

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, August 13, 2025
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: University of North Carolina at Chapel Hill, Chapel Hill, NC
Principal Investigator: Frances Collichio, 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 1:00 pm Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Seven voting members were present, including two local members unaffiliated with the institution and the institutional Associate Biosafety Officer. Also present were six 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:

Point of Discussion:

1. The Committee noted that "abstain" was spelled incorrectly under the site vote in the Prior Meeting Minutes, dated 06-05-2024.

Minutes Approved - YES: 7 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.

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9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 7

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. The Committee noted the discussion from a previous IBC meeting in which the Sponsor provided subject-facing materials which indicate that used dressings must be placed in a biohazard bag and returned to the clinic. An Institutional Representative was unable to confirm if this is being done or not. The Committee recommended that the Institution confirm with the Sponsor that used dressings must be handled in that manner and follow-up with IBC Services.
2. The Committee recommended that the Site Inspection Checklist (#10) be revised to indicate that any aerosol-generating activities are performed inside of a Biological Safety Cabinet (BSC), if applicable to the protocol.
3. The Committee recommended that biohazard symbols be placed on all biohazardous waste containers and that new photos of the biohazardous waste containers in the [REDACTED] labelled with biohazard symbols, be provided to IBC Services.
4. An Institutional Representative confirmed that the biohazardous waste storage boxes provided by Stericycle are labelled with biohazard symbols (on the sides).
5. The Committee noted that Metriguard has been discontinued and removed as a decontaminating agent from all study and site documents.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives and the institutional Associate Biosafety Officer.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 7

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:15 pm Eastern Time.