INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

**MEETING MINUTES**

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| **Meeting Date:** | **Friday, June 27, 2025** |
| **Time:** | 11:00 am Central Time |
| **Location:** | Zoom Teleconference |
| **Institution:** | Texas Oncology - Sammons Cancer Center, Dallas, TX |
| **Principal Investigator:** | **Charles L. Cowey, 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 11:00 am Central 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 one local member unaffiliated with the institution. 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:**

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

**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 Institution confirm the effective disinfectants that are available where the study agent is handled, and update the Biosafety SOP and Site Inspection Checklist with these disinfectants.
2. An Institutional Representative confirmed that biohazardous waste containers are closed with a lid when not in use.

**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 11:10 am Central 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, Protocol, Version 6.0, Amendment 5
Research Modification Evaluation, Protocol, Version 5.0, Amendment 4
Research Modification Evaluation, Investigator's Brochure, Version 18.0
Research Modification Evaluation, Investigator's Brochure, Version 17.0
Research Modification Evaluation, Investigator's Brochure, Version 16.0
Research Modification Evaluation, Pharmacy Manual, Version 8.0
Research Modification Evaluation, Pharmacy Manual, Version 7.0
Research Modification Evaluation, Pharmacy Manual, Version 6.0
Research Modification Evaluation, Pharmacy Manual, Version 5.0
Research Modification Evaluation, Sponsor Letter, dated 03-05-2025
Biological Risk Assessment and Summary, updated 05-16-2025
Research Modification Evaluation, Change in Dosing and Biohazard Locations, dated 06-03-2025
Site Maps, dated 06-03-2025
Site Inspection Checklist, expires 05-15-2026, updated 06-02-2025
Photos, dated 06-06-2025
Biohazard Sign, mRNA-4157, dated 05-18-2023
SOP, Biosafety for mRNA-4157, dated 06-06-2025
Biological Safety Cabinet Certification. expires 08-2025
Training, Shipping Certification, expires 04-29-2026
CRRF, dated 03-06-2025
Prior Meeting Minutes, Continuing, dated 06-03-2024