

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, October 20, 2025
Time: 2:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Ballad Health, Johnson City, TN
Principal Investigator: Kyle T. Colvett, MD
Protocol: MeiraGTx, LLC, MGT-AQP1-201
NCT Number: NCT05926765
Meeting Type: Initial Review of Protocol and Site
Title: A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of AAV2-hAQP1 Gene Therapy in Participants with Radiation-Induced Late Xerostomia

1. Call to order:

The Meeting was called to order at 2:06 pm Eastern 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for AAV2-hAQP1, since it consists of an AAV vector administered by injection in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of AAV2-hAQP1 locally**, provided that other biosafety criteria for study closure are also met.

8. 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

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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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 Institutional Representative confirmed that a sharps container is located inside the biological safety cabinet (BSC) during study agent preparation. The Committee recommended that site documents be revised accordingly.
2. The Committee recommended that photos of the following be provided to IBC Services:
 - a. A photo of the durable, leak-proof internal transport container labeled with a biohazard symbol.
 - b. A representative photo of the prefilled disposable eyewash bottles available in the preparation and dosing areas.
3. The Committee noted that the provided shipping training certificate is a "Certificate of Attendance" and recommended that the "Record of Training" portion of the document, which reflects the regulations covered and the date of expiration, be provided to IBC Services.
4. The Committee recommended that a "No Food or Drink" sign be posted on the study agent storage unit.
5. The Institutional Representative confirmed that there is no door between the anteroom and the preparation room and that staff can easily access the handwashing sink in the anteroom.
6. The Committee noted that safety needles will be recapped by engaging the safety mechanism.
7. The Committee recommended that Material Safety Data Sheets (MSDS) be referred to as Safety Data Sheets (SDS) in keeping with the Globally Harmonized System.

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 2:26 pm Eastern Time.