

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, March 17, 2026
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Allegheny Health Network Research Institute, Pittsburgh, PA
Principal Investigator: Warren C. Swegal, MD
Protocol: MeiraGTx, LLC, MGT-AQP1-201
NCT Number: NCT05926765
Meeting Type: Continuing 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 1:00 pm Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Three voting members were present, including one local member unaffiliated with the institution. Also present were three Institutional Representatives 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:

An 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: 3 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.

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 AAV2-hAQP1, 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 AAV2-hAQP1 locally**, provided that other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 3 NO: 0 ABSTAIN: 0

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. The Committee had no questions or concerns about the facilities and practices.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 3

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:08 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol Version 5.0, dated 05-06-2025

Investigator's Brochure, Version 7.0, dated 04-11-2025

Pharmacy Manual, Version 8.0, dated 12-01-2025

Research Modification Evaluation, Protocol Version 5.0

Research Modification Evaluation, Investigator's Brochure, Version 7.0

Research Modification Evaluation, Pharmacy Manual, Version 8.0

Research Modification Evaluation, Pharmacy Manual, Version 7.0

Biological Risk Assessment and Summary, updated 02-05-2026

Research Modification Evaluation, Additional Dosing Room, dated 04-04-2025

Site Maps, AH Cancer Center and Hospital Pharmacy, AGH, dated 02-13-2024

Site Map, AGH, SouthTower, 3rd Floor, dated 03-27-2025

Site Map, Allegheny General Hospital Loading Dock, dated 02-14-2024

Site Inspection Checklist, Allegheny General Hospital (AGH), expires 01-09-2027, updated 05-27-2025

Photos, AHN Cancer Institute and AGH, dated 02-14-2024

Photos, AGH, SouthTower, 3rd Floor, dated 03-27-2025

Biohazard Sign for AAV2-hAQP1, dated 03-10-2026

Biological Safety Cabinet Certifications, 132251 & 132252, AGCI, dated 12-12-2025

SOP, Biosafety for AAV2-hAQP1, dated 05-27-2025

Training, Shipping Certifications, AGH, expires 03-2026, 04-10-2026

CRRF, dated 02-03-2026

Prior Meeting Minutes, Continuing, dated 02-25-2025