

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, December 16, 2025
Time: 10:00 am Eastern Time
Location: Zoom Teleconference
Institution: University of North Carolina at Chapel Hill, Chapel Hill, NC
Principal Investigator: Xuguang Chen, 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 10:02 am Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Seven voting members were present, including three local members unaffiliated with the institution and the Institution's Associate Biosafety Officer. 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: 7 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: 7 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 current biological safety cabinet (BSC) certification reports for the cabinets located in the [REDACTED] and the [REDACTED] be provided to IBC Services.
2. The Committee recommended that the verbiage on slide 6 of the [REDACTED] Photos read "Per pharmacy, study agent syringes are capped with a red cap or phaseal."
3. The Committee noted that there appear to be ten BSCs in the [REDACTED] but that only seven BSC certification reports are available. The Committee recommended that the Institution confirm that only seven BSCs are used for study agent preparation in the [REDACTED] and that the Site Map accurately reflects the location of the BSCs that are used.
4. The Committee recommended that the Institution confirm the sink location in the [REDACTED] of the [REDACTED] and revise the Site Map as needed.
5. The Committee discussed the BSC located in the "[REDACTED]" room in the [REDACTED] and noted that there is no sink in the room or in an immediately adjacent room. The Committee recommended that the Institution confirm that the sink in the [REDACTED] would be used for handwashing after exiting this room and that hand sanitizer would be used prior to exiting the room.

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: 7

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:18 am Eastern Time.