

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, April 8, 2026
Time: 12:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Hackensack Meridian Health, Hackensack, NJ
Principal Investigator: Martin Gutierrez, MD
Protocol: Regeneron Pharmaceuticals, BPX-601-PSA-2540
NCT Number: N/A
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 1, Open-Label, Dose-Escalation Study of BPX-601, An Anti-PSCA CAR T Cell Drug Product, in Relapsed/Refractory Metastatic Castration-Resistant Prostate Cancer

1. Call to order:

The Meeting was called to order at 12:11 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, and the Institution's Biosafety Officer. Also present was 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:

The Biosafety Officer 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 BPX-601, since it consists of primary human cells genetically modified with a gammaretroviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of BPX-601 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:

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.

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Points of Discussion:

1. The Committee noted that a staff member is due for IATA Shipping Training recertification in May 2026.
2. The Committee noted that the Biological Safety Cabinet (BSC) Certifications indicate that some of the certifying company's equipment used to certify the BSC were due for recalibration in 2026.

11. Site requirements:

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

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 12:19 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 1, dated 12-09-2025

Investigator's Brochure, Edition 11, dated 12-16-2025

Cellular Laboratory Receipt, Preparation, and Infusion Manual, Version 0.3, dated 02-09-2026, draft

Biological Risk Assessment and Summary, dated 03-24-2026

Site Maps, Genetically Modified Human Cells, updated 11-19-2025

Site Inspection Checklist, Genetically Modified Human Cells, expires 08-19-2026, updated 03-26-2026

Biohazard Sign, Gutierrez, BSL2, dated 03-26-2026

Biological Safety Cabinet Certifications, CTMF, expire 05-31-2026

Biosafety Guidelines for Genetically Modified Human Cells, dated 12-11-2025

Biosafety Guidelines, Addendum for Autologous Cells, dated 03-26-2026

Training, Shipping Certifications, expire 05-2026, 10-2026, 11-2026, 12-2026, 2027

CV, Gutierrez, M., signed 04-10-2024