

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: David S. Siegel, MD, PhD
Protocol: Kelonia Therapeutics, Inc., KLN-001
NCT Number: NCT07075185
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 1 Study to Evaluate the Safety of KLN-1010, a Novel, In Vivo Gene Therapy to Generate Anti-BCMA CAR-T Cells in Patients with Relapsed and Refractory Multiple Myeloma

1. Call to order:

The Meeting was called to order at 12:02 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 KLN-1010, since it consists of primary human cells modified using a replication-deficient lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of KLN-1010 locally**, provided all other criteria for study closure are 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:

Point of Discussion:

1. The Committee noted that the second page of the Principal Investigator's curriculum vitae is blank.

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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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 the most recent Biological Safety Cabinet Certifications (dated March 2026) be submitted to IBC Services.
2. The Committee noted that a staff member is due for IATA Shipping Training recertification in May 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 12:11 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 3, dated 12-23-2025

Investigator's Brochure, Edition 2.0, dated 11-07-2025

Pharmacy Manual, Version 3.0, dated 10-22-2025

Biological Risk Assessment and Summary, dated 01-16-2026

Site Map, Cancer Center Loading Dock, dated 01-19-2022

Site Map, Cancer Center Pharmacy, dated 04-16-2025

Site Map, Inpatient APE 8th Floor, dated 11-19-2025

Site Inspection Checklist, JTCC Cancer Center, expires 04-15-2027, updated 03-27-2026

Biohazard Sign, Siegel, KLN-001, dated 04-02-2026

Biological Safety Cabinet Certifications, JTCC Pharmacy, expire 03-2026

Biosafety Guidelines, Biosafety for KLN-1010, dated 03-31-2026

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

CV, Siegel, D., signed 05-16-2024