

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, August 20, 2025
Time: 3:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Wayne State University, Detroit, MI
Principal Investigator: Andrew D. Kin, MD
Protocol: Poseida Therapeutics, Inc., P-BCMA-ALLO1-001
NCT Number: NCT04960579
Meeting Type: Continuing Review of Protocol and Site
Title: Open-Label, Multicenter, Phase 1 Study to Assess the Safety of P-BCMA-ALLO1 in Subjects with Relapsed / Refractory Multiple Myeloma (MM)

1. Call to order:

The Meeting was called to order at 3:01 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 were seven 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:

Minutes Approved - YES: 5 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 P-BCMA-ALLO1, since it consists of primary human cells modified using a plasmid and mRNA. 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 P-BCMA-ALLO1 locally**, provided all other criteria for study closure are met. The Committee reaffirmed this determination.

9. 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

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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 Addendum Section 3 be revised to include the [REDACTED] as a biohazardous waste storage location.
2. The Committee noted that Biosafety SOP Addendum Sections 3.2.1 and 3.2.6 cover both methods of dose preparation for the study agent and that a biological safety cabinet is used if a dose modification is required.
3. The Committee noted that the current IATA Training Certification is not compliant with IATA and DOT requirements for shipping dangerous goods as the certificate indicates it covers only specimen packaging. The Committee recommended that the Institution ensure that staff complete training that meets the requirements of DOT 49 CFR 172.700 and IATA 1.5 and noted that some providers, such as Mayo Clinic, may offer free shipping training that meets these requirements.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 3:14 pm Eastern Time.