

Meeting Minutes



Meeting Date:	July 22, 2025 at 4:00 PM Eastern Time	
Meeting Place:	Teleconference (Remote)	
Members in Attendance:	Rastein, Daniel	
	Ellis, Robert	
	Singh, Christopher	
	Browne, Angella	
	Guebre-Xabiher, Hiwot	
Members Not in Attendance:	None	
Guests:	Bisges, Samantha Clark, Brandon	
Staff:	Sreedharan, Aswathy	
Institution:	Medstar Washington Hospital Center	

Call to Order: The meeting was called to order at 4:00 PM Eastern Time. A quorum was present.

Conflicts of Interest: None declared by voting members of the IBC.

Meeting Minutes: Previous meeting minutes were reviewed and approved with no requested changes.

New Business:

PI:	Rapisuwon, Suthee MD
Sponsor:	Replimune, Inc.
Protocol:	RP1-104
	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]
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: RP1-104 is a Phase III, randomized, open-label study sponsored by Replimune, Inc. and designed to assess the efficacy of Vusolimogene Oderparepvec (VO; also known as RP1), a recombinant, selectively replicating oncolytic Type 1 Herpes Simplex Virus (HSV-1), in combination with nivolumab for the treatment of participants with qualifying advanced melanoma that has progressed on anti-PD-1 and anti-CTLA-4 treatment.

Biosafety Containment Level per Risk Assessment: BSL-2

Comments:

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- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
 - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.
- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, Annual Review Report and other applicable information provided by the Site for the purposes of the IBC review.
 - The Site verified that the information provided by the Chair was accurate.
 - The Committee recommended that when the BSC is in use, the sharps containers be placed away from the back vent, so that the airflow is not obstructed.
 - The Committee recommended that the Site provide updated photos of the yellow and black waste containers in the Pharmacies showing the biohazard stickers.

Motion: A motion of Full Approval for the study at BSL-2 was passed by majority vote. There were no abstentions on voting

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

Reminder of IBC Approval Requirements.

Adjournment: 4:27 PM Eastern Time

Post-Meeting Pre-Approval Note: None