

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Wednesday, October 8, 2025  
**Time:** 9:00 am Central Time  
**Location:** Zoom Teleconference  
**Institution:** Northwestern University, Chicago, IL  
**Principal Investigator:** George Georges, MD  
**Protocol:** Novartis Research and Development, CYTB323L12201  
**NCT Number:** NCT06665256  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase 2, randomized, open-label, controlled study to evaluate the efficacy and safety of rapcabtagene autoleucl versus comparator in participants with severe refractory idiopathic inflammatory myopathies

### 1. Call to order:

The Meeting was called to order at 9:16 am Central Time.

### 2. Introductions and orientation:

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

### 3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution, and the Institution's Biosafety Officer. Also present were six 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: 6                      NO: 0                      ABSTAIN: 0

### Point of Discussion:

1. The Committee recommended that the Prior Meeting Minutes, Points of Discussion Item #2 be revised to read "The Committee noted that [REDACTED] requires monitoring of oxygen levels and recommended that the Biosafety Officer ask staff why this area is noted as such since there are additional OSHA requirements that must be met for rooms like this."

### 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 YTB323 (rapcabtagene autoleucl), since it consists of autologous T cells modified by a lentiviral vector. 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 YTB323 (rapcabtagene autoleucl) locally**, provided all other criteria for study closure are met. The Committee reaffirmed this determination.

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### **9. Vote on the Protocol:**

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6                      NO: 0                      ABSTAIN: 0

### **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 Site Inspection Checklist #19 be revised to add Micro-Kill One Germicidal Wipes and Sani-Cloth Prime Wipes.
2. The Committee noted that the biological safety cabinets (BSCs) are due for recertification in October 2025 and recommended that the vendor indicate on the new certification reports that the BSCs are recertified every 6 months rather than annually.

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

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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: 6                      NO: 0                      ABSTAIN: 0

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

### **14. Meeting adjourned:** The meeting was adjourned at 9:21 am Central Time.