

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, December 1, 2025  
**Time:** 1:00 pm Central Time  
**Location:** Zoom Teleconference  
**Institution:** The West Clinic, Germantown, TN  
**Principal Investigator:** Ari VanderWalde, MD, MPH, FACP  
**Protocol:** Replimune, RPL-001-16  
**NCT Number:** NCT03767348  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** An Open-Label, Multicenter, Phase 1/2 Study of RP1 as a Single Agent and in Combination with PD1 Blockade in Patients with Solid Tumor

### 1. Call to order:

The Meeting was called to order at 1:00 pm Central Time.

### 2. Introductions and orientation:

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

### 3. Declaration of quorum:

Four 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: 4                      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 consists of a recombinant herpes simplex virus-1 strain. 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 RP1 locally**, provided that all 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: 4                      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 photos of Ultrasound Room 1266 and CT Room 1252 be provided to IBC Services.
2. An Institutional Representative confirmed that Clinic Exam Room 2618 has separate waste streams for sharps and non-sharp waste but could not verify which color container corresponds to each. The Committee recommended that the Institution follow-up with IBC Services and update the Photos document to specify which container is for sharps and which is for non-sharp items, such as PPE.

### **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: 4                      NO: 0                      ABSTAIN: 0

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

### **14. Meeting adjourned:** The meeting was adjourned at 1:10 pm Central Time.

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

#### **Documents reviewed:**

Agenda

Protocol, Amendment 12, dated 09-02-2022

Investigator's Brochure, Edition 11.0, dated 10-02-2025

Pharmacy and Administration Manual, Version 5.0, dated 09-29-2022

Intratumoral Injection Manual, Version 2.0, dated 08-30-2022

Post-Injection Instructions, Version 6, dated 09-07-2022

Research Modification Evaluation, Investigator's Brochure, Edition 11.0

Research Modification Evaluation, Investigator's Brochure, Edition 10.0

Biological Risk Assessment and Summary, updated 10-20-2025

Site Map, dated 07-31-2025

Site Inspection Checklist, expires 10-04-2026, updated 07-30-2025

Photos, dated 07-31-2025

Biohazard Sign, RP1 and RP2, dated 03-05-2025

Biological Safety Cabinet Certifications, dated 06-26-2025

SOP, Biosafety for RP1, and RP2, dated 03-05-2025

Training, Shipping Certification, expires 07-18-2027

CRRF, dated 09-04-2025

Prior Meeting Minutes, Continuing, dated 12-27-2024