Randomized, Open Label, Controlled, Phase 2 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 AAV Gene Therapy Administered via Subretinal Delivery in Participants with Center Involved-Diabetic Macular Edema

The WCG-administered Institutional Biosafety Committee (IBC) for Sierra Eye Associates has reviewed this research and made the following determination:

Meeting Date: March 2, 2026
Meeting Type: Initial Review of Protocol and Site
IBC Determination: **Approved** **Disapproved**
 Conditionally Approved **Tabled**
Applicable Section of the NIH Guidelines: III-C-1

Approval Expiration Date: March 31, 2027

Biosafety Level: BSL-1 plus Standard Precautions
IBC Oversight Period: 3 months after the last subject's final dose

Reminder: per NIH requirements, IBC meeting minutes must be publicly posted on an institutional website after allowable redactions have been made. If you have not already done so, **please provide WCG with the institutional website where IBC meeting minutes are posted** via email to IBCServices@wcgclinical.com. Your IBC registration will then be updated with this information to maintain compliance.

If you have changes to your research to submit, please complete an [IBC Change in Research Form](#) and submit the completed form to IBCServices@wcgclinical.com.

cc: Jordyn Vannavong, Sierra Eye Associates
Kellie Cassinelli, Sierra Eye Associates
Deanna Dorman, COA, CCRP, Sierra Eye Associates
Study File