

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, December 29, 2025
Time: 1:00 pm Arizona Time
Location: Zoom Teleconference
Institution: Medical Research of Arizona, Scottsdale, AZ
Principal Investigator: Michael E. Manning, MD
Protocol: Intellia Therapeutics, Inc., ITL-2002-CL-301
NCT Number: NCT06634420
Meeting Type: Continuing Review of Protocol and Site
Title: HAELO: A Phase 3, Multinational, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of NTLA-2002 in Participants With Hereditary Angioedema (HAE)

1. Call to order:

The Meeting was called to order at 1:00 pm Arizona 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 two 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: 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 noted changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for NTLA-2002 since it consists of a gene editing product administered directly to subjects which can permanently modify the cellular genome within the body. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **6 months after the last subject's last dose of NTLA-2002 locally**, provided that all biosafety criteria for study closure are 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. An Institutional Representative confirmed that reusable gowns used as personal protective equipment (PPE) are laundered through a medical-grade laundry facility.
2. An Institutional Representative confirmed that disposable gowns are also available at the site.

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 1:09 pm Arizona Time.