

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, October 13, 2025
Time: 12:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Bernstein Clinical Research Center, LLC, Cincinnati, OH
Principal Investigator: Jonathan Bernstein, 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 12:00 pm Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Three 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:

The 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: 3 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-2 containment facilities and practices** are required for NTLA-2002 since it consists of a CRISPR/Cas-based gene editing product that can permanently modify cellular genomes. 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: 3 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 Institutional Representative confirmed that there is a sink for handwashing in the preparation room. The Committee recommended that site documents be revised accordingly.
2. The Institutional Representative confirmed that biohazardous waste containers are available in the preparation and dosing rooms during study agent handling activities. The Committee recommended that a representative photo of the biohazardous waste container be submitted to IBC Services.
3. The Institutional Representative confirmed that an insect and rodent control program is in place for the exterior of the building and managed by the building owner and that there is a company that will provide service if pests are noted inside the building. The Committee recommended that the Site Inspection Checklist be revised to indicate that an insect and rodent control program is in effect and that the comments be updated to include the details related to the exterior pest control.
4. The Institutional Representative confirmed that the study agent storage unit is labeled with a biohazard symbol and that the study agent-specific Biohazard Sign is posted on the door to the preparation room and on the door at the end of the shared hallway during study agent handling activities.
5. The Institutional Representative confirmed that both subjects dosed to date have elected to receive the second administration of blinded study intervention.

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: 3

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

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