INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, March 25, 2026**
Time:	1:00 pm Central Time
Location:	Zoom Teleconference
Institution:	The West Clinic, Germantown, TN
Principal Investigator:	**Arnel M. Pallera, MD**
Protocol:	Replimune, Inc., **RP2-202**
NCT Number:	NCT06581406
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Randomized, Phase 2/3, Open-Label Study to Investigate the Efficacy and Safety of RP2 in Combination with Nivolumab versus Ipilimumab in Combination with Nivolumab in Immune Checkpoint Inhibitor-Naïve Adult Patients with Metastatic Uveal Melanoma

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:

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: 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 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 RP2 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 **3 months after the last subject's last dose of RP2 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

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. An Institutional Representative confirmed that no subjects to date have been dosed with the study agent.
2. The Committee recommended that the photo of the Biohazard Sign be removed from the Photos document.
3. An Institutional Representative confirmed that updated photos of Room 2618 will be submitted to IBC Services, documenting the types and locations of hazardous waste containers in the room.
4. The Committee noted that the Biological Safety Cabinet Certifications include a comment stating “Replace Exhaust Airflow Monitor” and recommended that the Institution confirm the monitors have been replaced.

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 1:16 pm Central Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Amendment 1, dated 04-15-2025
Investigator's Brochure, Edition 7, dated 12-17-2025
Pharmacy and Administration Manual, Version 1.0, dated 06-21-2024
Intratumoral Injection Manual, Version 1.0, received 06-20-2024
Instructions For Patients After Injection, RP2, dated 07-09-2024
Research Modification Evaluation, Protocol, Amendment 1
Research Modification Evaluation, Investigator's Brochure, Edition 7
Research Modification Evaluation, Investigator's Brochure, Edition 6
Biological Risk Assessment and Summary, updated 03-03-2026
Site Map, Germantown, dated 07-31-2025
Site Inspection Checklist, expires 10-04-2026, updated 12-02-2025
Photos, Germantown, dated 03-22-2026
Biohazard Sign, RP1 and RP2, dated 03-05-2025
Biological Safety Cabinet Certifications, dated 12-11-2025
SOP, Biosafety for RP1, and RP2, dated 03-11-2026
Training, Shipping Certification, expires 07-18-2027
CRRF, dated 12-03-2025
Prior Meeting Minutes, Initial, dated 03-18-2025