INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, September 5, 2025**
Time:	11:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	University of North Carolina at Chapel Hill, Chapel Hill, NC
Principal Investigator:	**Natalie Grover, MD**
Protocol:	Poseida Therapeutics, Inc., **P-CD19CD20-ALLO1-001**
NCT Number:	NCT06014762
Meeting Type:	Continuing Review of Protocol and Site
Title:	Open-Label, Multicenter, Phase 1 Study to Assess the Safety of P-CD19CD20-ALLO1 in Subjects with Selected Relapsed/Refractory B cell Malignancies

1. Call to order:

The Meeting was called to order at 11:01 am Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution and the Institution's Associate Biosafety Officer. Also present were six 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: 6 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-CD19CD20-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-CD19CD20-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: 6 NO: 0 ABSTAIN: 0

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 that the biological safety cabinet (BSC) report for the [redacted] did not contain information regarding the required airflow smoke test and was lacking other details found in the reports for the other four BSCs being used.
2. The Associate Biosafety Officer confirmed that the abbreviated report is typical of what is provided by the vendor for clinical areas and that in the past, they have had to request that the detailed reports be provided. The Committee recommended that a detailed certification report for the [redacted] BSC be requested and submitted to IBC Services upon receipt.
3. The Committee recommended that current and detailed certification reports for the four BSCs which were due to be re-certified in August 2025 be submitted to IBC Services.
4. The Committee recommended that updated overall room/area photos of the [redacted] preparation area where the BSCs are located, with arrows identifying the five BSCs in use, be provided to IBC Services.
5. The Committee recommended that the locations of the five BSCs in the [redacted] preparation area be identified on the Site Map.
6. The Associate Biosafety Officer confirmed that the plumbed eyewash station in the [redacted] is maintained by the hospital facilities staff and is tested at least monthly with the water being collected into a drain or bucket as appropriate. The Committee determined this to be acceptable.
7. The Committee discussed the Research Modification Evaluation, [redacted] and noted that the document indicates that the study agent may be provided in vials or cyrobags but that Biosafety SOP Section 3.3 only describes preparation from vials. The IBC Chair confirmed that the Protocol and Pharmacy Manual have not yet been updated by the Sponsor with instructions for preparation of cryobags but noted that the Biosafety SOP would be revised accordingly once that information is provided.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Associate Biosafety Officer and 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: 6 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:22 am Eastern Time.