

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, December 22, 2025  
**Time:** 9:00 am Mountain Time  
**Location:** Zoom Teleconference  
**Institution:** Asthma and Allergy Associates, PC, Colorado Springs, CO  
**Principal Investigator:** Daniel F. Soteres, MD, MS, MPH  
**Protocol:** Intellia Therapeutics, Inc., ITL-2002-CL-301  
**NCT Number:** NCT06634420  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** HAEL0: 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 9:00 am Mountain 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 the Principal Investigator, 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: 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-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: 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 the study agent storage unit be labeled with a biohazard symbol.
2. The Committee recommended that a plastic mat be placed under the study agent storage unit.
3. The Institutional Representative confirmed that the prefilled disposable eyewash bottles are not expired.

### **11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Principal Investigator and 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 9:13 am Mountain Time.

### **15. Post-meeting notes:** None.

#### **Documents reviewed:**

Agenda

Protocol, Version 2.0, dated 12-09-2024

Investigator's Brochure, Edition 4.0, dated 07-17-2024

Pharmacy Manual, Version 3.0, dated 05-20-2025

Research Modification Evaluation, Protocol, Version 2.0

Research Modification Evaluation, Pharmacy Manual, Version 2.0

Research Modification Evaluation, Pharmacy Manual, Version 3.0

Biological Risk Assessment and Summary, updated 06-13-2025

Research Modification Evaluation, Change in Storage Location, dated 06-18-2025

Site Map, dated 11-21-2025

Site Inspection Checklist, expires 9-25-2026, updated 06-17-2025

Photos, Asthma and Allergy Associates, dated 12-17-2025

Biohazard Sign, BSL-2, dated 09-26-2024

SOP Biosafety for NTLA-2002, dated 09-18-2025

Training, Shipping Certificate, expires 04-17-2026

CRRF, dated 07-31-2025

Prior Meeting Minutes, Initial, dated 11-19-2024