January 29, 2026

Dennis M. Marcus, MD
Southeast Retina Center, PC

Dear Dr. Marcus,

SUBJECT: **INSTITUTIONAL BIOSAFETY COMMITTEE DETERMINATION**

Sponsor:	AbbVie, Inc.
Protocol:	**RGX-314-2202**, Version 10.0, dated 07-02-2024
Protocol 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)

The Institutional Biosafety Committee (IBC) for Southeast Retina Center, PC has reviewed this research and made the following determination:

MEETING DATE: **January 29, 2026**

MEETING TYPE: **Continuing Review of Protocol and Site**

IBC DETERMINATION:
☒ **Approved** ☐ **Disapproved**
☐ **Conditionally Approved** ☐ **Tabled**
Applicable Section of the NIH Guidelines: III-C-1

EXPIRATION DATE: **January 31, 2027**

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

This IBC is administered by WCG IBC Services. If we can be of assistance, please contact us at IBCServices@wcgirb.com or by phone at (360) 252-2850.

If you have changes to your research to submit, please complete the "IBCS Change in Research Submission Form" on our website (https://www.wcgirb.com/how-to-submit/ibc-forms/), and submit the completed form with any other applicable documents to IBCServices@wcgirb.com.

cc: Davis Starnes, BS, Southeast Retina Center, PC
Christina Rex, Southeast Retina Center, PC
Diane Leibach, Southeast Retina Center, PC
Abigail Brown, Fortrea
Kylie Hardin, Fortrea
Patricia Reeves, Fortrea
Cleo James, Fortrea
RGX-314-2202@regenxbio.com
Study File

ALL IBC-APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Report the following site-specific information to the IBC within 5 days:
    a. Violations of the *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines).
    b. New information bearing on the NIH Guidelines.
    c. Significant research-related accidents and/or illnesses.
    d. Research-related spills, exposures, and/or laboratory-acquired infections.
    e. Loss of containment.
    f. Suspension or termination of the study by the sponsor, investigator, or institution.
    g. Unresolved complaints related to biosafety.

2. Training:
    a. Be adequately trained in good microbiological techniques and IBC-approved standard operating procedures.
    b. Instruct and train the research staff in:
        i. The practices and techniques required to ensure safety;
        ii. The procedures for dealing with accidents, spills, and/or exposures.
    c. Inform the research staff of the reasons and provisions for any precautionary medical practices advised or requested.

3. Safety:
    a. Supervise the safety performance of the research staff to ensure that the required safety practices and techniques are employed.
    b. Make available to all research staff descriptions of the potential biohazards and the precautions to be taken.
    c. Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.
    d. Remain in communication with the IBC throughout the conduct of the project.

4. Accountability:
    a. Correct work errors and conditions that may result in the loss of containment of recombinant or synthetic nucleic acid molecules.
    b. Ensure the integrity of the physical and biological containment of recombinant or synthetic nucleic acid molecules.
    c. Comply with shipping requirements for recombinant or synthetic nucleic acid molecules.
    d. Notify WCG IBC Services and obtain IBC approval before making any changes to the protocol, facilities, practices, and key study staff associated with the research.

The NIH Guidelines require that the IBC conduct periodic reviews of approved research. You will receive Continuing Review Report Forms from WCG IBC Services. These reports must be returned in a timely manner, even if research at your site has not yet begun.