

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Tuesday, December 30, 2025  
**Time:** 8:00 am Pacific Time  
**Location:** Zoom Teleconference  
**Institution:** Swedish Health Services, Seattle, WA  
**Principal Investigator:** Christyn Edmundson, MD  
**Protocol:** Cabaletta Bio Inc., CAB-201-004  
**NCT Number:** NCT06359041  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase 1/2, Open-Label Study to Evaluate the Safety and Efficacy of Autologous CD19-specific Chimeric Antigen Receptor T cells (CABA-201) in Participants with Generalized Myasthenia Gravis

### 1. Call to order:

The Meeting was called to order at 8:15 am Pacific 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 five 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 CABA-201 since it consists of human cells modified with 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 CABA-201 locally**, provided all other 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

## INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

### **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 agreed to confirm if the [REDACTED] is locked since this room is located in an area not restricted to the public. If this room is not locked, the Committee recommended that a lock be installed on this door to ensure this area is restricted to only staff members.
2. The Committee recommended that Biosafety SOP for Genetically Modified Human Cells Section 5.1 be revised to add another subsection noting how soiled linens will be disposed of in the event of a spill (e.g., In the event of a spill on bed linens, contaminated soiled linens will be disposed of into a biohazardous waste container).
3. The Committee recommended that the Institution clarify if the Principal Investigator's phone number on the Biohazard Sign is a "24/7" number.

### **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 8:20 am Pacific Time.

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