INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, July 28, 2025**
Time:	10:00 am Central Time
Location:	Zoom Teleconference
Institution:	Northwestern University, Chicago, IL
Principal Investigator:	**Farrah Mateen, MD, PhD**
Protocol:	Poseida Therapeutics, Inc., **GN45773**
NCT Number:	NCT07008378
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase I, Multicenter, Open-Label Study to Evaluate the Safety, Tolerability, Cellular Kinetics, And Pharmacodynamics Of P-CD19CD20-ALLO1 In Patients with Multiple Sclerosis

1. Call to order:

The Meeting was called to order at 10:01 am Central 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 one local member unaffiliated with the institution and the Institution's 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:

The Biosafety Officer confirmed that the notice of the meeting was not publicly posted. The Committee recommended that the notice of the meeting be publicly posted for one week from today and that any questions or comments received be forwarded to IBC Services.

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 P-CD19CD20-ALLO1 since it consists of primary human cells modified using a plasmid and mRNA.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of PCD19CD20-ALLO1 locally**, provided all 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.

Points of Discussion:

1. An Institutional Representative confirmed that study agent preparation will occur on a countertop in the dosing room and not inside a biological safety cabinet (BSC). The Committee recommended that the site confirm that study staff will wear full personal protective equipment (PPE) and that an absorbent pad will be placed on the countertop during study agent preparation.
2. The Committee recommended that Biosafety SOP Addendum Section 3.2.8 be revised to accurately reflect dose preparation procedures.

11. Site requirements:

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

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:17 am Central Time.