

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, June 11, 2025
Time: 9:00 am Pacific Time
Location: Zoom Teleconference
Institution: Beverly Hills Cancer Center, Beverly Hills, CA
Principal Investigator: Afshin Eli Gabayan, MD
Protocol: Replimune, Inc., RP2-003
NCT Number: NCT05733598
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 2, Open-label, Multicenter Study Investigating RP2 Oncolytic Immunotherapy in Combination with Second-line Therapy in Patients with Locally Advanced Unresectable, Recurrent and/or Metastatic Hepatocellular Carcinoma

1. Call to order:

The Meeting was called to order at 9:00 am Pacific 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 one local member 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. Review of proposed research:

The Chair provided an overview of the protocol.

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

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

The Committee 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 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.

8. 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

9. Review of Principal Investigator qualifications:

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

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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 Biosafety SOP Section 3.1 be revised to change “Biohazardous Waste Storage Room” to “Soiled Utility Room.”
2. An Institutional Representative confirmed that the syringe is primed inside the Compounding Aseptic Containment Isolator (CACI) during study agent preparation. The Committee recommended that Biosafety SOP Section 3.3 be revised accordingly.
3. The Committee noted that Biosafety SOP Section 3.5 states that subjects are to dispose of used dressings into a biohazardous waste container and return the container to the clinic. An Institutional Representative confirmed that subjects would either be kept in the clinic until the dressing could be removed or would be sent home with a small biohazardous waste container that would be used in the event the dressing were to come off prior to the next visit. The Committee recommended that Biosafety SOP Section 3.5 be revised to reflect these details.
4. The Committee recommended that a photo of the small biohazardous waste container that will be provided to subjects for disposal of used dressings be submitted to IBC Services.
5. The Committee discussed that it was unclear how long injection sites are to remain covered after dosing and recommended that Sponsor documents be reviewed to determine whether this information is available.
6. An Institutional Representative confirmed that there is a handwashing sink inside the CT Room. The Committee recommended that the Site Map be revised accordingly.
7. The Committee recommended that the biohazard symbol on the internal transport container be printed on a red/orange background.
8. An Institutional Representative confirmed that the study agent will be stored in the small freezer in the Pharmacy and that the side and top are labeled with a biohazard symbol. The Committee recommended that an updated photo clearly showing the biohazard label on the freezer be submitted to IBC Services.
9. The Committee had questions regarding disposal of the paper lining the exam table and the cloth bag labeled with a biohazard symbol as shown in Slide 12 in the Photos document. An Institutional Representative confirmed that the room will not be used for subject dosing and was pictured only to show the mobile ultrasound cart which may be moved to one of the Infusion Rooms if needed. The Committee recommended that those photos be removed from the Photos document.
10. The Committee recommended that the dosing room photos be clearly labeled as to which specific room the photo represents.
11. An Institutional Representative confirmed that there are hard-sided biohazardous waste containers with a step-on lid, similar to the one shown in the Soiled Utility Room photos, available in the dosing rooms for disposal of used personal protective equipment (PPE).
12. An Institutional Representative confirmed that a small biohazardous waste container will be placed inside the CACI during study agent preparation and that the CACI is decontaminated with a freshly prepared 10% bleach solution.
13. An Institutional Representative confirmed that the CT Room will primarily be used for subject dosing while the Infusion Rooms will be used as a back-up.
14. An Institutional Representative confirmed that safety needles are used for study agent preparation while non-safety needles are used for intratumoral injection.
15. An Institutional Representative confirmed that there is a soap dispenser located behind the sink in the Pharmacy.
16. An Institutional Representative confirmed that the flooring in the CT Room is scratched but not cracked.
17. An Institutional Representative confirmed that only institutional staff have access to the Soiled Utility Room.

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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 9:31 am Pacific Time.

15. Post-meeting notes: The IBC Chair confirmed after the meeting that WCG IBC Services did not receive any comments or questions regarding this review. Additionally, the IBC Chair noted that Section 6.8 in the Investigator's Brochure states the following regarding injection sites: "The dressing should be maintained as long as deemed medically necessary. If the dressing comes off before 1 week, where possible, it should be replaced especially if the injection site is oozing or weeping."

Documents reviewed:

Agenda

Protocol, Amendment 3, dated 06-19-2024

Investigator's Brochure, Edition 6, dated 04-01-2025

Pharmacy and Administration Manual, Version 2.0, dated 04-12-2024

Intratumoral Injection Manual, Version 1.0, dated 01-20-2023

Post-injection Instructions, Version 2.0, dated 04-17-2024

Biological Risk Assessment and Summary, updated 04-25-2025

Site Maps, dated 05-19-2025

Site Inspection Checklist, expires 05-12-2027

Photos, dated 05-27-2025

Biohazard Sign, RP2, dated 05-21-2025

Compounding Aseptic Containment Isolator Certification, expires 09-2025

SOP, Biosafety for RP2, dated 05-27-2025

Training, Shipping Certification, expires 2026, 2027

CV, Gabayan, A., signed 04-22-2025