INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, March 12, 2026**
Time:	2:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Baptist MD Anderson Cancer Center, Jacksonville, FL
Principal Investigator:	**Konstantinos Chouliaras, MD**
Protocol:	Replimune, Inc., **RP1-104**
NCT Number:	NCT06264180
Meeting Type:	Initial 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 2:01 pm Eastern 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 was the Principal Investigator, nine 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. Review of proposed research:

The Chair and Principal Investigator provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

Point of Discussion:

1. The Principal Investigator noted that this study will investigate RP1 as a third line treatment and that subjects must have been previously exposed to anti-PD1 and anti-CTLA-4 treatments.

7. Determination for biosafety level and period of IBC oversight:

The Committee 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 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.

8. 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

9. Review of Principal Investigator qualifications:

Point of Discussion:

1. The Principal Investigator confirmed he has experience as an Investigator on clinical trials.
2. The Committee recommended that the Principal Investigator s clinical trial experience be added to his curriculum vitae when it is next updated.

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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 discussed the Institution's use of a chemo spill kit with a large absorbent pad for study agent spills and noted that best biosafety practice for biological spills involves covering the spill with thin absorbent material (e.g., paper towels) and saturating it from the outside in with an effective disinfectant.
2. An Institutional Representative confirmed that both the small and large spills decontamination process is the same.
3. The Committee recommended that Biosafety SOP Sections 5.1.4a and 5.1.4b be revised to be combined into one "All Spills" section and that it be revised to read as: i. Overlay the spill with thin absorbent material (e.g., paper towel(s) or a lint free disposable cloth) and saturate the absorbent material from the outside in with PeridoxRTU solution. ii. Allow to sit for wet contact time of 3 minutes.
4. An Institutional Representative confirmed that they Institution follows USP Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*. The Committee noted that this regulation may not apply to certain recombinant biologicals or include best biosafety practices.
5. An Institutional Representative confirmed that biohazardous waste is also stored in the Soiled Holding Room on the 9th floor Pharmacy. The Committee recommended that the Site Inspection Checklist, Site Map, and Biosafety SOP be updated to reflect that this location will be used for storage of full containers of biohazardous waste.
6. The Committee recommended that the 4 oz. eyewash bottles do not contain sufficient liquid to flush eyes for an extended period of time in the event of an eye contamination. The Committee recommended that the Institution purchase prefilled disposable eyewash bottles designed for specifically flushing eyes in the event of an eye exposure. These bottles typically come in volumes of 16 or 32 ounces.
7. An Institutional Representative confirmed that the Pharmacy can deliver larger eyewash bottles to the dosing room when a subject will be dosed with the study agent.
8. An Institutional Representative confirmed that a 10% bleach solution would not be used for decontamination. The Committee recommended that the Site Inspection Checklist item 19 be revised to remove 10% bleach as an available disinfectant.
9. An Institutional Representative confirmed that the "-7300" phone number is a "24/7" number. The Committee recommended that the Biohazard Sign be updated accordingly to note this number is a "24/7" number.
10. The Committee recommended that the Institution provide fully signed copies of Shipping Training Certifications to IBC Services.
11. The Committee recommended that internal transport container for prepared study agent contain a biohazard symbol on the outside rather than a chemotherapy symbol.
12. An Institutional Representative confirmed that the study agent will be prepared on the same day as dosing and that it is unlikely that prepared study agent will be temporarily stored in a refrigerator.
13. An Institutional Representative confirmed that study agent–specific biohazard signage will be posted during handling and that the storage freezer will display a biohazard symbol when the agent is stored onsite.
14. An Institutional Representative confirmed that a handwashing sink is available in anteroom directly outside of the Pharmacy preparation room through a hands-free door.

15. The Principal Investigator confirmed that the gown used during subject dosing is disposable and that a large yellow colored biohazardous waste container will be available in the dosing room for disposal of non-sharps Personal Protective Equipment.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Principal Investigator 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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 2:42 pm Eastern Time.

15. Post-meeting note: An Institutional Representative confirmed that the photo of a non-sharps biohazardous waste container used for another study, is representative of what will be used in the dosing room. The Committee recommended updating the Photos document to include this representative photo.

Documents reviewed:
Agenda
Protocol, Amendment 2, dated 06-21-2025
Investigator's Brochure, Edition 11.0, dated 10-02-2025
Pharmacy and Administration Manual, Version 2.0, dated 10-03-2025
Intratumoral Injection Manual, Version 2.0, dated 08-30-2022
Instructions For Patients After Injection, dated 04-12-2024
Biological Risk Assessment and Summary, updated 01-21-2026
Site Map, 9th floor, BMDA Pharmacy, dated 01-21-2026
Site Map, 5th floor, dated 01-21-2026
Site Inspection Checklist, expires 01-28-2028, updated 02-26-2026
Site Photos, dated 02-26-2026
Biohazard Sign, RP1, dated 01-26-2026
Biological Safety Cabinet Certification, dated 11-20-2025
SOP, Biosafety for RP1, dated 02-18-2026
Training, Shipping Certifications, expire 03-28-2027, 11-20-2026
CV, Chouliaras, K., signed 01-20-2026