INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, September 8, 2026**
Time:	10:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Hackensack Meridian Health, Hackensack, NJ
Principal Investigator:	**Anna Broder, MD**
Protocol:	Nkarta, Inc., **NKX019-103**
NCT Number:	N/A
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 1 Study of NKX019, a CD19 Chimeric Antigen Receptor Natural Killer (CAR NK) Cell Therapy, in Subjects with Immune-Mediated Diseases

1. Call to order:

The Meeting was called to order at 10:00 am 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 were two 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 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 noted 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 NKX019, since it consists of allogeneic natural killer cells modified using a replication-defective gammaretroviral vector. 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 NKX019 locally**, provided that other biosafety criteria for study closure are also 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

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. The Committee noted that IATA/DOT training will expire for one member of the study staff in October 2026.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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 10:07 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Amendment 5.0, dated 04-20-2026
Protocol Clarification Letter 3, dated 05-22-2026
Investigator's Brochure, Version 4.0, dated 04-16-2024
Pharmacy Manual, Version 10.0, dated 05-12-2026
Research Modification Evaluation, Protocol Amendment 4.0
Research Modification Evaluation, Protocol Amendment 5.0
Research Modification Evaluation, Protocol Clarification Letter 1
Research Modification Evaluation, Protocol Clarification Letter 2
Research Modification Evaluation, Protocol Clarification Letter 3
Research Modification Evaluation, Pharmacy Manual, Version 7.0
Research Modification Evaluation, Pharmacy Manual, Version 8.0
Research Modification Evaluation, Pharmacy Manual, Version 8.1
Research Modification Evaluation, Pharmacy Manual, Version 8.2
Research Modification Evaluation, Pharmacy Manual, Version 9.0
Research Modification Evaluation, Pharmacy Manual, Version 10.0
Biological Risk Assessment and Summary, updated 06-09-2026
Site Maps, Genetically Modified Human Cells, updated 11-19-2025
Site Inspection Checklist, Genetically Modified Human Cells, expires 08-19-2028
Biohazard Sign, Broder, dated 09-30-2024
Biological Safety Cabinet Certifications, CTMF, expire 11-30-2026
Biosafety Guidelines, Addendum for Allogeneic Cells, dated 04-28-2025
Biosafety Guidelines for Genetically Modified Human Cells, dated 12-11-2025
Training, Shipping Certifications, expire 10-2026, 11-2026, 12-2026, 2027
CRRF, dated 06-02-2026
Prior Meeting Minutes, Continuing, dated 09-30-2025