

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Friday, September 26, 2025  
**Time:** 10:00 am Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Northside Hospital, Cumming, GA  
**Principal Investigator:** Harpaul S. Gill, MD  
**Protocol:** Moderna Therapeutics, Inc., mRNA-4157-P201  
**NCT Number:** NCT03897881  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase 2 Randomized Study of Adjuvant Immunotherapy With the Personalized Cancer Vaccine mRNA-4157 and Pembrolizumab Versus Pembrolizumab Alone After Complete Resection of High-Risk Melanoma

### 1. Call to order:

The Meeting was called to order at 10:17 am Eastern Time.

### 2. Introductions and orientation:

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

### 3. Declaration of quorum:

Four voting members were present, including two local members unaffiliated with the institution. Also present were four 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: 4                      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-1 containment facilities and practices plus Standard Precautions** are required for mRNA-4157 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 mRNA-4157 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: 4                      NO: 0                      ABSTAIN: 0

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### **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 had no questions or concerns about the facilities and practices.

### **11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with 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: 4

NO: 0

ABSTAIN: 0

### **13. Advice to the Institution:** None.

**14. Meeting adjourned:** The meeting was adjourned at 10:22 am Eastern Time.

**15. Post-meeting notes:** None.

### **Documents reviewed:**

Agenda

Protocol, Version 6.0, Amendment 5, dated 04-08-2025

Investigator's Brochure, Version 18, dated 12-17-2024

Pharmacy Manual, Version 8.0, dated 11-08-2024

Sponsor Letter, dated 03-05-2025

Research Modification Evaluation, Sponsor Letter, dated 03-05-2025

Research Modification Evaluation, Protocol, Version 5.0, Amendment 4

Research Modification Evaluation, Protocol, Version 6.0, Amendment 5

Research Modification Evaluation, Investigator's Brochure, Version 18

Research Modification Evaluation, Pharmacy Manual, Version 8.0

Biological Risk Assessment and Summary, updated 05-16-2025

Site Map, ACC Cumming, dated 09-12-2024

Site Map, GSC-Stemmer, dated 09-12-2024

Site Map, SHOA, Duluth, dated 09-12-2024

Site Map, 3N Investigational Pharmacy, dated 09-12-2024

Site Inspection Checklist, 3N Invest Pharm, GCS, ACC, SHOA, expires 08-26-2026, updated 09-16-2025

Site Inspection Checklist, Autoclave Addendum, dated 02-11-2025, updated 02-24-2025

Photos, ACC-Cumming, GCS-Stemmer, SHOA-Duluth, dated 08-23-2024

Photos, 3N Investigational Pharmacy, dated 09-08-2025

Biohazard Sign, mRNA-4157, dated 09-16-2025

Biological Safety Cabinet Certifications, 3N Investigational Pharmacy, expire 12-2025

SOP, Biosafety for mRNA-based Vaccines, dated 09-16-2025

Training, Shipping Certification, expire 03-10-2026, 04-30-2026

CRRF, dated 09-15-2025

Prior Meeting Minutes, Initial, dated 09-20-2024