Meeting Minutes

Meeting Date:	June 16 at 9:00 AM Central Time
Meeting Place:	Teleconference (Remote) Meeting is open to the public
Members in Attendance:	Hauke, Caitlyn Rastein, Daniel Ellis, Robert Whalen, Diva Britt, Anne
Members Not in Attendance:	Bourassa, Erick
Guests:	Canoy, Casey
Staff:	Hemmelgarn, Marian
Institution:	Mississippi Retina Associates

Call to Order: The meeting was called to order at 9:03 AM. A quorum was present.

Conflicts of Interest: None declared by voting members of the IBC.

Meeting Minutes: Previous meeting minutes were reviewed and approved with no requested changes.

New Business:

PI:	Borne, Michael, MD
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:	III-C

Trial Summary: RGX-314-3101 (also known as M23-409) is a Phase 3, multi-center, 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).

Biosafety Containment Level per Risk Assessment: BSL-1 plus Standard Precautions

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic

acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.

- The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, 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.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by majority vote. There were no abstentions on voting.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

Reminder of IBC Approval Requirements.

Adjournment: 9:29am AM

Post-Meeting Pre-Approval Note: None