Montefiore Medical Center
BRANY INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
Tuesday, December 9, 2025[1]

[1]*The materials for this agenda were made available electronically to all appropriate parties*

MMC IBC Members Present

1. Brian Currie, MD (IBC Chair)
2. James Wetmur, PhD (Member)
3. Alan Yood (Member)
4. Izzy Fujiwara (Non-Affiliated Community Member)

Guests Present

1. Vanessa Rodriguez, CIP, IRB/IBC Supervisor
2. Kyla Sumter, Junior Associate IRB/IBC Coordinator
3. Andy Merino
4. Jan R. Figueira

This meeting was called to order at 3:12 PM with a quorum[2] present.

[2]*Note: According to the roster registered with NIH on 03/06/25, the MMC BRANY IBC membership totals 5, making the members required for quorum 3 or greater.*

Announcements

I. IBC members were reminded to disclose any potential conflicts of interests prior to reviewing items on this agenda by recusing yourself. Contact BRANY IBC staff in advance of the meeting if this is the case.

II. IBC members were reminded to state their names when joining or leaving the call ensures that all of the meeting proceedings occur with quorum present.

Minutes:

- 9/22/2025
- 12/11/2024

IBC Action and Vote: Having no comments or concerns, the committee voted to accept the minutes as submitted

Total: 4 For: 4 Against: 0 Abstentions: 0

I. Continuing Review

Protocol Title: An open label Phase II randomized trial of BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first line therapy in patients with unresectable recurrent, or metastatic Head and Neck Squamous Cell Carcinoma (HNSCC) which is positive for human papilloma virus 16 (HPV16+) and expresses PD-L1.

Principal Investigator: Castellucci, Enrico, MD
BRANY File # IBC20-008-01 (Montefiore Medical Center)

Discussion: The IBC discussed the continuation of this study, noting that there have been no material changes to the study protocol or study agent affecting the biosafety considerations for

this research. The committee noted the study continues to fall under sections III-C-1 and III-E of the NIH Guidelines.

The site reported that there have not been any emergencies, potential biohazard problems, spills, significant safety issues, or contamination since the last IBC review.

This site is actively enrolling new subjects. To date a total of 5 subjects have been enrolled: 1 is still undergoing research related interventions and 4 exited prior to completion. Among those who exited: 2 were screening failures; 1 is deceased; and 1 withdrew voluntarily. The study drug has been administered 17 times since the last review with no subjects reporting benefits or complaints. No SAE's or unanticipated problems have been reported since the last review.

The DSMB met on March 13, 2025, and recommended continuing the study.

The informed consent form remains adequate.

The designated Biosafety Liaison for this project has not changed since the last IBC review. There have been no changes to the staff or to the facility used for this research and it continues to be adequate.

The risks assessment has not changed since the prior review of this project. There were no concerns that would necessitate termination of the protocol. The biosafety level remains unchanged (BL 1).

IBC Action and Vote: Having no further comments or concerns, the committee voted unanimously to continue its approval for this project for a period of 12 months.

Total: 4 For: 4 Against: 0 Abstentions: 0

This meeting adjourned at 3:17 PM (EST).

Respectfully submitted,

Vanessa Rodriguez, CIP IRB/IBC Coordinator Brian Currie, MD, IBC Chairman