

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, August 1, 2025
Time: 12:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Henry Ford Health, Detroit, MI
Principal Investigator: Samantha Tam, MD, FRCSC, MPH
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 12:01 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 were five 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 could not confirm that a notice of the meeting was publicly posted. The Committee recommended that notice of the meeting be publicly posted for one week from today and that any questions or comments received be forwarded to IBC Services.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 5 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.

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 being administered 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: 5 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.

Points of Discussion:

1. The Committee recommended that the study agent-specific Biohazard Sign be revised to remove the dosing location or updated to list all possible dosing locations.
2. The Committee recommended that a photo of the biohazardous waste container in the [REDACTED] be provided to IBC Services.
3. An Institutional Representative confirmed that the biological safety cabinet (BSC) was certified in May 2025. The Committee recommended that the updated certification report be provided to IBC Services.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 12:13 pm Eastern Time.