

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, February 2, 2026
Time: 1:00 pm Central Time
Location: Zoom Teleconference
Institution: Ellis Fischel Cancer Center - University of Missouri, Columbia, MO
Principal Investigator: Patrick Tassone, MD, MSAM, FACS
Protocol: MeiraGTx, LLC, MGT-AQP1-202
NCT Number: NCT06544798
Meeting Type: Continuing Review of Protocol and Site
Title: Long-term Follow-up of AAV2-hAQP1 Gene Therapy in Participants with Radiation-Induced Late Xerostomia

1. Call to order:

The Meeting was called to order at 1:18 pm Central Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four voting members were present, including one local member 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:

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: 4 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 being 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: 4 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 Biosafety SOP Section 3.3 be revised to indicate that needles will be recapped by engaging the safety mechanism or the one-handed scoop method, removed, and disposed of into a sharps container.
2. The Institutional Representative confirmed that the biohazard symbols on posted biohazard signs are printed in orange, as shown in site photos. The Committee recommended that photos of the posted signage at the entrance to all study agent handling areas, including preparation and dosing rooms, be provided to IBC Services.
3. The Institutional Representative confirmed the following, regarding waste:
 - Red containers, labelled with biohazard symbols, are used for biohazardous waste
 - Yellow containers, labelled with biohazard symbols, are used for chemotherapy waste
 - Un-labelled, black containers are used for general waste
4. The Committee also recommended that photos of both sharps and non-sharps red biohazardous waste containers, labelled with biohazard symbols, be provided to IBC Services.
5. The Institutional Representative confirmed that the Biological Safety Cabinets (BSCs) used for study agent preparation were recently re-certified. The Committee recommended that the most recent BSC certifications be provided to IBC Services.
6. The Institutional Representative confirmed that a small sharps container is placed inside the BSC during study agent preparation.
7. The Institutional Representative confirmed that disposable eyewash bottles are available in the dosing rooms.
8. The Institutional Representative confirmed that in the event of an eye exposure disposable eyewash bottles will be used first and then the individual will be escorted to the closest plumbed eyewash as written in section 5.2.4 of the Biosafety SOP.

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: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:21 pm Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 3.0, dated 07-02-2025

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

Pharmacy Manual, Version 1.0, dated 05-31-2024

Research Modification Evaluation, Protocol, Version 3.0

Research Modification Evaluation, Investigator's Brochure, Version 7.0

Biological Risk Assessment and Summary, updated 09-22-2025

Site Maps, dated 03-19-2025

Site Map, PCT Ground Pharmacy, dated 01-12-2026

MeiraGTx, LLC/MGT-AQP1-202/Tassone/2/2/2026/Continuing Review

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Site Inspection Checklist, expires 11-21-2026, updated 01-20-2026

Photos, dated 01-21-2026

Biohazard Sign, for AAV2-hAQP1, dated 10-26-2023

Biological Safety Cabinet Certifications, AIU Pharmacy, expired 12-2025

Biological Safety Cabinet Certifications, PCT Ground Pharmacy, expired 12-2025

SOP, Biosafety for AAV2-hAQP1, dated 01-08-2026

Training, Shipping Certifications, expire 2026 and 2027

CRRF, dated 01-07-2026

Prior Meeting Minutes, Initial, dated 04-25-2025