

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Thursday, February 12, 2026  
**Time:** 9:00 am Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** OhioHealth Research Institute, Columbus, OH  
**Principal Investigator:** Naveen Saha, MD  
**Protocol:** Intellia Therapeutics, Inc., ITL-2001-CL-301  
**NCT Number:** NCT06128629  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A phase 3, multinational, multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of NTLA-2001 in participants with Transthyretin Amyloidosis with Cardiomyopathy (ATTR-CM)

### 1. Call to order:

The Meeting was called to order at 9:24 am Eastern 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 were eight 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: 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-2001 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 **3 months after the last subject's last dose of NTLA-2001 locally**, provided that all 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 discussed that Biosafety SOP Section 5.1.4b. discusses how large spills will be handled but that Section 5.1.8 indicates that Environmental Services (EVS) will be called to handle large spills.
2. An Institutional Representative confirmed that spills greater than 1mL but less than 25mL would be handled as referenced in Biosafety SOP Section 5.1.4b. but that EVS will be called for spills greater than 25mL.
3. The Committee discussed whether spills greater than 25mL would be decontaminated by a trained study staff member as indicated in Biosafety SOP Sections 5.1.8 and 5.1.9 or by EVS. An Institutional Representative confirmed that a trained study staff member would be available to provide guidance to EVS regarding how to decontaminate the spill.
4. The Committee recommended that Biosafety SOP Section 5.1.4c. be added to describe the procedures for handling spills greater than 25mL and that this section incorporate information currently found in Biosafety SOP Sections 5.1.8 and 5.1.9.
5. The Committee recommended that Biosafety SOP Section 5.1.4b.ii be revised to indicate that spills will be treated with bleach to achieve a final concentration of 10%.
6. The Committee recommended that Site Inspection Checklist, Item #19 be revised to include bleach.

### **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: 4

NO: 0

ABSTAIN: 0

### **13. Advice to the Institution:** None.

### **14. Meeting adjourned:** The meeting was adjourned at 9:36 am Eastern Time.

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

#### **Documents reviewed:**

Agenda

Protocol, Version 5.0, dated 08-19-2025

Investigator's Brochure, Edition 9, dated 07-31-2025

Pharmacy Manual, Version 3.0, dated 06-27-2024

Research Modification Evaluation, Protocol, Version 5.0

Research Modification Evaluation, Investigator's Brochure, Edition 9

Biological Risk Assessment and Summary, updated 11-10-2025

Site Maps, dated 01-15-2025

Site Map, Outpatient Bing Suite A4, Infusion Rooms 1-17, ABCC , dated 01-15-2025

Site Inspection Checklist, expires 10-20-2027, dated 11-20-2025

Photos, dated 10-27-2025

Biohazard Sign, dated 01-16-2025

Biological Safety Cabinet Certifications, expire 05-31-2026

SOP, Biosafety for NTLA-2001, dated 02-05-2026

Training, Shipping Certification, expires 10-04-2026

CRRF, dated 11-04-2025

Prior Meeting Minutes, Initial, dated 02-05-2025