

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Wednesday, December 3, 2025  
**Time:** 8:00 am Central Time  
**Location:** Zoom Teleconference  
**Institution:** Northwestern University, Chicago, IL  
**Principal Investigator:** Sunandana Chandra, MD, MS  
**Protocol:** Replimune, Inc., RP1-104  
**NCT Number:** NCT06264180  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Randomized, Controlled, Multicenter, Phase 3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination with Nivolumab Versus Treatment of Physician's Choice in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen (IGNYTE-3)

### 1. Call to order:

The Meeting was called to order at 8:00 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 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:

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

### 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 RP1 since it is based on a recombinant herpes simplex virus-1 administered in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **6 months after the last subject's last dose of RP1 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 that Biosafety SOP Section 5.6 be revised to include priming steps prior to injection of superficial lesions.
2. The Committee recommended that current Biological Safety Cabinet (BSC) and Compounding Aseptic Containment Isolator (CACI) certification reports be submitted to IBC Services when available.
3. The Committee noted that the [REDACTED] indicates that prefilled disposable eyewash bottles are only available in two of the twelve dosing rooms. The Biosafety Officer confirmed that prefilled disposable eyewash bottles are brought into each dosing room during subject dosing.
4. The Committee discussed the Prior Meeting Minutes and the recommendation that site-specific documents be revised to remove references to PAPRs, as they are unnecessary for handling spills of this study agent. The Committee noted that PAPRs are listed as being available on [REDACTED] for a nebulizer-administered study agent and determined this to be acceptable.

### **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: 6

NO: 0

ABSTAIN: 0

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

**14. Meeting adjourned:** The meeting was adjourned at 8:12 am Central Time.