INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, May 12, 2026**
Time:	11:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Hackensack Meridian Health, Hackensack, NJ
Principal Investigator:	**Andre Goy, MD**
Protocol:	Kite Pharma, Inc., a Gilead Company, **KT-US-740-0603**
NCT Number:	NCT07479797
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 3, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of KITE-753 Versus Axicabtagene Ciloleucel in Participants with Relapsed or Refractory Large B-Cell Lymphoma After First-Line Therapy

1. Call to order:

The Meeting was called to order at 11:00 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 three 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. 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 KITE-753 and axicabtagene ciloleucel, since they consist of genetically modified primary human cells.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of KITE-753 and axicabtagene ciloleucel locally**, provided all other biosafety criteria required 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:

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. The Committee noted that a staff member is due for IATA Shipping Training recertification in May 2026.
2. The Committee noted that the Biological Safety Cabinets (BSCs) are due for recertification in May 2026.
3. The Committee acknowledged that the Biosafety Guidelines for Genetically Modified Human Cells contains information about the disposal of used study agent infusion bags.
4. The Committee recommended that the description of axicabtagene ciloleucel in Section 2.5 of the Biosafety Guidelines Addendum be revised to read as “Autologous T cells genetically modified using a gammaretroviral vector encoding a CD19-specific CAR”.

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 11:13 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Original, dated 01-09-2026
KITE-753, Investigator's Brochure, Edition 3.0, dated 09-12-2025
Axicabtagene ciloleucel, Investigator's Brochure, Edition 16, dated 01-07-2026
KITE-753, Investigational Product Manual, Version 6.0, dated 10-09-2025
Axicabtagene ciloleucel, Investigational Product Manual, Version 12, dated 11-26-2025
Biological Risk Assessment and Summary, dated 03-25-2026
Site Maps, Genetically Modified Human Cells, updated 11-19-2025
Site Inspection Checklist, Genetically Modified Human Cells, expires 08-19-2026, updated 05-04-2026
Biohazard Sign, Goy, dated 04-30-2026
Biological Safety Cabinet Certifications, CTMF, expire 05-31-2026
Biosafety Guidelines for Genetically Modified Human Cells, dated 12-11-2025
Biosafety Guidelines, Addendum for Autologous Cells, dated 05-04-2026
Training, Shipping Certifications, expire 05-2026, 10-2026, 11-2026, 12-2026, 2027
CV, Goy, A., signed 03-03-2026

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, May 12, 2026**
Time:	11:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Hackensack Meridian Health, Hackensack, NJ
Principal Investigator:	**Martin Gutierrez, MD**
Protocol:	ModernaTX, Inc., **mRNA-4359-P101**
NCT Number:	NCT05533697
Meeting Type:	Continuing Review of Protocol and Site
Title:	Phase 1/2 Study of mRNA-4359 Administered Alone and in Combination With Immune Checkpoint Blockade in Participants with Advanced Solid Tumors

1. Call to order:

The Meeting was called to order at 11:13 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 three 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-1 containment facilities and practices plus Standard Precautions** are required for mRNA-4359 since it consists of lipid nanoparticle (LNP)-encapsulated mRNA molecules administered in a clinical setting. 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 mRNA-4359 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 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 11:20 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Amendment 3, dated 07-28-2025
Investigator's Brochure, Edition 4.0, dated 07-30-2025
Pharmacy Manual, Version 7.0, dated 01-26-2026
Research Modification Evaluation, Protocol, Amendment 3
Research Modification Evaluation, Investigator's Brochure, Edition 4.0
Research Modification Evaluation, Pharmacy Manual, Version 5.0
Research Modification Evaluation, Pharmacy Manual, Version 6.0
Research Modification Evaluation, Pharmacy Manual, Version 7.0
Biological Risk Assessment and Summary, updated 04-21-2026
Site Map, Cancer Center Loading Dock, dated 01-19-2022
Site Map, Outpatient, 4th Floor JTCC, updated 10-01-2025
Site Map, Cancer Center Pharmacy, dated 04-16-2025
Site Map, Outpatient, 3rd Floor JTCC, updated 10-01-2025
Site Inspection Checklist, JTCC Cancer Center, expires 04-15-2027, updated 03-27-2026
Biohazard Sign, mRNA-based study agents, dated 03-27-2026
Biological Safety Cabinet Certifications, JTCC Pharmacy, expire 09-2026
Biosafety Guidelines for mRNA-based Vaccines, dated 01-30-2026
Training, Shipping Certifications, expire 05-2026, 10-2026, 11-2026, 12-2026, 2027
CRRF, dated 04-16-2026
Prior Meeting Minutes, Continuing, dated 05-12-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, May 12, 2026**
Time:	11:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Hackensack Meridian Health, Hackensack, NJ
Principal Investigator:	**Andrew Pecora, MD**
Protocol:	Merck Sharp & Dohme LLC, **V940-012**
NCT Number:	NCT06961006
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 2, Randomized, Double-Blind, Placebo- and Active-Comparator-Controlled Clinical Study of V940 (mRNA-4157) Plus Pembrolizumab Versus Placebo Plus Pembrolizumab in Participants With First-Line Advanced Melanoma (INTerpath-012)

1. Call to order:

The Meeting was called to order at 11:21 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 three 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-1 containment facilities and practices plus Standard Precautions** are required for V940 because the study agent consists of synthetic mRNA administered via intramuscular injection. 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 V940 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 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 11:27 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Amendment 03, dated 02-05-2026
Investigator's Brochure, Version 19, dated 09-05-2025
Pharmacy Manual, Version 4.0, dated 03-19-2026
Research Modification Evaluation, Protocol, Amendment 02
Research Modification Evaluation, Protocol, Amendment 03
Research Modification Evaluation, Investigator's Brochure, Version 19
Research Modification Evaluation, Pharmacy Manual, Version 2.0
Research Modification Evaluation, Pharmacy Manual, Version 3.0
Research Modification Evaluation, Pharmacy Manual, Version 4.0
Biological Risk Assessment and Summary, updated 04-22-2026
Site Map, Outpatient, 3rd Floor JTCC, updated 10-01-2025
Site Map, From Road, dated 09-04-2024
Site Map, Cancer Center Pharmacy, dated 04-16-2025
Site Map, Cancer Center Loading Dock, dated 01-19-2022
Site Map, Outpatient, 4th Floor JTCC, updated 10-01-2025
Site Inspection Checklist, JTCC Cancer Center, expires 04-15-2027, updated 03-27-2026
Site Inspection Checklist, From Road, expires 09-05-2026, updated 04-16-2025
Biohazard Sign, mRNA-based study agents, dated 03-27-2026
Biological Safety Cabinet Certifications, JTCC Pharmacy, expire 09-2026
Biosafety Guidelines for mRNA-based Vaccines, dated 01-30-2026
Training, Shipping Certifications, expire 05-2026, 10-2026, 11-2026, 12-2026, 2027
CRRF, dated 04-16-2026
Prior Meeting Minutes, Initial, dated 05-12-2025