

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: Cabaletta Bio Inc., CAB-201-002
NCT Number: NCT06154252
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 Subjects with Active Idiopathic Inflammatory Myopathy or Active Juvenile Idiopathic Inflammatory Myopathy

1. Call to order:

The Meeting was called to order at 9:11 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 MCCT Room 7-613 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 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.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 9:16 am Central Time.

15. Post-meeting notes: The IBC Chair revised the Prior Meeting Minutes per the Committee's recommendation.

Documents reviewed:

Agenda

Protocol, Version 4.1, dated 08-06-2025

Investigator's Brochure, Edition 2.0, dated 07-24-2025

Drug Product Manual, Version 7.0, dated 07-31-2025

Research Modification Evaluation, Protocol, Version 4.0

Research Modification Evaluation, Protocol, Version 4.1

Research Modification Evaluation, Investigator's Brochure, Edition 1.0

Research Modification Evaluation, Investigator's Brochure, Edition 2.0

Research Modification Evaluation, Leukapheresis and Drug Product Manual, Version 5.0

Research Modification Evaluation, Leukapheresis and Drug Product Manual, Version 6.0

Research Modification Evaluation, Drug Product Manual, Version 7.0

Biological Risk Assessment and Summary, updated 08-21-2025

Site Map, Olson, 7th Floor, MCCT, Rooms 7-424, dated 02-27-2025

Site Map, Olson, 7th Floor, MCCT, Room 7-613, dated 02-19-2024

Site Map, Prentice, 16th Floor, dated 04-12-2024

Site Map, Olson, 1st Floor, dated 03-12-2025

Site Map, Feinberg and Olson Loading Docks, received 10-16-2018

Site Inspection Checklist, Cell Therapies, expires 03-05-2027, updated 08-12-2025

Photos, Prentice Hospital, dated 04-12-2024

Photos, Olson Pavilion, MCCT, dated 06-05-2025

Photos, Olson Pavilion, Dosing, dated 11-26-2024

Photos, Feinberg and Olson Loading Dock, dated 03-05-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

Biohazard Sign, Olson MCCT, dated 08-12-2025

Biohazard Sign, Prentice and Olson, dated 08-12-2025

Biological Safety Cabinet Certifications, Olson MCCT, expires 10-2025

SOP, Biosafety for Genetically Modified Human Cells, dated 03-17-2025

SOP Addendum, Biosafety for Autologous Cells, dated 08-12-2025

Training, Shipping Certification, expires 06-05-2027

CRRF, dated 06-02-2025

Prior Meeting Minutes, Continuing, dated 09-23-2024