

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, August 8, 2025
Time: 2:00 pm Eastern Time
Location: Zoom Teleconference
Institution: University of Tennessee Medical Center, Knoxville, TN
Principal Investigator: Ardy Davarifar, MD
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 2:00 pm Eastern 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 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: 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 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 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: 4 NO: 0 ABSTAIN: 0

10. Review of proposed facilities and practices:

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

Points of Discussion:

1. An Institutional Representative confirmed that a sharps container is within the Biological Safety Cabinet (BSC) during study agent preparation.
2. The Committee noted that sponsor documents mention priming of the dosing needle and the Committee recommended that the Biosafety SOP be updated to include details about where and how the dosing needle is primed.
3. An Institutional Representative confirmed that BSCs are certified every 6 months and that [REDACTED] are available in the [REDACTED] and [REDACTED] are available in the N [REDACTED].
4. The Committee recommended that the [REDACTED] Site Map be revised to indicate where the hazardous and non-hazardous rooms are located.
5. The Committee noted that the BSC Certification lists different areas of location for the BSCs and an Institutional Representative confirmed that the different areas are actually the same location and the names of these areas are used interchangeably.
6. The Committee recommended that the Institution clarify if full containers of biohazardous waste are stored in the dosing rooms.
7. An Institutional Representative confirmed that black hazardous waste containers are labeled with a biohazard symbol.

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 2:17 pm Eastern Time.