

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Thursday, May 21, 2026  
**Time:** 9:00 am Central Time  
**Location:** Zoom Teleconference  
**Institution:** Northwestern University, Chicago, IL  
**Principal Investigator:** Reem Karmali, MD, MS  
**Protocol:** Celgene Corporation, JCAR017-FOL-001  
**NCT Number:** NCT04245839  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase 2, Open-label, Single-arm, Multicohort, Multicenter Trial to Evaluate the Efficacy and Safety of JCAR017 in Adult Subjects with Relapsed or Refractory Indolent B-cell Non-Hodgkin Lymphoma (NHL)

### 1. Call to order:

The Meeting was called to order at 9:18 am Central Time.

### 2. Introductions and orientation:

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

### 3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were four 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: 5                      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 JCAR017, 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 JCAR017 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: 5                      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.

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

1. The Biosafety Officer confirmed that biohazardous waste generated in studies under IBC review is disposed of in the red biohazardous waste containers available in the Olson Pavilion dosing areas.

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

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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: 5

NO: 0

ABSTAIN: 0

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

### **14. Meeting adjourned:** The meeting was adjourned at 9:22 am Central Time.

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

#### **Documents reviewed:**

Agenda

Protocol, Amendment 4.0, dated 10-11-2024

Protocol Administrative Letter, dated 04-03-2025

Investigator's Brochure, Version 13, dated 02-04-2026

Global Product Administration Manual, Version 1.0, dated 10-31-2025

Research Modification Evaluation, Protocol Administrative Letter, dated 04-03-2025

Research Modification Evaluation, Investigator's Brochure, Version 13

Research Modification Evaluation, Global Product Administration Manual, Version 1.0 (dated 10-31-2025)

Biological Risk Assessment and Summary, updated 02-17-2026

Site Map, Olson, 1st Floor, dated 01-23-2026

Site Map, Prentice, 5th Floor, Rube Walker Blood Center, dated 03-07-2023

Site Map, Olson, 7th Floor, MCCT, Room 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 Inspection Checklist, Cell Therapies, expires 03-05-2027, updated 02-20-2026

Photos, Olson Pavilion, Dosing, dated 05-01-2025

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

Photos, Prentice Hospital, dated 04-25-2025

Photos, Feinberg and Olson Loading Dock, dated 03-25-2026

Biohazard Sign, Prentice and Olson, dated 04-01-2026

Biohazard Sign, Olson MCCT, dated 02-20-2026

Biological Safety Cabinet Certifications, Olson MCCT, expires 09-2026

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

SOP Addendum, Biosafety for Autologous Cells, dated 02-20-2026

Training, Shipping Certification, expires 06-05-2027

CRRF, dated 02-02-2026

Prior Meeting Minutes, Continuing, dated 05-28-2025