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Allison Ayala

I agree to the terms defined by the placement of my
signature in this document

Tuesday, January 09, 2024

RE: Gyrate Atrophy Ocular and Systemic Study (GYROS)

Dear Investigator,

This Protocol Administrative Change Letter (PACL) is to notify you of the following administrative changes and clarifications to the **GYROS Protocol; Version 1.2, dated 28-Nov-22**. The edit described below is to clarify inconsistencies in the text of the protocol and provide an administrative change that does not impact the safety of subjects, the scope of the trial, or the scientific quality of the study, and therefore does not qualify as an amendment.

This PACL identifies the following discrepancies:

- **Page 13, Protocol Overview/Synopsis**, states *"Participants who enroll into the study cohort will return to the clinic within sixty (60) days of the Screening Visit date to start baseline testing, and no later than two (2) weeks after receiving confirmation of meeting final study cohort criteria from the CGA"*.
- **Page 16, Schedule of Study Visits and Procedures: Vision Cohort 1 & Vision Cohort 2**, states that *"Baseline Visit date (defined as the start date of all Baseline testing) must be no later than two (2) weeks after receiving confirmation of meeting final study cohort criteria from the CGA."*
- **Page 17, Schedule of Study Visits and Procedures: Vision Cohort 3**, states that *"Baseline Visit date (defined as the start date of all Baseline testing) must be no later than two (2) weeks after receiving confirmation of meeting final study cohort criteria from the CGA."*
- **Page 34, Chapter 3: Baseline Visit**, states that *"Participants meeting criteria to enter the natural history study will return for a Baseline Visit within sixty (60) days after receiving confirmation of meeting final study cohort criteria from the CGA"*.

To clarify, participants who enroll into the study cohort will return to the clinic within sixty (60) days of the Screening Visit date to start the Baseline Visit. Therefore, Page 13, Protocol Overview/Synopsis, Page 16, Schedule of Study Visits and Procedures: Vision Cohort 1 & Vision Cohort 2, and Page 17, Schedule of Study Visits and Procedures: Vision Cohort 3 will be amended to indicate that ***"Participants meeting criteria to enter the natural history study will return for a Baseline Visit within sixty (60) days after receiving confirmation of meeting final study cohort criteria from the CGA"***.

If this protocol requires substantial changes in the future, the administrative changes described in this letter will be incorporated into the amended protocol.

Please inform your institutional review board/independent ethics committee of these changes, as required.

If you have any questions, please feel free to contact me via email at aayala@jaeb.org.

Sincerely,

Allison Ayala, MS
GYROS Project Director