

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Thursday, July 3, 2025  
**Time:** 9:00 am Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Northside Hospital, Atlanta, GA  
**Principal Investigator:** Lizamarie Bachier-Rodriguez, MD  
**Protocol:** Janssen Research and Development, 68284528MMY4006  
**NCT Number:** NCT05346835  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** Intermediate-Size Population Expanded Access Program (EAP) for Ciltacabtagene autoleucl (cilta-cel) Out-of-Specification (OOS) in patients with Multiple Myeloma.

### 1. Call to order:

The Meeting was called to order at 9:20 am Eastern 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 two 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 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 JNJ68284528, 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 JNJ-68284528 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: 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.

#### **Points of Discussion:**

1. Although a Biological Safety Cabinet (BSC) is not used to prepare the study agent, the Committee noted that the BSCs were due to be recertified. An Institutional Representative confirmed that this has been done and agreed to forward the newer BSC Certifications to IBC Services.
2. An Institutional Representative confirmed that used personal protective equipment (PPE) is disposed of into an appropriate container. The Committee recommended that the Institution confirm the specific type of container used and the Main Biosafety SOP Section 4 be updated accordingly.
3. The Committee recommended that the following language be added to the Main Biosafety SOP Section 5.2.4, "If a plumbed eyewash is not readily available, immediately start rinsing the affected eye using a prefilled disposable eyewash bottle, and escort the exposed individual to the closest eyewash station."
4. An Institutional Representative confirmed that the Institution's policy for flushing eyes in the event of an exposure is 15 minutes. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to include the amount of time an eye must be flushed (15 minutes).

### **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: 5

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 4.0, dated 09-30-2024

Investigator's Brochure, Edition 10, dated 04-15-2025

Carvytki Prescribing Information, dated 04-01-2024

Research Modification Evaluation, Protocol, Version 4.0

Research Modification Evaluation, Investigator's Brochure, Edition 9

Research Modification Evaluation, Investigator's Brochure, Edition 9, Addendum 1

Research Modification Evaluation, Investigator's Brochure, Edition 10

Research Modification Evaluation, Carvytki Prescribing Information

Biological Risk Assessment and Summary, updated 06-02-2025

Site Map, BMT Unit, 4th Floor, dated 01-29-2024

Site Map, HSC Laboratory, dated 01-29-2024

Site Inspection Checklist, GMHC, expires 02-10-2027, updated 06-11-2025

Site Inspection Checklist, Autoclave Addendum, dated 02-11-2025, updated 02-24-2025

Photos, HSC Lab, BMT Unit, dated 02-12-2025

Biohazard Sign, Genetically Modified Human Cells, dated 06-11-2025

Biological Safety Cabinet Certifications, HSC Lab, expires 06-2025

SOP, Biosafety for Genetically Modified Human Cells, dated 06-18-2025

SOP Addendum, Biosafety for Autologous Cells, dated 06-11-2025

Training, Shipping Certification, expires 03-10-2026

CRRF, dated 03-03-2025

Prior Meeting Minutes, Continuing, dated 06-21-2024