

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, October 8, 2025
Time: 9:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: Laila A. Gharzai, MD, LLM
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 9:21 am Central Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution, and the Institution's Biosafety Officer. Also present were six 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: 6 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

Point of Discussion:

1. An Institutional Representative confirmed that Cohort 2 is currently enrolling at the site.

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.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6 NO: 0 ABSTAIN: 0

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 Committee recommended that Biosafety SOP Section 5.7.4 be revised to indicate that concentrated bleach will be added to the post-dosing suction containers such that the final concentration of bleach is approximately 10%.
2. The Committee discussed the Biological Risk Assessment and Summary which indicates that betadine or other effective disinfecting agent should be added to the post-dosing suction containers and questioned whether betadine was effective against non-enveloped viruses. The Biosafety Officer confirmed that betadine is effective against non-enveloped viruses.
3. The Committee noted that per the vendor, a sharps container cannot be connected under the Bioquell Compounding Aseptic Containment Isolator (CACI) as indicated in site documents. An Institutional Representative confirmed that sharps are safely recapped, removed through the rapid transfer port, and then disposed of into a sharps container. The Committee determined this to be acceptable.
4. The Committee recommended that sharps containers stored on the floor be placed inside a stand to minimize the risk of them being tipped over since they tend to be top-heavy.
5. The Committee recommended that handwashing sinks be kept clear of extraneous items to minimize the potential for them to become contaminated.
6. The Committee recommended that the absorbent towels located on the countertop near the sink, as shown in [REDACTED], be replaced routinely.
7. The Committee recommended that clean supplies not be stored in the open space under the countertop next to the sink, as shown in the [REDACTED].
8. The Biosafety Officer confirmed that study staff are reminded to replace cloth chairs when feasible and that at a minimum, cloth chairs are removed from the dosing rooms prior to subject dosing.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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: 6 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:42 am Central Time.