

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, April 27, 2026  
**Time:** 9:00 am Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Hackensack Meridian Health, Hackensack, NJ  
**Principal Investigator:** Michele Donato, MD  
**Protocol:** TScan Therapeutics, Inc., TSCAN-001  
**NCT Number:** NCT05473910  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase 1/3 Study Evaluating the Efficacy and Safety of T-Cell Receptor Engineered Donor T Cells in Subjects Undergoing Allogeneic Peripheral Blood Stem Cell Transplantation (ALLOHA™)

### 1. Call to order:

**The Meeting** was called to order at 9:00 am Eastern 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 three 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:

The Biosafety Officer 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

### 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 TSC-100 and TSC-101 since they consist of genetically modified allogeneic donor T-cells. 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 TSC-100 and TSC-101 locally**, provided that other 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: 6 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 the Biosafety Guidelines, Addendum for Allogenic Cells Section 2.2. be revised to add a Dose Modification subsection for this study agent that indicates that the Sponsor will provide instructions for a dose modification if a partial dose is required.
2. The Committee noted that Shipping Training Certification will expire for a member of the study staff in May 2026 and recommended that an updated certificate be provided to IBC Services once the training is renewed.
3. The Committee noted that the Continuing Review Report Form (CRRF) section F is marked "yes" due to the Change in Principal Investigator from Dr. Suh to Dr. Donato.
4. The Committee discussed that the study agent must be dosed within 45 minutes of thawing and that study staff should be informed of this requirement through Sponsor documentation.

### **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 9:13 am Eastern Time.

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

#### **Documents reviewed:**

Agenda

Protocol, Amendment 6, dated 12-16-2025

Investigator's Brochure, TSC-100, Edition 3.0, dated 03-07-2025

Investigator's Brochure, TSC-101, Edition 4.0, dated 07-17-2025

Pharmacy Manual, Version 5, dated 01-12-2026

Research Modification Evaluation, Protocol, Amendment 6

Research Modification Evaluation, TSC-100, Investigator's Brochure, Edition 3.0

Research Modification Evaluation, TSC-101, Investigator's Brochure, Edition 4.0

Research Modification Evaluation, Pharmacy Manual, Version 5

Research Modification Evaluation, Pharmacy Manual, Version 4

Biological Risk Assessment and Summary, updated 01-14-2026

Research Modification Evaluation, PI Change, dated 06-12-2025

Site Maps, Genetically Modified Human Cells, updated 11-19-2025

Site Inspection Checklist, Genetically Modified Human Cells, expires 08-19-2026, updated 03-26-2026

Biohazard Sign, Donato, dated 11-13-2025

Biosafety Guidelines for Genetically Modified Human Cells, dated 12-11-2025

Biosafety Guidelines, Addendum for Allogeneic Cells, dated 04-28-2025

Training, Shipping Certifications, expire 05-2026, 10-2026, 11-2026, 12-2026, 2027

CV, Donato, M., dated 01-08-2024

CRRF, revised 04-23-2026

Prior Meeting Minutes, Continuing, dated 04-25-2025

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, April 27, 2026  
**Time:** 9:00 am Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Hackensack Meridian Health, Hackensack, NJ  
**Principal Investigator:** David S. Siegel, MD, PhD  
**Protocol:** Caribou Biosciences, Inc., CB11A  
**NCT Number:** NCT05722418  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase 1, Multicenter, Open-Label Study of CB-011, a CRISPR-Edited Allogeneic anti-BCMA CAR-T Cell Therapy in Patients with Relapsed/Refractory Multiple Myeloma (CaMMouflage Trial)

### **1. Call to order:**

The Meeting was called to order at 9:13 am Eastern 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 three 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:**

The Biosafety Officer 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 Chair confirmed that no response to the previous IBC Letter of Advice to the Sponsor was received.

### **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 CB-011 since it consists of primary human cells modified using an adeno-associated viral (AAV) vector and a chRDNA Cas12 complex. 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 CB-011 locally**, provided that all biosafety criteria for study closure are also 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 the Biosafety Guidelines, Addendum for Allogenic Cells Section 2.2.1 be revised to remove this study agent as a dose modification is always required.
2. The Committee noted that Shipping Training Certification will expire for a member of the study staff in May 2026 and recommended that an updated certificate be provided to IBC Services once the training is renewed.
3. The Committee noted that the biological safety cabinets (BSCs) are due to be recertified next month and recommended that the updated certification reports be provided to IBC Services once they are available.
4. The Committee discussed the differences between the dose modification and dose preparation steps for this study agent listed in Biosafety Guidelines, Addendum for Allogenic Cells Sections 2.2.2 and 2.2.3 noting that for dose modification, the volume in the syringe is discarded and for dose preparation, the volume in the syringe is used for dosing.

### **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 9:20 am Eastern Time.

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

#### **Documents reviewed:**

Agenda

Protocol, Amendment 2, dated 05-08-2025

Investigator's Brochure, Version 5.0, dated 02-11-2026

Pharmacy Manual, Version 6.0, dated 07-15-2025

Research Modification Evaluation, Protocol, Amendment 2

Research Modification Evaluation, Investigator's Brochure, Version 4.0

Research Modification Evaluation, Investigator's Brochure, Version 5.0

Research Modification Evaluation, Pharmacy Manual, Version 3.0

Research Modification Evaluation, Pharmacy Manual, Version 4.0

Research Modification Evaluation, Pharmacy Manual, Version 6.0

Biological Risk Assessment and Summary, updated 04-17-2026

Site Maps, Genetically Modified Human Cells, updated 11-19-2025

Site Inspection Checklist, Genetically Modified Human Cells, expires 08-19-2026, updated 03-26-2026

Biohazard Sign, Siegel, dated 03-26-2026

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Biological Safety Cabinet Certifications, CTMF, expire 05-31-2026  
Biosafety Guidelines for Genetically Modified Human Cells, dated 12-11-2025  
Biosafety Guidelines, Addendum for Allogeneic Cells, dated 04-28-2025  
Training, Shipping Certifications, expire 05-2026, 10-2026, 11-2026, 12-2026, 2027  
CRRF, dated 04-01-2026  
Prior Meeting Minutes, Continuing, dated 04-25-2025

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, April 27, 2026  
**Time:** 9:00 am Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Hackensack Meridian Health, Hackensack, NJ  
**Principal Investigator:** Martin Gutierrez, MD  
**Protocol:** Legend Biotech USA, Inc., LB1908-1001  
**NCT Number:** NCT05539430  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A phase 1, open-label, dose escalation and expansion, multicenter study of Claudin 18.2-Targeted Chimeric Antigen Receptor T-cells in subjects with unresectable, locally advanced, or metastatic gastric, gastroesophageal junction (GEJ), esophageal, or pancreatic adenocarcinoma.

### 1. Call to order:

The Meeting was called to order at 9:21 am Eastern 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 three 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:

The Biosafety Officer 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

### 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 LB1908, since it consists of genetically modified primary human cells. 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 LB1908 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: 6 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.

#### **Point of Discussion:**

1. The Committee noted that Shipping Training Certification will expire for a member of the study staff in May 2026 and recommended that an updated certificate be provided to IBC Services once the training is renewed.

### **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 9:25 am Eastern Time.

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

#### **Documents reviewed:**

Agenda

Protocol, Version 5.0, dated 04-02-2025

Investigator's Brochure, Edition 4, dated 07-25-2025

Investigational Product Preparation and Administration Instructions, Version 3.0, dated 03-02-2023

Research Modification Evaluation, Protocol, Version 5.0

Research Modification Evaluation, Investigator's Brochure, Edition 4

Biological Risk Assessment and Summary, updated 01-05-2026

Site Maps, Genetically Modified Human Cells, updated 11-19-2025

Site Inspection Checklist, Genetically Modified Human Cells, expires 08-19-2026, updated 03-26-2026

Biohazard Sign, Gutierrez, BSL2, dated 03-26-2026

Biosafety Guidelines for Genetically Modified Human Cells, dated 12-11-2025

Biosafety Guidelines, Addendum for Autologous Cells, dated 03-26-2026

Training, Shipping Certifications, expire 05-2026, 10-2026, 11-2026, 12-2026, 2027

CRRF, dated 03-27-2026

Prior Meeting Minutes, Continuing, dated 04-28-2025